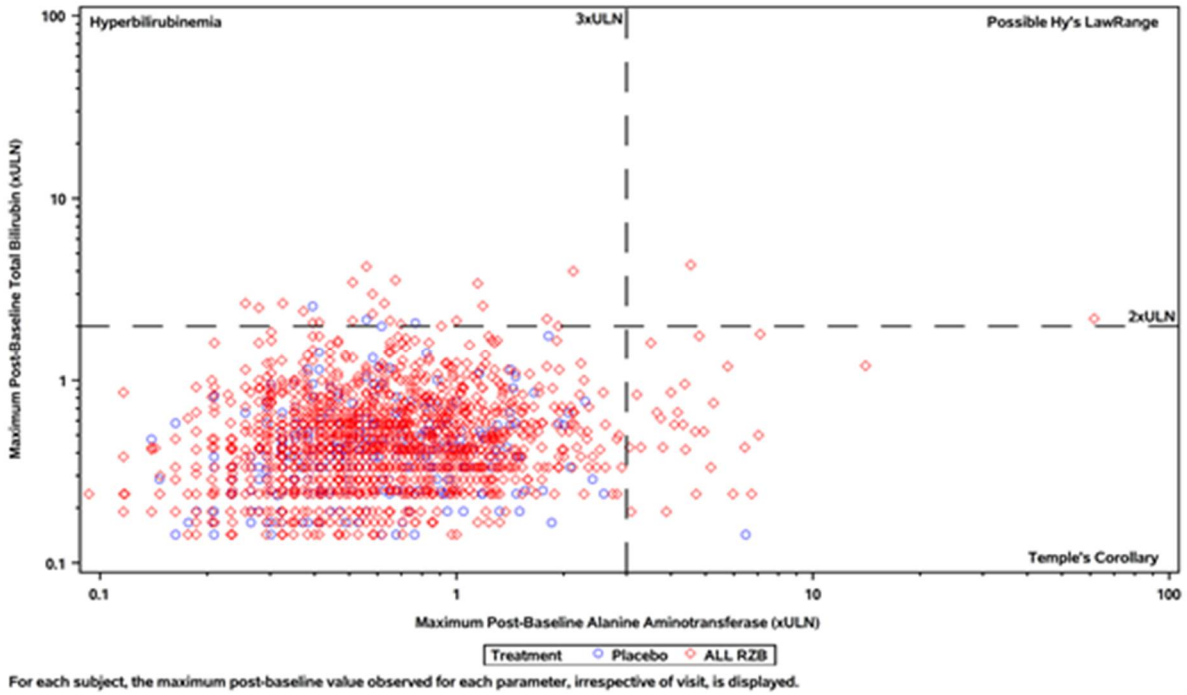
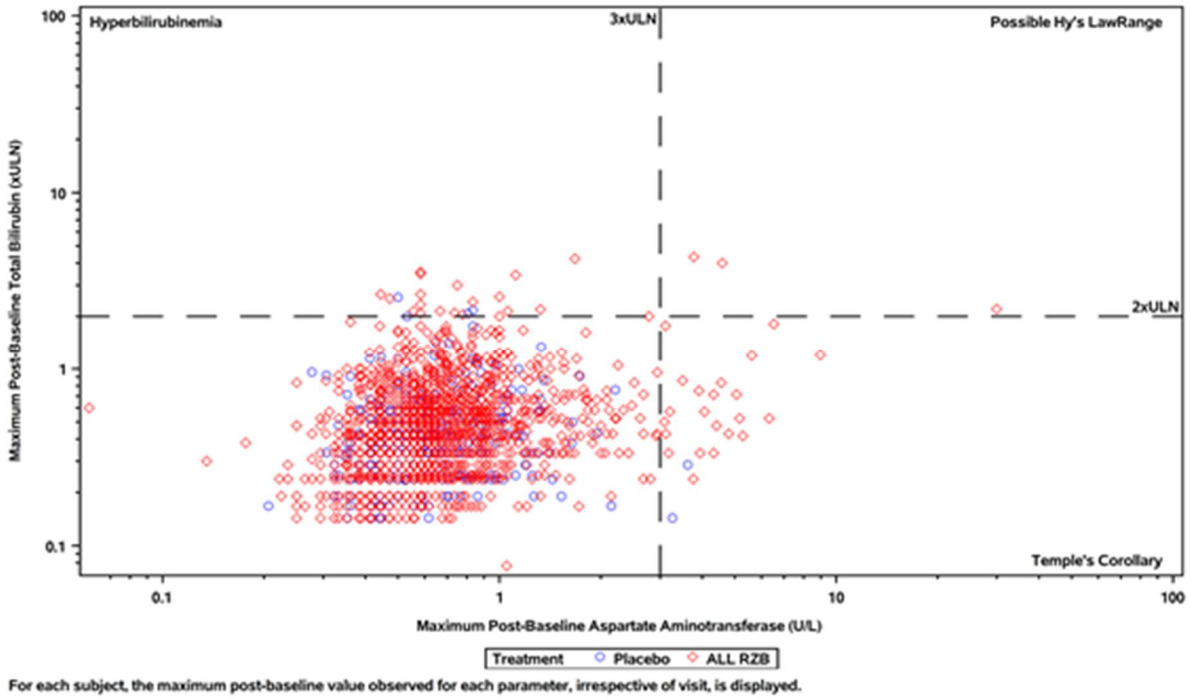
図 2.7.4-4. 全安全性併合解析集団での総ビリルビンのベースライン後の最大値に対する ALT のベースライン後の最大値の eDISH プロット



Cross Reference：ISS Figure 2.5　1.5.4.4

図 2.7.4-5. 全安全性併合解析集団での総ビリルビンのベースライン後の最大値に対する AST のベースライン後の最大値の eDISH プロット



Cross Reference：ISS Figure 2.5　1.5.4.5

全安全性併合解析集団の日本人部分集団での肝機能検査値上昇の基準に該当した被験者の割合を J-ISS Table 2.5　1.5.4.1_J に示す。

全安全性併合解析集団の日本人部分集団の全リサンキズマブ群では，ALT が ULN の 3 倍以上の被験者が 2 例（うち 1 例は ULN の 5 倍以上 10 倍未満），AST が ULN の 3 倍以上 5 倍未満の被験者が 2 例，総ビリルビンが ULN の 2 倍以上の被験者が 3 例であった。ALT 又は AST が ULN の 3 倍以上及び総ビリルビンが ULN の 1.5 倍以上が同時に認められた被験者は 1 例であった。

肝関連事象

全安全性併合解析集団の全リサンキズマブ SC 群では，肝関連事象の 100 人年あたりの発現件数は 4.1 件/100 人年であり（ISS Table 2.4　1.5.4.1.25），52 週維持療法安全性解析集団のリサンキズマブ SC 群全体（5.1 件/100 人年）と同様であった。全リサンキズマブ SC 群で発現した肝関連事象の多くは，肝酵素上昇に関するものであり，「肝機能関連の臨床検査値」の箇所に記載した。肝関連事象の多くは非重篤で（ISS Table 2.4　1.5.4.2.19），軽度又は中等度であり（ISS Table 2.4　1.5.6.15），治験薬の投与中止に至った肝関連事象は 1 例（0.1%未満）に発現した

（ISS Table 2.4　1.5.4.3.13）。全リサンキズマブ群では，重篤な肝関連事象は 2 例に発現し（ISS Table 2.4　1.5.4.2.19），いずれも 12 週導入療法期の箇所に詳述した被験者であった（1 例［被験者番号 [redacted]］は治験薬の投与を中止し，他の 1 例［被験者番号 [redacted]］は治験薬の投与を中断した）。全リサンキズマブ群で治験薬の投与中止に至った肝関連事象は計 3 例（0.2%）に発現した（ISS Table 2.4　1.5.4.3.13）。1 例は上述の重篤な肝関連事象を発現した被験者であり，その他の 2 例は非重篤の肝関連事象により治験薬の投与を中止した（1 例［被験者番号 [redacted]］は 12 週導入療法期の箇所に既述，他の 1 例［被験者番号 [redacted]］は 52 週までの維持療法期の箇所に既述）。

探索的な Cox 比例ハザードモデルで，投与群と事前に規定した肝関連事象のベースラインの予測因子を評価した。12 週導入療法安全性併合解析集団の第 III 相サブセット（M15-991 試験及び M16-006 試験のデータのみ）及び全安全性併合解析集団のデータを用いた。事前に規定した重要なベースラインの予測因子（元喫煙者，喫煙者及び免疫調節薬の使用）で調整した場合，有意な治療の影響は認められなかった（ISS Table 2.4　1.5.8.1.3）。

全安全性併合解析集団の肝関連事象の累積発現率プロットより，リサンキズマブ投与での肝関連事象の発現リスクは経時的に一定であることが示唆された（ISS Figure 2.4　1.5.8.2.5）。後期の時点では分母となる被験者数が少なかったため，発現率に大きなばらつきがみられた。

全安全性併合解析集団の日本人部分集団では，肝関連事象の 100 人年あたりの発現件数は全リサンキズマブ SC 群で 11.2 件/100 人年（8 件）であった（表 2.7.4-23）。重篤な肝関連事象及び治験薬の投与中止に至った肝関連事象は発現しなかった（J-ISS Table 2.4　1.5.2.3 J 及び Table 2.4　1.5.2.5 J）。

2.7.4.2.1.5.1.5　過敏症（重篤な過敏症を含む）及び委員会判定されたアナフィラキシー反応

背景

免疫グロブリン蛋白として，リサンキズマブの IV 又は SC 投与は過敏症及び免疫原性（すなわち抗薬物抗体の発現）と関連がある可能性がある。ただし，ほとんどの場合，生物学的製剤に対する抗体反応の発現は，安全性に悪影響を及ぼすものではない[25, 26]。過敏症は即時型（例：免疫グロブリン E［以下「IgE」］介在性）の場合があり，投与後最初の数時間に発現する。この反応の症状は一様ではなく，悪心，嘔吐，皮疹，呼吸器症状及び低血圧等が現れる場合がある。遅延型反応（免疫グロブリン G［以下「IgG」］の形成及び T 細胞介在性によるもの）は，投与後 1～2 時間から 14 日までに認められ，血清病様症状，多形紅斑，スティーヴンス・ジョンソン症候群及び中毒性表皮壊死融解症として発現する[27]。

結果

過敏症の定義は表 2.7.4-6 に示した。なお，過敏症に含まれる PT のいくつかは，次項で検討する注射部位反応に含まれる PT と重複している。重篤な過敏症も評価し，より詳細に記述する。

独立した外部委員会であるアナフィラキシー判定委員会により判定されたアナフィラキシー反応も評価した。なお，第 II 相試験では判定委員会を設置していなかった。

抗薬物抗体のデータを有する第 II 相及び第 III 相試験の被験者を対象に，過敏症に及ぼす免疫原性の影響を評価した。12 週導入療法安全性併合解析集団，24 週導入療法安全性併合解析集団及び全安全性併合解析集団で，過敏症の発現割合を抗薬物抗体陽性と陰性の被験者で比較した（免疫原性統合報告書［R&D/20/1400］［5.3.5.4-1 項］）。

12 週導入療法

12 週導入療法安全性併合解析集団では，リサンキズマブ IV 群全体で委員会判定されたアナフィラキシー反応は発現しなかった（表 2.7.4-16）。

12 週導入療法安全性併合解析集団の過敏症の発現割合を表 2.7.4.7-40 に，100 人年あたりの発現件数を ISS Table 2.4　1.1.2.2 に示す。試験サイズで調整したデータを以下に示す。

12 週導入療法安全性併合解析集団では，過敏症の発現割合及び 100 人年あたりの発現件数は，リサンキズマブ 600 mg IV 群（4.7%及び 20.2 件/100 人年）及びリサンキズマブ 1200 mg IV 群（5.3%及び 21.4 件/100 人年）とプラセボ群（4.3%及び 21.8 件/100 人年）で同様であった。リサンキズマブ IV 群全体で発現した過敏症の多くは，非重篤で（ISS Table 2.4　1.1.4.1.11），軽度又は中等度であった（ISS Table 2.4　1.1.6.12）。治験薬の投与中止に至った過敏症を発現した被験者はわずかであった（リサンキズマブ 600 mg IV 群：2 例［0.3%］，リサンキズマブ 1200 mg IV 群：4 例［0.7%］）（ISS Table 2.4　1.1.4.3.10）。

リサンキズマブ 1200 mg IV 群の 2 例は，薬物過敏症（PT）により治験薬の投与を中止した。いずれの事象も非重篤で，治験責任（分担）医師により治験薬と関連ありと判断された（ISS Table 2.4　1.1.6.12）。1 例（被験者番号 [redacted]）では投与 1 日目（リサンキズマブの投与日）に中等度の「治験薬に対するアレルギー反応」が発現し，他の 1 例（被験者番号 [redacted]）では投与 29 日目（リサンキズマブの投与日）に高度の「治験薬に対するアレルギー」が発現した（M15-991 試験 CSR 12.2.1.3.2 項）。

リサンキズマブ IV 群全体では，1 例が斑状丘疹状皮疹（PT）により治験薬の投与を中止し，2 例が注入に伴う反応（PT）により治験薬の投与を中止した（ISS Table 2.4　1.1.4.3.10）。リサンキズマブ 1200 mg IV 群の 1 例（被験者番号 [redacted]）は，投与 6 日目に中等度の斑状丘疹状皮疹を発現し，治験薬の投与を中止した（ISS Table 2.4　1.1.6.12）。また，リサンキズマブ 1200 mg IV 群の 1 例（被験者番号 [redacted]）は，投与 1 日目に中等度の注入に伴う反応を発現し，治験薬の投与を中止した。両事象とも，治験責任（分担）医師により治験薬と関連ありと判断された。リサンキズマブ 600 mg IV 群の 1 例（被験者番号 [redacted]）は，投与 36 日目に軽度の注入に伴う反応を発現し，治験薬の投与を中止した。本事象は，治験責任（分担）医師により治験薬と関連ありと判断された。なお，注入に伴う反応（PT）は，プラセボ群でも 3 例に発現し，うち 2 例は治験薬の投与に変更はなく，1 例は投与を中断した（ISS Table 2.4　1.1.6.12）。

重篤な過敏症の発現割合及び 100 人年あたりの発現件数は，リサンキズマブ 600 mg IV 群で 0.2%及び 0.6 件/100 人年，リサンキズマブ 1200 mg IV 群で 0%，プラセボ群で 0.1%及び 0.5 件/100 人年であった（表 2.7.4-16 及び ISS Table 2.4　1.1.2.2）。リサンキズマブ IV 群全体で重篤な過敏症が 1 例（600 mg）に発現した（ISS Table 2.4　1.1.4.1.11）。本被験者（被験者番号 [redacted]）で発現した重篤な過敏症については 2.7.4.2.1.5.1.4 項に示した。投与 55 日目に非重篤の発疹が発現し，治験薬の投与を中止し，最終投与日は投与 29 日目であった。発疹は 7 日後に自然消失した。投与 80 日目に重篤な発疹が発現し，被験者は入院した。投与 82 日目に重篤な肝機能異常が発現し，ALT，AST 及びビリルビンの増加が認められた。重篤な発疹は，治験責任（分担）医師により治験薬と関連ありと判断された。発疹の治療のため，副腎皮質ステロイドが投与された（M16-006 試験 CSR 12.2.1.3.2 項）。なお，プラセボ群でも重篤な過敏症が 1 例（被験者番号 [redacted]）に発現した（ISS Table 2.4　1.1.6.13）。

リサンキズマブ IV 群で抗薬物抗体検査を受けた被験者のうち，陽性であった被験者の過敏症の発現割合は，リサンキズマブ 600 mg IV 群で 7.7%（1/13 例，発疹），リサンキズマブ 1200 mg IV 群で 0%（0/4 例）であった（ISS Table 2.4　1.1.7.11）。陰性であった被験者の過敏症の発現割合はリサンキズマブ 600 mg IV 群で 4.7%（28/596 例），リサンキズマブ 1200 mg IV 群で 5.0%（28/561 例）であった。抗薬物抗体陽性の被験者に発現した事象（発疹）は軽度で，治験薬の投与中止に至らなかった（ISS Table 2.4　1.1.7.14）。

抗薬物抗体陽性の被験者が少なかったものの，これらの結果よりリサンキズマブの免疫原性が過敏症に及ぼす臨床的に重要な影響はないことが示唆された（免疫原性統合報告書［R&D/20/1400］［5.3.5.4-1 項］）。

12 週導入療法期の日本人部分集団では，過敏症がリサンキズマブ 1200 mg IV 群で 3 例（10.7%）に発現し，リサンキズマブ 600 mg IV 群及びプラセボ群では発現しなかった（M16-006 試験 JSA Table 14.3　2.1.7.5_J）。リサンキズマブ 1200 mg IV 群で発現した過敏症はいずれも湿疹であった。いずれの事象も，軽度，非重篤であり，治験責任（分担）医師により治験薬と関連なしと判断された（ISS Table 2.4　1.1.6.12）。治験薬の投与中止に至った事象は発現しなかった。

52 週までの維持療法

52 週維持療法安全性解析集団では，委員会判定されたアナフィラキシー反応は発現しなかった（表 2.7.4-18）。

52 週維持療法安全性解析集団の過敏症の 100 人年あたりの発現件数を表 2.7.4.7-41 に示す。

52 週維持療法安全性解析集団では，過敏症の 100 人年あたりの発現件数は，リサンキズマブ 180 mg SC 群（12.4 件/100 人年），リサンキズマブ 360 mg SC 群（12.6 件/100 人年）及び休薬群（プラセボ群）（11.8 件/100 人年）で同様であった。発現した過敏症はいずれも非重篤で（M16-000 試験 SS1 CSR Table 14.3　2.1.7.4），軽度又は中等度であった（M16-000 試験 SS1

CSR Table 14.3 2.1.11.4 及び 12.2.1.3.2 項）。治験薬の投与中止に至った過敏症は 1 件発現した（休薬群［プラセボ群］の 1 例に蕁麻疹が発現）。

リサンキズマブ SC 群全体で抗薬物抗体陽性の被験者は 4 例であり，うち 1 例で過敏症が発現した（M16-000 試験 SS1 CSR Table 14.3 2.1.7.5）。本被験者（被験者番号 [redacted]，2[redacted] 歳の白人女性，リサンキズマブ 180 mg SC 群）では，中和抗体も陽性であった。投与 183 日目（SS1 の投与 15 日目）に軽度の皮膚炎が発現した。本事象は治験薬の投与中止には至らず，治験責任（分担）医師により治験薬と関連なしと判断された（M16-000 試験 SS1 CSR Table 14.3 2.1.11.4, 12.2.1.3.2 項）。

52 週維持療法安全性解析集団の日本人部分集団では，過敏症の 100 人年あたりの発現件数は，リサンキズマブ 180 mg SC 群で 25.5 件/100 人年（3 件），リサンキズマブ 360 mg SC 群で 17.8 件/100 人年（2 件），休薬群（プラセボ群）で 8.8 件/100 人年（1 件）であった（M16-000 試験 SS1_JSA Table 14.3 2.1.7.2 J）。発現した過敏症はいずれも非重篤で（M16-000 試験 SS1_JSA Table 14.3 2.1.7.4 J），治験薬の投与中止には至らなかった（M16-000 試験 SS1 CSR Table 14.3 2.1.11.4）。

全安全性併合解析集団

クローン病患者を対象とした第 III 相試験では，委員会判定されたアナフィラキシー反応は発現しなかった（表 2.7.4-22）。

全安全性併合解析集団の全リサンキズマブ SC 群では，過敏症の 100 人年あたりの発現件数は 9.8 件/100 人年であり（ISS Table 2.4 1.5.4.1.19），52 週維持療法安全性解析集団のリサンキズマブ SC 群全体（12.5 件/100 人年）と同様であった。過敏症の多くは，非重篤で（ISS Table 2.4 1.5.4.1.21），軽度又は中等度であった（ISS Table 2.4 1.5.6.12）。全リサンキズマブ SC 群で治験薬の投与中止に至った過敏症は発現しなかった（ISS Table 2.4 1.5.4.3.10）。重篤な過敏症は，全リサンキズマブ群で 2 例に 3 件発現し，内訳は発疹（上述した 12 週導入療法期での発現），アナフィラキシー反応及び循環虚脱であった。重篤なアナフィラキシー反応及び循環虚脱は同一被験者での発現であり（ISS Table 2.4 1.5.6.13），以下に詳述する。

- 被験者番号 [redacted]：本被験者（4[redacted] 歳女性，第 II 相 M15-993 試験）では，投与 99 日目（非盲検のリサンキズマブ 600 mg IV 投与期）に重篤な循環虚脱が発現した。本事象による治験薬の投与中断はなく，薬物投与もなかった。その後，被験者は非盲検継続投与第 II 相 M15-989 試験に組み入れられ，リサンキズマブ 180 mg SC 投与を受けた。投与 611 日目にカルボキシマルトース第二鉄の IV 投与に対する重篤なアナフィラキシー反応が発現した（M15-989 試験 CSR 12.3.1.3.2 項）。本事象による治験薬の投与中止はなかった。循環虚脱及びアナフィラキシー反応は，治験責任（分担）医師により治験薬と関連なしと判断された。いずれの事象も発現当日に回復した。第 II 相試験では判定委員会を設置していなかったことから，アナフィラキシー反応に関する判定結果はない。

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全リサンキズマブ群で抗薬物抗体検査を受けた被験者では，過敏症の発現割合は陽性の被験者で 17.1%（6/35 例），陰性の被験者で 11.1%（150/1349 例）であった（ISS Table 2.4 1.5.7.13）。抗薬物抗体陽性の被験者に発現した事象はおおむね軽度で（高度の事象はなし），1 件が治験薬の投与中止に至った（ISS Table 2.4 1.5.7.16）。これらの結果より，リサンキズマブの免疫原性が過敏症に及ぼす臨床的に重要な影響はないことが示唆された（免疫原性統合報告書［R&D/20/1400］［5.3.5.4-1 項］）。

探索的な Cox 比例ハザードモデルで，投与群と事前に規定した過敏症のベースラインの予測因子を評価した。12 週導入療法安全性併合解析集団の第 III 相サブセット（M15-991 試験及び M16-006 試験のデータのみ）及び全安全性併合解析集団のデータを用いた。事前に規定した重要なベースラインの予測因子（性別［男性］及びベースラインのクローン病活動度指数）で調整した場合，有意な治療の影響は認められなかった（ISS Table 2.4 1.5.8.1.5）。

全安全性併合解析集団の過敏症の累積発現率プロットより，リサンキズマブ投与で過敏症の発現リスクは経時的に一定であることが示唆された（ISS Figure 2.4 1.5.8.2.9）。後期の時点では分母となる被験者数が少なかったため，発現率に大きなばらつきがみられた。

全安全性併合解析集団の日本人部分集団では，過敏症の 100 人年あたりの発現件数は，全リサンキズマブ SC 群で 11.2 件/100 人年（8 件）であった（表 2.7.4-23）。全リサンキズマブ SC 群で発現した過敏症はいずれも非重篤であり（J-ISS Table 2.4 1.5.2.4 J），治験薬の投与中止に至った事象は発現しなかった（J-ISS Table 2.4 1.5.2.6 J）。重篤な過敏症はいずれの投与群でも発現しなかった（J-ISS Table 2.4 1.5.2.4 J）。

2.7.4.2.1.5.1.6 注射部位反応（注入に伴う反応を含む）

注射部位反応の定義は 2.7.4.1.1.2.2.1 項に示した。なお，注射部位反応に含まれる PT のいくつかは，過敏症に含まれる PT と重複している。

抗薬物抗体のデータを有する第 II 相及び第 III 相試験の被験者を対象に，注射部位反応（注入に伴う反応を含む）に及ぼす免疫原性の影響を評価した。12 週導入療法安全性併合解析集団，24 週導入療法安全性併合解析集団及び全安全性併合解析集団で，注射部位反応の発現割合を抗薬物抗体陽性と陰性の被験者で比較した（免疫原性統合報告書［R&D/20/1400］［5.3.5.4-1 項］）。

12 週導入療法

12 週導入療法安全性併合解析集団の注射部位反応（注入に伴う反応を含む）の発現割合を表 2.7.4.7-42 に，100 人年あたりの発現件数を ISS Table 2.4 1.1.2.2 に示す。試験サイズで調整したデータを以下に示す。

12 週導入療法安全性併合解析集団では，注射部位反応（注入に伴う反応を含む）の発現割合及び 100 人年あたりの発現件数は，リサンキズマブ 600 mg IV 群で 0.8%及び 4.4 件/100 人年，リ

サンキズマブ 1200 mg IV 群で 2.0%及び 8.2 件/100 人年，プラセボ群で 1.0%及び 4.2 件/100 人年であった。リサンキズマブ IV 群全体で，重篤な注射部位反応（注入に伴う反応を含む）は発現せず（ISS Table 2.4 1.1.7.6），すべての事象は軽度又は中等度であった（ISS Table 2.4 1.1.7.9）。注射部位反応の発現までの期間は投与 1 日目～104 日目の範囲であった。治験薬の投与中止に至った注射部位反応は，計 2 例（リサンキズマブ 600 mg IV 群及び 1200 mg IV 群で各 1 例［0.2%］）に発現し，いずれも注入に伴う反応であった（ISS Table 2.4 1.1.7.7）。これら 2 例の詳細は 2.7.4.2.1.5.1.5 項（過敏症）に示した。いずれの事象も非重篤で，軽度又は中等度であった（ISS Table 2.4 1.1.7.9）。

抗薬物抗体検査を受けた被験者のうち，陽性の被験者では注射部位反応（注入に伴う反応を含む）は発現しなかったが（リサンキズマブ 600 mg IV 群：0%［0/13 例］，リサンキズマブ 1200 mg IV 群：0%［0/4 例］），陰性の被験者では注射部位反応（注入に伴う反応を含む）の発現割合はリサンキズマブ 600 mg IV 群で 0.8%（5/596 例），リサンキズマブ 1200 mg IV 群で 2.0%（11/561 例）であった（ISS Table 2.4 1.1.7.10）。これらの結果より，リサンキズマブの免疫原性が注射部位反応（注入に伴う反応を含む）に及ぼす影響はないことが示唆された（免疫原性統合報告書［R&D/20/1400］［5.3.5.4-1 項］）。

12 週導入療法期の日本人部分集団では，注射部位反応がリサンキズマブ 600 mg IV 群で 1 例（3.2%）に発現し，リサンキズマブ 1200 mg IV 群及びプラセボ群では発現しなかった（M16-006 試験 JSA Table 14.3 2.1.10.3 J）。発現した事象は注射部位疼痛であった。本事象は軽度で，非重篤であり，治験薬の投与中止に至らなかった（ISS Table 2.4 1.1.7.9）。

52 週までの維持療法

52 週維持療法安全性解析集団の注射部位反応の 100 人年あたりの発現件数を表 2.7.4.7-43 に示す。

52 週維持療法安全性解析集団では，注射部位反応の 100 人年あたりの発現件数は，リサンキズマブ 180 mg SC 群で 9.5 件/100 人年，リサンキズマブ 360 mg SC 群で 13.8 件/100 人年，休薬群（プラセボ群）で 8.1 件/100 人年であった。いずれの投与群でも最も多かった事象は注射部位紅斑であった。重篤な事象，高度の事象及び治験薬の投与中止に至った事象は発現しなかった（M16-000 試験 SS1 CSR Table 14.3 2.1.11.7）。

リサンキズマブ SC 群全体で抗薬物抗体陽性であった被験者 4 例では，注射部位反応は発現しなかった（M16-000 試験 SS1 CSR Table 14.3 2.1.10.3）。

52 週維持療法安全性解析集団の日本人部分集団では，注射部位反応の 100 人年あたりの発現件数は，リサンキズマブ 360 mg SC 群で 8.9 件/100 人年（1 件，注射部位疼痛），休薬群（プラセボ群）で 8.8 件/100 人年（1 件，注射部位紅斑）であり，リサンキズマブ 180 mg SC 群では発現しなかった（M16-000 試験 SS1_JSA Table 14.3 2.1.10.2 J）。重篤な事象及び治験薬の投与中止に至った事象は発現しなかった（M16-000 試験 SS1 CSR Table 14.3 2.1.11.7）。

全安全性併合解析集団

全安全性併合解析集団の全リサンキズマブ SC 群では，注射部位反応の 100 人年あたりの発現件数は 9.5 件/100 人年であり（ISS Table 2.4 1.5.7.6），52 週維持療法安全性解析集団のリサンキズマブ SC 群全体（11.6 件/100 人年）と比較して低かった。全リサンキズマブ群では，重篤な事象（ISS Table 2.4 1.5.7.8）及び高度の事象（ISS Table 2.4 1.5.7.11）は発現せず，治験薬の投与中止に至った事象を発現した被験者はわずか（3 例［0.2%］）であった（ISS Table 2.4 1.5.7.9）。

全リサンキズマブ SC 群で抗薬物抗体検査を受けた被験者では，注射部位反応の発現割合は陽性の被験者で 7.1%（2/28 例），陰性の被験者で 4.0%（45/1134 例）であった（ISS Table 2.4 1.5.7.12）。陽性の被験者 2 例に発現した注射部位反応はいずれも軽度であった（ISS Table 2.4 1.5.7.15）。これらの結果より，リサンキズマブの免疫原性が注射部位反応に及ぼす臨床的に重要な影響はないことが示唆された（免疫原性統合報告書［R&D/20/1400］［5.3.5.4-1 項］）。

探索的な Cox 比例ハザードモデルで，投与群と事前に規定した注射部位反応のベースラインの予測因子を評価した。12 週導入療法安全性併合解析集団の第 III 相サブセット（M15-991 試験及び M16-006 試験のデータのみ）及び全安全性併合解析集団のデータを用いた。事前に規定した重要なベースラインの予測因子（地域［北米］及び性別［男性］）で調整した場合，有意な治療の影響は認められなかった（ISS Table 2.4 1.5.8.1.4）。

全安全性併合解析集団の注射部位反応の累積発現率プロットより，リサンキズマブ投与で注射部位反応の発現リスクは経時的に一定であることが示唆された（ISS Figure 2.4 1.5.8.2.8）。後期の時点では分母となる被験者数が少なかったため，発現率に大きなばらつきがみられた。

全安全性併合解析集団の日本人部分集団では，注射部位反応の 100 人年あたりの発現件数は，全リサンキズマブ SC 群で 5.6 件/100 人年（4 件）であった（表 2.7.4-23）。全リサンキズマブ群では，重篤な事象（J-ISS Table 2.4 1.5.7.8 J）及び治験薬の投与中止に至った事象（J-ISS Table 2.4 1.5.7.9 J）は発現しなかった。

2.7.4.2.2 個別有害事象の文章による説明

M15-993 試験，M16-006 試験，M16-000 試験 SS1，M15-989 試験，M15-991 試験及び M19-128 試験での死亡例及び重篤な有害事象発現例の詳細（叙述）は，2.7.6 項及び各試験の CSR（14.3__3 項）に示す。M16-000 試験 SS2 及び SS3 の死亡例及び重篤な有害事象発現例の詳細は 5.3.5.4-4 項に示す。

2.7.4.3 臨床検査値の評価

個々の試験の結果は 2.7.6 項及び CSR に示す。肝機能検査値の結果は 2.7.4.2.1.5.1.4 項に示したことから，本項には記載しない。

2.7.4.3.1 臨床検査値の推移

12 週導入療法

12 週導入療法安全性併合解析集団では，血液学的検査及び血液生化学検査パラメータ（肝機能検査を除く）のベースラインからの平均変化量は，おおむね小さく，臨床的に意味のあるものではないと考えられた（ISS Table 2.5　1.1.1 及び Figure 2.5　1.1.4.4）。いずれの投与群でも，血小板数を除き血液学的検査及び血液生化学検査パラメータの推移に臨床的に重要な傾向及び用量依存的な傾向は認められなかった。リサンキズマブ 600 mg IV 群及び 1200 mg IV 群では，血小板数の平均値がわずかに減少したが，平均値は基準範囲内であった。血小板数の平均値で認められた減少は，リサンキズマブを投与された被験者で全身性の炎症が減少（例：高感度 C 反応性蛋白質が減少）したことによるものと考えられる。

52 週までの維持療法

52 週維持療法安全性解析集団では，血液学的検査及び血液生化学検査パラメータ（肝機能検査を除く）の SS1 の投与 0 週時からの平均変化量は，おおむね小さく，臨床的に意味のあるものではないと考えられた（M16-000 試験 SS1 CSR Table 14.3　4.1.2.3 及び Table 14.3　4.1.2.4）。いずれの投与群でも，血小板数を除き血液学的検査及び血液生化学検査パラメータの推移に臨床的に重要な傾向及び用量依存的な傾向は認められなかった。リサンキズマブ 180 mg SC 群及び 360 mg SC 群では，血小板数の平均値がわずかに減少したが，平均値は基準範囲内であった（M16-000 試験 SS1 CSR 12.3.2.1.1 項）。血小板数の平均値で認められた減少は，リサンキズマブの投与を継続した被験者で炎症が減少したことによるものと考えられる。

2.7.4.3.2 個々の被験者の変化

2.7.4.3.2.1 血液学的検査

12 週導入療法

12 週導入療法安全性併合解析集団では，血液学的検査値がベースラインの Grade 0，1 又は 2 から投与期間中に Grade 3 以上となった被験者は，いずれの投与群でもおおむね少なく，投与群間で臨床的に意味のある差は認められなかった（ISS Table 2.5　1.1.2）。

52 週までの維持療法

52 週維持療法安全性解析集団では，血液学的検査値が導入療法試験のベースラインの Grade 0，1 又は 2 から投与期間中に Grade 3 以上となった被験者は，いずれの投与群でもおおむね少なく，投与群間で臨床的に意味のある差は認められなかった（M16-000 試験 SS1 CSR Table 14.3　4.1.4.1）。

2.7.4.3.2.2 血液生化学検査（肝機能検査を除く）

12 週導入療法

12 週導入療法安全性併合解析集団では，血液生化学検査値のうちクレアチニンを評価した。クレアチニン値がベースラインの Grade 0，1 又は 2 から投与期間中に Grade 3 以上となった被験者は，いずれの投与群でもおおむね少なく，投与群間で臨床的に意味のある差は認められなかった（ISS Table 2.5　1.1.2）。

52 週までの維持療法

52 週維持療法安全性解析集団では，血液生化学検査値（肝機能検査を除く）が導入療法試験のベースラインの Grade 0，1 又は 2 から投与期間中に Grade 3 以上となった被験者は，いずれの投与群でもおおむね少なく，投与群間で臨床的に意味のある差は認められなかった（M16-000 試験 SS1 CSR Table 14.3　4.1.4.2）。

2.7.4.3.3 個々の臨床的に重要な異常

2.7.4.3.3.1 血液学的検査

12 週導入療法

12 週導入療法安全性併合解析集団では，試験サイズで調整したデータを以下に示す。Grade 3 又は 4 の基準に該当した血液学的検査値が認められた被験者の割合は低く（リサンキズマブ IV の各用量群でいずれのパラメータも 3.5%未満），投与群間でおおむね同様であった（ISS Table 2.5　1.1.3.1）。リサンキズマブ IV 群全体では，4 例が Grade 4 の基準値に該当した。リンパ球数が Grade 4 の基準に該当した 1 例（投与 58 日目及び 85 日目に該当）は，スクリーニング時，ベースライン及び試験期間を通して Grade 3 の基準に該当するリンパ球数も認められた（ISS Table 2.5　1.1.3.2 及び M16-006 試験 CSR 12.3.2.3.1 項）。リサンキズマブ IV 群全体では，血液学的検査パラメータで Grade 4 の基準に該当した異常値は，いずれも有害事象として報告されなかった（ISS Table 2.5　1.1.3.2 及び M16-006 試験 CSR Appendix 16.2　7.1.1）。

Grade 3 の基準値に該当した好中球数がリサンキズマブ IV 群全体で 4 例（0.3%）に認められたが，プラセボ群では認められなかった（ISS Table 2.5　1.1.3.1）。このうちリサンキズマブ 600 mg IV 群の 1 例では，投与 92 日目（追跡調査期間中）に非重篤の好中球減少症（中等度）が発現し，治験薬と関連ありと判断された（ISS Table 2.5　1.1.3.2 及び M16-006 試験 CSR Appendix 16.2　7.1.1）。

52 週までの維持療法

52 週維持療法安全性解析集団では，Grade 3 又は 4 の基準（SS1 の投与 0 週時との比較）に該当した血液学的検査値が認められた被験者の割合は低く（リサンキズマブ SC の各用量群でいず

れのパラメータも 3.0%未満），投与群間で同様であった（M16-000 試験 SS1 CSR Table 14.3　4.1.5.3）。

リサンキズマブ 180 mg SC 群及び 360 mg SC 群では，Grade 3 の血小板数，Grade 4 の血小板数，白血球数及びリンパ球数は認められなかった（M16-000 試験 SS1 CSR Table 14.3　4.1.5.3）。リサンキズマブ 180 mg SC 群及び 360 mg SC 群で有害事象として報告された異常値の多くは，治験責任（分担）医師により治験薬と関連なしと判断され，投与中止に至った有害事象は発現しなかった（M16-000 試験 SS1 CSR 12.3.2.3.1 項）。

リサンキズマブ 360 mg SC 群の 1 例（被験者番号 [redacted]）では，1 時点で Grade 4 に該当した好中球数が認められた（M16-000 試験 SS1 CSR Table 14.3　4.1.5.4）。異常値（0.138 × 10^9/L）は投与 343 日目（SS1 の投与 252 日目）に認められ，有害事象として報告はされなかった（M16-000 試験 SS1 CSR 12.3.2.3.1 項）。2 日後の再検査では基準値範囲内であった。

全安全性併合解析集団

全安全性併合解析集団の全リサンキズマブ SC 群では，Grade 3 又は 4 の基準に該当した血液学的検査値が認められた被験者の割合は低かった（いずれのパラメータも 2.0%未満）（ISS Table 2.5　1.5.3.1）。Grade 3 又は 4 の異常値の多くは一過性であった（ISS Table 2.5　1.5.3.2）。

2.7.4.3.3.2　血液生化学検査（肝機能検査を除く）

12 週導入療法

12 週導入療法安全性併合解析集団では，試験サイズで調整したデータを以下に示す。Grade 3 又は 4 の基準に該当した血液生化学検査値が認められた被験者の割合は低く（リサンキズマブ IV の各用量群でいずれのパラメータも 2.0%未満），投与群間で同様であった（ISS Table 2.5　1.1.3.1）。リサンキズマブ 600 mg IV 群の 2 例が Grade 4 の基準値に該当した。1 例では Grade 4 のカリウム低値が認められ，有害事象として低カリウム血症及び低リン酸血症が報告され，同時に血中マグネシウム減少も報告された（ISS Table 2.5　1.1.3.2 及び M15-993 試験 CSR Appendix 16.2　7.1）。これらの事象はいずれも重篤で，治験薬と関連なしと判断され，治験薬の投与は中止されなかった。他の 1 例で認められた Grade 4 のトリグリセリド高値は，有害事象として報告されなかった（ISS Table 2.5　1.1.3.2 及び M16-006 試験 CSR Appendix 16.2　7.1.1）。

試験来院の前に絶食は必要としなかった。いずれの投与群でも Grade 4 のグルコース高値は認められなかった（ISS Table 2.5　1.1.3.1）。Grade 3 のグルコース高値が認められた被験者の割合は，リサンキズマブ IV 群全体（0.6%）とプラセボ群（1.0%）で同様であった。

52 週までの維持療法

52 週維持療法安全性解析集団では，Grade 3 又は 4 の基準（SS1 の投与 0 週時との比較）に該当した血液生化学検査値が認められた被験者の割合は低く（リサンキズマブ SC の各用量群でい

ずれのパラメータも 1.5%未満），投与群間で同様であった（M16-000 試験 SS1 CSR Table 14.3　4.1.6.3）。

リサンキズマブ 360 mg SC 群の 1 例で，Grade 4 の基準に該当した検査値が認められた。本被験者では，トリグリセリド増加が投与 262 日目（M16-000 試験 SS1 の投与 170 日目，12.52 mmol/L［Grade 4］），SS1 の投与 190 日目（8.45 mmol/L［Grade 3］）及び SS1 の投与 282 日目（16.25 mmol/L［Grade 4］）で認められた（M16-000 試験 SS1 CSR Table 14.3　4.1.6.4）。この増加は，SS1 の投与 172 日目に非重篤の有害事象（血中トリグリセリド増加）として報告された（M16-000 試験 SS1 CSR 12.3.2.3.2 項）。本事象は，治験責任（分担）医師により治験薬と関連なしと判断され，治験薬の投与に変更はなかった。

また，リサンキズマブ 180 mg SC 群の 1 例で，Grade 3 の基準に該当した検査値が有害事象として報告された。本被験者は，Grade 3 のトリグリセリド増加が 2 時点で認められた。最初に認められたトリグリセリド増加は，非重篤の有害事象として報告された（M16-000 試験 SS1 CSR 12.3.2.3.2 項）。本事象は，治験責任（分担）医師により治験薬と関連なしと判断され，治験薬の投与に変更はなかった。

Grade 4 のグルコース高値はいずれの投与群でも認められなかった（M16-000 試験 SS1 CSR Table 14.3　4.1.6.3）。リサンキズマブ 360 mg SC 群の 2 例で Grade 3 のグルコース高値が認められた。リサンキズマブ SC 群全体で Grade 3 のグルコース高値が認められた被験者の割合（0.6%）は，休薬群（プラセボ群）と同じであった（M16-000 試験 SS1 CSR Table 14.3　4.1.6.3）。

全安全性併合解析集団

全安全性併合解析集団の全リサンキズマブ SC 群では，Grade 3 又は 4 の基準に該当した血液生化学検査値が認められた被験者の割合は低かった（いずれのパラメータも 1.5%未満）（ISS Table 2.5　1.5.3.1）。Grade 3 又は 4 の異常値の多くは一過性であった（ISS Table 2.5　1.5.3.2）。

2.7.4.3.4　臨床検査値結果の要約

血液学的及び血液生化学検査で，検査値の平均変化量の推移，個々の被験者での変化及び臨床的に意義があると判断した異常値を検討した結果，リサンキズマブ投与で用量依存的な傾向及び重要な安全性の懸念は認められなかった。

2.7.4.4　バイタルサイン，身体的所見及び安全性に関連する他の観察項目

個々の試験の結果は 2.7.6 項及び CSR に示す。

12 週導入療法安全性併合解析集団では，リサンキズマブ投与期間中のバイタルサインパラメータの平均変化量は，臨床的に意味のあるものではなく，プラセボ群の変化量と同様であった（ISS Table 2.6　1.1.1）。リサンキズマブ IV 群全体で臨床的に意義があると判断したバイタル

サインの基準に該当した被験者の割合（試験サイズで調整）は低かった（各投与群でいずれのパラメータも 2.4%以下）（ISS Table 2.6　1.1.2.1）。

52 週維持療法安全性解析集団では，リサンキズマブ投与でバイタルサインパラメータの投与 0 週時からの平均変化量は，臨床的に意味のあるものではなかった（M16-000 試験 SS1 CSR Table 14.3　5.1.1.3）。臨床的に意義があると判断したバイタルサインの基準に該当した被験者の割合は低かった（各投与群でいずれのパラメータも 6.0%未満）（M16-000 試験 SS1 CSR Table 14.3　5.1.2.3）。全安全性併合解析集団の全リサンキズマブ SC 群でも同様の結果が認められ，臨床的に意義があると判断したバイタルサインの基準に該当した被験者の割合はいずれのパラメータでも 6.0%未満であった（ISS Table 2.6　1.5.2.1）。

2.7.4.5 特別な患者集団及び状況下における安全性

2.7.4.5.1 補足的な安全性併合解析対象集団及び第 I 相試験の安全性の結果

2.7.4.5.1.1 導入療法期 2（投与 24 週時）にリサンキズマブにより臨床的改善を達成した被験者（24 週導入療法安全性併合解析集団）

本解析集団の主な目的は，12 週導入療法期の終了時にリサンキズマブ IV 投与で臨床的改善を達成せず，導入療法期 2 に再ランダム化され，リサンキズマブ 1200 mg IV，180 mg SC 又は 360 mg SC を投与された被験者の安全性を評価することであった（表 2.7.4-3）。したがって，本安全性解析集団には，12 週導入療法期にプラセボを IV 投与され，導入療法期 2 にリサンキズマブ 1200 mg を IV 投与された被験者（プラセボ / リサンキズマブ 1200 mg IV 群）及びリサンキズマブ IV を 12 週導入療法期及び導入療法期 2 を通して 24 週間受けた被験者が含まれた。

全体集団

24 週導入療法安全性併合解析集団での導入療法期 2（投与 12 週時から 24 週時）の有害事象の概要を表 2.7.4-24 及び ISS Table 2.4　1.2.1.3（100 人年あたりの発現状況）に示す。

24 週導入療法安全性併合解析集団での導入療法期 2 の有害事象，重篤な有害事象，高度の有害事象及び治験薬の投与中止に至った有害事象の発現割合及び 100 人年あたりの発現件数は，12 週導入療法安全性併合解析集団（表 2.7.4-8 及び表 2.7.4.7-1）と比較しておおむね低かった。リサンキズマブ 1200 mg IV 群の 1 例が導入療法期 2 に死亡した（ISS Table 2.4　1.2.5.3）。主な死因は敗血症であった（詳細は 2.7.4.2.1.2 項参照）。リサンキズマブ SC の用量と有害事象の発現に明らかな関連は認められず，リサンキズマブの投与群では有害事象に関して特定の傾向は認められなかった。

24 週導入療法安全性併合解析集団での導入療法期 2（投与 12 週時から 24 週時）の特に注目すべき事象の概要を表 2.7.4-25 及び ISS Table 2.4　1.2.2.3（100 人年あたりの発現状況）に示す。

24 週導入療法安全性併合解析集団での導入療法期 2 の特に注目すべき事象の発現割合及び 100 人年あたりの発現件数は，12 週導入療法安全性併合解析集団（表 2.7.4-16 及び ISS Table 2.4　1.1.2.2）とおおむね同様であった。リサンキズマブ SC の用量と特に注目すべき事象の発現に明らかな関連は認められず，リサンキズマブの投与群では特に注目すべき事象に関して特定の傾向は認められなかった。リサンキズマブ 1200 mg IV 群では，4 例に 6 件の肝関連事象が認められた。いずれの事象も非重篤で，軽度又は中等度であり，治験薬の投与中止には至らなかった（ISS Table 2.4　1.2.5.15）。

12 週導入療法期後に追加でリサンキズマブ 180 mg SC，360 mg SC 又は 1200 mg IV を 12 週間投与したとき，おおむね安全で忍容性は良好であった。12 週間の追加導入療法で新たな安全性のリスクは特定されず，全体の安全性プロファイルは，12 週導入療法期の安全性プロファイルと同様であった。

表 2.7.4-24. 24 週導入療法安全性併合解析集団での導入療法期 2（投与 12 週時から 24 週時）の有害事象の概要

	Risankizumab				
	180 mg SC (N = 108) n (%) [SSA %]	360 mg SC (N = 110) n (%) [SSA %]	1200 mg IV (N = 109) n (%) [SSA %]	Placebo IV/ Risankizumab 1200 mg IV (N = 162) n (%) [SSA %]	Total (N = 489) n (%) [SSA %]
Subjects with:					
All TEAEs	50 (46.3) [46.3]	54 (49.1) [49.0]	59 (54.1) [54.4]	83 (51.2) [51.5]	246 (50.3) [50.3]
Any COVID-19 related TEAEs	1 (0.9) [0.8]	0	1 (0.9) [0.8]	2 (1.2) [1.0]	4 (0.8) [0.8]
TEAEs related to study drug per investigator	16 (14.8) [15.0]	26 (23.6) [23.8]	13 (11.9) [11.7]	34 (21.0) [21.2]	89 (18.2) [18.2]
Severe TEAEs	4 (3.7) [3.8]	4 (3.6) [3.3]	5 (4.6) [4.6]	11 (6.8) [6.8]	24 (4.9) [4.9]
Serious TEAEs	5 (4.6) [4.7]	5 (4.5) [4.6]	7 (6.4) [6.5]	13 (8.0) [7.5]	30 (6.1) [6.1]
TEAEs leading to discontinuation of study drug	1 (0.9) [1.1]	2 (1.8) [1.9]	1 (0.9) [1.0]	1 (0.6) [0.5]	5 (1.0) [1.0]
TEAEs leading to death	0	0	1 (0.9) [1.0]	0	1 (0.2) [0.2]

Note: TEAEs are events occurring after the first dose of study drug in Period 2 and within 140 days after the last administration of study drug in Period 2, or until the first dose of study drug in Study M16-000.
ISS2 includes all subjects that have received at least one dose of study drug in the induction Period 2 from the two global Phase 3 studies: M15-991 and M16-006.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 are counted as severe.
Events with unknown relationship to study drug are being counted as having a reasonable possibility of being related to study drug.
SSA = Study size adjusted.

	Risankizumab				
	180 mg SC (N = 108) n (%) [SSA %]	360 mg SC (N = 110) n (%) [SSA %]	1200 mg IV (N = 109) n (%) [SSA %]	Placebo IV/ Risankizumab 1200 mg IV (N = 162) n (%) [SSA %]	Total (N = 489) n (%) [SSA %]
Subjects with:					
All deaths	0	0	1 (0.9) [1.0]	0	1 (0.2) [0.2]
Deaths occurring <= 140 days after last dose of study drug	0	0	1 (0.9) [1.0]	0	1 (0.2) [0.2]
Deaths occurring > 140 days after last dose of study drug	0	0	0	0	0
COVID-19 related deaths	0	0	0	0	0

Note: TEAEs are events occurring after the first dose of study drug in Period 2 and within 140 days after the last administration of study drug in Period 2, or until the first dose of study drug in Study M16-000.
ISS2 includes all subjects that have received at least one dose of study drug in the induction Period 2 from the two global Phase 3 studies: M15-991 and M16-006.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 are counted as severe.
Events with unknown relationship to study drug are being counted as having a reasonable possibility of being related to study drug.
SSA = Study size adjusted.

Cross Reference：ISS Table 2.4　1.2.1.1

表 2.7.4-25. 24 週導入療法安全性併合解析集団での導入療法期 2（投与 12 週時から 24 週時）の特に注目すべき事象の概要

	Risankizumab				
	180 mg SC (N = 108) n (%) [SSA %]	360 mg SC (N = 110) n (%) [SSA %]	1200 mg IV (N = 109) n (%) [SSA %]	Placebo IV/ Risankizumab 1200 mg IV (N = 162) n (%) [SSA %]	Total (N = 489) n (%) [SSA %]
Subjects with:					
Adjudicated MACE	0	0	0	0	0
Adjudicated extended MACE	0	0	0	0	0
Serious infections	0	1 (0.9) [0.8]	1 (0.9) [1.0]	4 (2.5) [2.3]	6 (1.2) [1.2]
Active tuberculosis	0	0	0	0	0
Opportunistic infection excluding tuberculosis and herpes zoster	0	0	0	2 (1.2) [1.0]	2 (0.4) [0.4]

Note: TEAEs are events occurring after the first dose of study drug in Period 2 and within 140 days after the last administration of study drug in Period 2, or until the first dose of study drug in Study M16-000.
ISS2 includes all subjects that have received at least one dose of study drug in the induction Period 2 from the two global Phase 3 studies: M15-991 and M16-006.
SSA = Study size adjusted.

	Risankizumab				
	180 mg SC (N = 108) n (%) [SSA %]	360 mg SC (N = 110) n (%) [SSA %]	1200 mg IV (N = 109) n (%) [SSA %]	Placebo IV/ Risankizumab 1200 mg IV (N = 162) n (%) [SSA %]	Total (N = 489) n (%) [SSA %]
Subjects with:					
Herpes zoster	0	1 (0.9) [0.8]	0	1 (0.6) [0.5]	2 (0.4) [0.4]
Malignant tumours	0	0	0	1 (0.6) [0.7]	1 (0.2) [0.2]
Non-melanoma skin cancer (NMSC)	0	0	0	1 (0.6) [0.7]	1 (0.2) [0.2]
Malignant tumours excluding NMSC	0	0	0	0	0
Hypersensitivity	4 (3.7) [3.6]	6 (5.5) [5.8]	9 (8.3) [8.0]	7 (4.3) [5.0]	26 (5.3) [5.3]
Serious hypersensitivity	0	0	0	0	0
Adjudicated anaphylactic reactions	0	0	0	0	0
Hepatic events	1 (0.9) [1.1]	1 (0.9) [1.0]	4 (3.7) [3.4]	1 (0.6) [0.7]	7 (1.4) [1.4]
Injection Site Reactions	2 (1.9) [2.1]	3 (2.7) [2.9]	3 (2.8) [2.5]	5 (3.1) [3.5]	13 (2.7) [2.7]

Note: TEAEs are events occurring after the first dose of study drug in Period 2 and within 140 days after the last administration of study drug in Period 2, or until the first dose of study drug in Study M16-000.
ISS2 includes all subjects that have received at least one dose of study drug in the induction Period 2 from the two global Phase 3 studies: M15-991 and M16-006.
SSA = Study size adjusted.

Cross Reference：ISS Table 2.4　1.2.2.1

日本人部分集団

24 週導入療法安全性併合解析集団に含まれる 2 試験のうち，M16-006 試験のみに日本人が含まれたことから，24 週導入療法安全性併合解析集団の全体集団に対する日本人部分集団の結果のうち，有害事象の概要は M16-006 試験の日本人部分集団の結果から示す。日本人部分集団での導入療法期 2 の有害事象の概要を表 2.7.4-26 に，特に注目すべき事象の概要を J-ISS Table 2.4 1.2.2.1 J に示す。

24 週導入療法期の日本人部分集団は少数であったため，明確な解釈は困難であった。

表 2.7.4-26. 日本人部分集団での導入療法期 2（投与 12 週時から 24 週時）の有害事象の概要

	Risankizumab 180 mg SC (N=5) n (%)	Risankizumab 360 mg SC (N=4) n (%)	Risankizumab 1200 mg IV (N=4) n (%)	Placebo IV/ Risankizumab 1200 mg IV (N=8) n (%)	Total (N=21) n (%)
Subjects with any treatment-emergent					
Adverse event (AE)	1 (20.0)	1 (25.0)	2 (50.0)	4 (50.0)	8 (38.1)
AE related to COVID-19	0	0	0	0	0
AE related to study drug according to the investigator	0	1 (25.0)	0	1 (12.5)	2 (9.5)
Severe AE	0	0	0	1 (12.5)	1 (4.8)
Serious AE	0	0	1 (25.0)	1 (12.5)	2 (9.5)
AE leading to discontinuation of study drug	0	0	0	0	0
AE leading to death	0	0	0	0	0
All deaths					
Deaths occurring <= 140 days after last dose of study drug	0	0	0	0	0
Deaths occurring > 140 days after last dose of study drug	0	0	0	0	0
Deaths related to COVID-19	0	0	0	0	0

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Subjects are counted once in each row, regardless of the number of events they may have had.

Cross Reference：M16-006 試験 JSA Table 14.3 1.2.1.1 J

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2.7.4.5.1.2 維持療法 1 安全性併合解析集団

本解析集団では，12 週導入療法期でリサンキズマブ又はプラセボの IV 投与により投与 12 週時に臨床的改善を達成し，又はプラセボ IV 投与により投与 12 週時に臨床的改善を達成せず，導入療法期 2 でリサンキズマブ 1200 mg IV 投与により投与 24 週時に臨床的改善を達成し，M16-000 試験 SS1 でリサンキズマブ又はプラセボの SC 投与を 1 回以上受けた被験者を対象に，リサンキズマブ又はプラセボの SC 投与による維持療法の安全性を解析する（表 2.7.4-3）。本集団には，リサンキズマブ IV 投与により臨床的改善を達成し，リサンキズマブ 180 mg SC，360 mg SC 又はプラセボ（すなわち，プラセボ SC［リサンキズマブ投与あり］群）に再ランダム化された被験者の安全性とプラセボ IV 投与により臨床的改善を達成し，維持療法でもプラセボ SC を投与された被験者（すなわち，プラセボ SC［リサンキズマブ未投与］群）の安全性を含めた。

全体集団

維持療法 1 安全性併合解析集団で得られた結果（ISS Table 2.4 1.3.1.2 及び Table 2.4 1.3.2.2）は，52 週維持療法安全性解析集団と同様であり，特筆すべき点は認められなかった。MACE，悪性腫瘍及び感染症（重篤な感染症を含む）の発現が全安全性併合解析集団（表 2.7.4-22）と比較して多くなることはなかった。

日本人部分集団

維持療法 1 安全性併合解析集団の日本人部分集団の有害事象の概要を J-ISS Table 2.4 1.3.1.2 J に，特に注目すべき事象の概要を J-ISS Table 2.4 1.3.2.2 J に示す。

維持療法 1 安全性併合解析集団の日本人部分集団は少数であったため，明確な解釈は困難であった。

2.7.4.5.1.3 維持療法 2 安全性併合解析集団

本解析集団では，12 週導入療法期でリサンキズマブ IV 投与により投与 12 週時に臨床的改善を達成せず，導入療法期 2 でリサンキズマブ SC 投与により投与 24 週時に臨床的改善を達成した被験者を対象にリサンキズマブ SC 投与による維持療法の安全性を解析する。また，12 週導入療法期でプラセボ IV 投与により投与 12 週時に臨床的改善を達成し，維持療法でもプラセボ SC 投与を受けた被験者（すなわちリサンキズマブ未投与）の安全性も解析する（表 2.7.4-3）。

全体集団

維持療法 2 安全性併合解析集団で得られた結果（ISS Table 2.4 1.4.1.2 及び Table 2.4 1.4.2.2）は，52 週維持療法安全性解析集団と同様であり，特筆すべき点は認められなかった。

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日本人部分集団

維持療法 2 安全性併合解析集団の日本人部分集団の有害事象の概要を J-ISS Table 2.4 1.4.1.2 J に，特に注目すべき事象の概要を J-ISS Table 2.4 1.4.2.2 J に示す。

維持療法 2 安全性併合解析集団の日本人部分集団は少数であったため，明確な解釈は困難であった。

2.7.4.5.1.4 第 I 相 M19-128 試験

クローン病患者を対象とした第 III 相試験で用いたコンビネーション製剤は，市販予定製剤とは異なる。M19-128 試験は，導入療法及び維持療法で用いるコンビネーション製剤について，第 III 相試験と市販予定製剤をブリッジするために実施した。M19-128 試験の主な目的は，健康被験者を対象に，第 III 相試験製剤と市販予定製剤間のバイオアベイラビリティを比較することであった。付加的な目的は，市販予定製剤の安全性及び忍容性を第 III 相試験製剤と比較することであった。本試験は 2 つの Substudy で構成された。Substudy 1 では，リサンキズマブ 360 mg を PFS（1 mL，90 mg/mL，第 III 相試験製剤）により 90 mg を 4 回 SC 投与したときと，オンボディデリバリーシステム（以下「OBDS」）（2.4 mL，150 mg/mL，市販予定製剤）により 1 回 SC 投与したときのリサンキズマブのバイオアベイラビリティを比較した。Substudy 2 では，リサンキズマブ 1800 mg を 300 mg のバイアル（3.33 mL，90 mg/mL，第 III 相試験製剤）で 6 バイアルを IV 投与したときと，600 mg のバイアル（10 mL，60 mg/mL，市販予定製剤）で 3 バイアルを IV 投与したときのバイオアベイラビリティを比較した。

Substudy 1 の安全性

SC 投与での PFS と OBDS を評価する SS1 では，市販予定製剤（リサンキズマブ 360 mg, OBDS）の注射部位反応の発現割合（34.9%［45/129 例］）は，第 III 相試験で用いた PFS 製剤（8.7%［11/127 例］）と比較して高かった（M19-128 試験 CSR Table 14.3 1.1.1）。注射部位反応はすべて軽度であり，その多くは発現当日に回復した（M19-128 試験 CSR 12.1.3 項，Table 14.3 1.7.1 及び Appendix 16.2 7.1）。リサンキズマブ 360 mg OBDS 群で発現した注射部位反応の多くは，注射部位紅斑又は注射部位硬結であった（M19-128 試験 CSR Table 14.3 1.10.1）。本試験での注射部位反応の発現割合は，第 I 相試験のデザインの特徴（健康被験者は施設に滞在し，注意深く観察される）の影響を受けていると考えられる。なお，本試験では 1 例（PFS 製剤）に重篤な有害事象（うつ病）が発現し，2.7.4.2.1.3.4 項に記載した。

日本人部分集団では，注射部位反応の発現割合は，リサンキズマブ 360 mg OBDS 群で 100%（8/8 例），リサンキズマブ 360 mg PFS 群で 50.0%（4/8 例）であった（M19-128 試験 CSR Table 14.3 1.1.1）。

Substudy 2 の安全性

IV 投与では，市販予定製剤（リサンキズマブ 600 mg，60 mg/mL バイアル）の安全性及び忍容性は第 III 相試験製剤（リサンキズマブ 300 mg，90 mg/mL バイアル）と同様であった（M19-128 試験 CSR Table 14.3　1.1.2）。

2.7.4.5.1.5　第 I 相 M16-324 試験及び M16-533 試験

健康被験者を対象とした第 I 相の薬物動態及び忍容性試験である M16-324 試験及び M16-533 試験の結果は，本概要で示した主要及び補足的な安全性併合解析対象集団での結論を裏づけるものであった。安全性の懸念は特定されなかった。

2.7.4.5.2　内因性要因

有害事象の概要，特に注目すべき事象の概要及び各有害事象について，内因性要因（年齢，性別，体重，人種及び地域）を因子とした部分集団解析を実施した。日本人部分集団では，年齢，性別及び体重について実施した。

2.7.4.5.2.1　年齢

12 週導入療法安全性併合解析集団のリサンキズマブ IV 群全体及びプラセボ群では，16 歳以上 18 歳未満が 9 例（0.8%）及び 5 例（1.2%），18 歳以上 40 歳未満が 670 例（56.0%）及び 255 例（59.0%），40 歳以上 65 歳未満が 463 例（38.7%）及び 150 例（34.7%），65 歳以上が 55 例（4.6%）及び 22 例（5.1%）であった（ISS Table 2.2　1.1.1）。12 週導入療法安全性併合解析集団では，年齢別の有害事象及び特に注目すべき事象の各カテゴリーの発現に明らかな傾向は認められなかった（ISS Table 2.4　1.1.5.1.1 及び Table 2.4　1.1.5.2.1）。65 歳以上の被験者では，いずれの投与群でも特に注目すべき事象の各カテゴリーを発現した被験者はわずかであった。

全安全性併合解析集団の全リサンキズマブ群では，18 歳未満を除き年齢別の有害事象及び特に注目すべき事象の各カテゴリーの発現に傾向はおおむね認められなかったが，18 歳未満の被験者では有害事象の 100 人年あたりの発現件数が 18 歳以上の被験者と比較して数値的に高かった（ISS Table 2.4　1.5.5.1.1 及び Table 2.4　1.5.5.2.2）。ただし，18 歳未満の被験者は少なく，ばらつきが大きかったことから，これらの差の解釈には留意する必要がある。

全体のデータから，リサンキズマブ投与と年齢の間に新たな安全性の知見は特定されなかった。

2.7.4.5.2.2　性別

12 週導入療法安全性併合解析集団のリサンキズマブ IV 群全体及びプラセボ群では，女性の割合が 47.7%及び 50.9%，男性が 52.3%及び 49.1%であった（ISS Table 2.2　1.1.1）。12 週導入療法安全性併合解析集団では，リサンキズマブ IV の両用量群及びプラセボ群の有害事象及び特に

注目すべき事象の各カテゴリー（感染症の各有害事象を含む）の発現割合は，女性で男性と比較しておおむね高かった（ISS Table 2.4 1.1.5.1.2，Table 2.4 1.1.5.2.2 及び Table 2.4 1.1.5.4.2）。全安全性併合解析集団の全リサンキズマブ群でも，有害事象及び特に注目すべき事象の各カテゴリーの 100 人年あたりの発現件数で同様の傾向が認められた（ISS Table 2.4 1.5.5.1.3，Table 2.4 1.5.5.2.3 及び Table 2.4 1.5.5.4.2）。

全体のデータから，リサンキズマブ投与と性別の間に新たな安全性の知見は特定されなかった。

2.7.4.5.2.3 体重

12 週導入療法安全性併合解析集団のリサンキズマブ IV 群全体及びプラセボ群では，60 kg 未満が 352 例（29.4%）及び 134 例（31.0%），60 kg 以上が 845 例（70.6%）及び 298 例（69.0%）であった（ISS Table 2.2 1.1.1）。12 週導入療法安全性併合解析集団では，リサンキズマブ IV の両用量群及びプラセボ群の有害事象及び特に注目すべき事象の各カテゴリーの発現割合は，60 kg 未満の被験者で 60 kg 以上の被験者と比較しておおむね高かった（ISS Table 2.4 1.1.5.1.3 及び Table 2.4 1.1.5.2.3）。全安全性併合解析集団の全リサンキズマブ群でも，有害事象及び特に注目すべき事象の各カテゴリーの 100 人年あたりの発現件数で同様の傾向が認められた（ISS Table 2.4 1.5.5.1.5 及び Table 2.4 1.5.5.2.5）。

全体のデータから，リサンキズマブ投与と体重の間に新たな安全性の知見は特定されなかった。

2.7.4.5.2.4 人種

12 週導入療法安全性併合解析集団のリサンキズマブ IV 群全体及びプラセボ群では，白人の被験者が 975 例（81.5%）及び 352 例（81.5%），白人以外の被験者が 222 例（18.5%）及び 80 例（18.5%）であった（ISS Table 2.2 1.1.1）。12 週導入療法安全性併合解析集団では，リサンキズマブ IV 群全体及びプラセボ群の有害事象及び特に注目すべき事象の各カテゴリーの発現割合は，白人の被験者で白人以外の被験者と比較しておおむね高かった（ISS Table 2.4 1.1.5.1.4 及び Table 2.4 1.1.5.2.4）。全安全性併合解析集団の全リサンキズマブ群でも，有害事象及び特に注目すべき事象の各カテゴリーの 100 人年あたりの発現件数で同様の傾向が認められた（ISS Table 2.4 1.5.5.1.7 及び Table 2.4 1.5.5.2.7）。

全体のデータから，リサンキズマブ投与と人種の間に新たな安全性の知見は特定されなかった。

2.7.4.5.2.5 地域

12 週導入療法安全性併合解析集団では，組み入れられた被験者が多かった地域は，西欧及び北米であった（両地域とも約 30%）（ISS Table 2.2 1.1.1）。12 週導入療法安全性併合解析集団

では，地域別の有害事象及び特に注目すべき事象の各カテゴリーの発現割合に明らかな傾向は認められなかった（ISS Table 2.4　1.1.5.1.5 及び Table 2.4　1.1.5.2.5）。全安全性併合解析集団の全リサンキズマブ群でも，有害事象及び特に注目すべき事象の各カテゴリーの 100 人年あたりの発現件数に明らかな傾向は認められなかった（ISS Table 2.4　1.5.5.1.9 及び Table 2.4　1.5.5.2.9）。

全体のデータから，リサンキズマブ投与と地域の間に新たな安全性の知見は特定されなかった。

2.7.4.5.2.6　日本人部分集団解析

12 週導入療法期の日本人部分集団での人口統計学特性を M16-006 試験 JSA Table 14.1　1.5.4 J に示す。

12 週導入療法期の日本人部分集団での年齢別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.1 J に，全安全性併合解析集団の日本人部分集団での年齢別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.1 J に示す。

12 週導入療法期の日本人部分集団での性別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.2 J に，全安全性併合解析集団の日本人部分集団での性別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.3 J に示す。

12 週導入療法期の日本人部分集団での体重別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.3 J に，全安全性併合解析集団の日本人部分集団での体重別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.5 J に示す。

12 週導入療法期及び全安全性併合解析集団の日本人部分集団の各部分集団は少数であったため，明確な解釈は困難であった。

2.7.4.5.3　外因性要因

有害事象の概要，特に注目すべき事象の概要及び各有害事象について，外因性要因（Bio-IR の有無，過去に無効であった生物学的製剤の数，ベースラインでの副腎皮質ステロイドの使用の有無［第 III 相試験はランダム化時のデータを使用］，ベースラインでの免疫調節薬の使用の有無）を因子とした部分集団解析を実施した。

2.7.4.5.3.1　Bio-IR の有無

12 週導入療法安全性併合解析集団では，Bio-IR の被験者の割合は，リサンキズマブ IV 群全体で 71.5%，プラセボ群で 78.9%であった（ISS Table 2.2　1.1.2）。12 週導入療法安全性併合解析集団では，Bio-IR の有無別の有害事象及び特に注目すべき事象の各カテゴリーの発現割合に明らかな傾向は認められなかった（ISS Table 2.4　1.1.5.1.7 及び Table 2.4　1.1.5.2.7）。

52 週維持療法安全性解析集団では，Bio-IR の有無別の特に注目すべき事象を確認した結果，リサンキズマブ 360 mg SC 群では，重篤な感染症の 100 人年あたりの発現件数は，Bio-IR あり（9.2 件/100 人年）で Bio-IR なし（0 件）と比較して多かった（M16-000 試験 SS1 CSR Table 14.3 1.1.1.19 及び Table 14.3 1.1.1.20）。休薬群（プラセボ群）でも同様の傾向が認められ，重篤な感染症の 100 人年あたりの発現件数は，Bio-IR あり（6.2 件/100 人年）で Bio-IR なし（2.1 件/100 人年）と比較して多かった。ただし，リサンキズマブ 180 mg SC 群では，重篤な感染症の 100 人年あたりの発現件数は，Bio-IR あり（1.7 件/100 人年）で Bio-IR なし（5.6 件/100 人年）と比較して少なかった。注目すべき点として，Bio-IR の有無に関係なく，リサンキズマブ SC 群全体での重篤な感染症の 100 人年あたりの発現件数（Bio-IR あり：5.3 件/100 人年，Bio-IR なし：2.7 件/100 人年）は，休薬群（プラセボ群）（それぞれ 6.2 件/100 人年及び 2.1 件/100 人年）と同様であった。このことから，重篤な感染症の Bio-IR 有無別の発現傾向が投与群間で異なったのは，概して発現件数が少なかったためであり，リサンキズマブ 360 mg SC 群で重篤な感染症の 100 人年あたりの発現件数が Bio-IR ありの被験者で多かった原因は，リサンキズマブ投与ではなく，Bio-IR の有無である可能性の方が高いことが示唆された。

全安全性併合解析集団の全リサンキズマブ群では，有害事象，重篤な有害事象及び治験薬の投与中止に至った有害事象の 100 人年あたりの発現件数は，Bio-IR ありで Bio-IR なしと比較しておおむね多かった（ISS Table 2.4 1.5.5.1.13）。特に注目すべき事象の各カテゴリーについては，全リサンキズマブ群での過敏症の 100 人年あたりの発現件数が Bio-IR あり（14.9 件/100 人年）で Bio-IR なし（8.1 件/100 人年）と比較して数値的に多かった（ISS Table 2.4 1.5.5.2.13）。全プラセボ IV / SC（リサンキズマブ未投与）群でも同様の傾向が認められ，過敏症の 100 人年あたりの発現件数は Bio-IR あり（19.6 件/100 人年）で Bio-IR なし（10.7 件/100 人年）と比較して多かった。全リサンキズマブ群での過敏症の 100 人年あたりの発現件数は，Bio-IR あり及びなし共に全プラセボ IV / SC（リサンキズマブ未投与）群と比較して少なかった。その他の特に注目すべき事象の 100 人年あたりの発現件数は，Bio-IR ありと Bio-IR なしでおおむね同様であったか，発現件数が少なく意味のある比較ができなかったかのいずれかであった。全リサンキズマブ群での重篤な感染症の 100 人年あたりの発現件数は，Bio-IR あり（3.7 件/100 人年）と Bio-IR なし（3.1 件/100 人年）で同様であったことから，リサンキズマブ投与による重篤な感染症の発現リスクに Bio-IR ありとなしの集団で意味のある違いはないことが更に示唆された。

2.7.4.5.3.2 過去に無効であった生物学的製剤の数

12 週導入療法安全性併合解析集団では，過去に無効であった生物学的製剤の数が 1 及び 2 以上の被験者の割合は，リサンキズマブ IV 群全体でそれぞれ 34.7%及び 36.5%，プラセボ群でそれぞれ 35.4%及び 42.5%であった（ISS Table 2.2 1.1.2）。12 週導入療法安全性併合解析集団では，過去に無効であった生物学的製剤の数別の有害事象及び特に注目すべき事象の各カテゴリーの発現割合に明らかな傾向は認められなかった（ISS Table 2.4 1.1.5.1.6 及び Table 2.4 1.1.5.2.6）。全安全性併合解析集団の全リサンキズマブ群でも，有害事象及び特に注目すべ

き事象の各カテゴリーの 100 人年あたりの発現件数に明らかな傾向は認められなかった（ISS Table 2.4　1.5.5.1.11 及び Table 2.4　1.5.5.2.11）。

2.7.4.5.3.3　　ベースラインでの副腎皮質ステロイドの使用の有無

12 週導入療法安全性併合解析集団では，ベースラインで副腎皮質ステロイドを使用していた被験者の割合は，リサンキズマブ IV 群全体で 32.6%，プラセボ群で 33.8%であった（ISS Table 2.2　1.1.2）。12 週導入療法安全性併合解析集団では，ベースラインの副腎皮質ステロイドの使用の有無別の有害事象及び特に注目すべき事象の各カテゴリーの発現割合に明らかな傾向は認められなかった（ISS Table 2.4　1.1.5.1.8 及び Table 2.4　1.1.5.2.8）。全安全性併合解析集団の全リサンキズマブ群でも，同様の傾向が認められた（ISS Table 2.4　1.5.5.1.15 及び Table 2.4　1.5.5.2.15）。

2.7.4.5.3.4　　ベースラインでの免疫調節薬の使用の有無

12 週導入療法安全性併合解析集団では，ベースラインで免疫調節薬（アザチオプリン，6-メルカプトプリン及びメトトレキサート）を使用していた被験者の割合は，リサンキズマブ IV 群全体で 24.6%，プラセボ群で 25.7%であった（ISS Table 2.2　1.1.2）。12 週導入療法安全性併合解析集団では，ベースラインでの免疫調節薬の使用の有無別の有害事象及び特に注目すべき事象の各カテゴリーの発現割合に明らかな傾向は認められなかった（ISS Table 2.4　1.1.5.1.9 及び Table 2.4　1.1.5.2.9）。全安全性併合解析集団の全リサンキズマブ群でも，同様の傾向が認められた（ISS Table 2.4　1.5.5.1.17 及び Table 2.4　1.5.5.2.17）。

2.7.4.5.3.5　　日本人部分集団解析

12 週導入療法期の日本人部分集団での Bio-IR の有無，過去に無効であった生物学的製剤の数，ベースラインの副腎皮質ステロイドの使用の有無（ランダム化時から更新されたデータを使用），ベースラインの免疫調節薬の使用の有無を M16-006 試験 JSA Table 14.1　1.6.4 J に示す。

12 週導入療法期の日本人部分集団での Bio-IR の有無別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.7 J に，全安全性併合解析集団の日本人部分集団での Bio-IR の有無別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.13 J に示す。

12 週導入療法期の日本人部分集団での過去に無効であった生物学的製剤の数別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.6 J に，全安全性併合解析集団の日本人部分集団での過去に無効であった生物学的製剤の数別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.12 J に示す。

12 週導入療法期の日本人部分集団でのベースラインの副腎皮質ステロイドの使用の有無別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.8 J に，全安全性併合解析集団の日本人部分集団での

ベースラインの副腎皮質ステロイドの使用の有無別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.15 J に示す。

12 週導入療法期の日本人部分集団でのベースラインの免疫調節薬の使用の有無別の有害事象の概要を J-ISS Table 2.4　1.1.5.1.9 J に，全安全性併合解析集団の日本人部分集団でのベースラインの免疫調節薬の使用の有無別の有害事象の概要（100 人年あたりの発現件数）を J-ISS Table 2.4　1.5.5.1.17 J に示す。

12 週導入療法期及び全安全性併合解析集団の日本人部分集団の各部分集団は少数であったため，明確な解釈は困難であった。

2.7.4.5.4　薬物相互作用

リサンキズマブと，シトクロム P450（以下「CYP」）1A2，CYP2C9，CYP2C19，CYP2D6，CYP3A などの CYP450 酵素の活性との薬物相互作用の可能性は，それらのプローブ基質を用いて，尋常性乾癬患者を対象とした第 I 相 M16-007（1311.36）試験で評価した。本試験は尋常性乾癬に対するリサンキズマブの承認申請で提出した（「スキリージ皮下注 75mg シリンジ 0.83mL」平成 30 年 05 月 25 日承認申請の CTD 2.7.2.2.4 項）。尋常性乾癬患者でリサンキズマブと併用投与したとき，プローブ基質の曝露量に臨床的に重要な変化は認められなかった。

2.7.4.5.5　妊娠及び授乳時の使用

IgG 抗体は妊娠 14 週以後に発現する合胞体栄養膜細胞上の Fc 受容体を介して母体から胎児に盛んに移行し，妊娠第二期から活発な移行が始まり，妊娠第三期の終わりまで増大する。妊娠第一期の Fc 受容体の欠如が示唆することは，妊娠第一期の胎児は器官形成期（3 週から 8 週）に IgG クラスのモノクローナル抗体に曝露されないため，IgG クラス抗体への母体内曝露による変異原性及び催奇形作用のリスクは無視できることである[28, 29, 30]。

妊婦でのリサンキズマブの使用に関するデータは限られている。ヒト IgG は特に妊娠第三期に胎盤関門を越えることが知られている。したがって，リサンキズマブは妊娠後期に母体から発育中の胎児に移行する可能性がある。

動物試験では妊娠，胚発生 / 胎児発生，出産又は生後発達に対して直接的又は間接的な有害作用は示されていない。出生前及び出生後の発生に関する拡大毒性試験をカニクイザルで実施した。本試験では，薬物関連の胎仔 / 出生仔の奇形，死亡又は 6 ヵ月齢までの仔の成長や発達への影響を認めなかった。

リサンキズマブのクローン病臨床開発プログラムでは，妊娠可能な女性被験者は有効性の高い（失敗率が年間 1%未満と低い）受胎調節法を実施する必要があるとした。授乳中又は妊娠中の女性は試験参加に不適格とした。試験期間中に妊娠した場合，被験者は参加中止とした。被験者の妊娠は有害事象とみなさなかった。

リサンキズマブのクローン病臨床開発プログラムでは，母体内曝露妊娠が 20 件発生した（表 2.7.4-27）。

妊娠の転帰は以下のとおりである（表 2.7.4-27）。

- M15-989 試験：選択的中絶（胎児の欠陥あり）1 件及び先天異常なく生児出生 1 件
- M15-993 試験：選択的中絶（胎児の欠陥なし）1 件及び先天異常なく生児出生 1 件
- M15-991 試験：先天異常なく生児出生 2 件及び自然流産 1 件
- M16-006 試験：選択的中絶（胎児の欠陥なし）1 件
- M16-000 試験：妊娠継続 6 件，先天異常なく生児出生 2 件，選択的中絶（胎児の欠陥なし）2 件，追跡不能 1 件及び自然流産 1 件

妊娠転帰を叙述として記録し，各試験の CSR に示す。

M15-989 試験では，胎児の欠陥が認められた選択的中絶が 1 件発生した。本件は，2[redacted] 歳の白人女性被験者で妊娠 12 週に発生し，胎児嚢胞性ヒグローマ及び胎児水腫によるものであった。本被験者は，M15-993 試験に組み入れられ，その後 M15-989 試験に移行し，リサンキズマブ（180 mg SC 投与を 8 週ごと）を 20[redacted]年[redacted]月[redacted]日から投与され，妊娠判明後の投与 560 日後に中止した。被験者は妊娠前から妊娠第一期までの間にリサンキズマブの曝露を受けており，ノルトリプチリン，アセトアミノフェン及びデソゲストレル等が併用投与されていた。絨毛膜標本採取による染色体分析の結果は正常であり，ヒトパルボウイルス検査で急性感染は示唆されなかった。治験責任（分担）医師により本件は治験薬と関連ありと判断された。アッヴィ社は，公表されているデータに基づき治験薬と関連なしと判断した。公表されているデータによると，IgG 抗体は妊娠 14 週以後に発現する合胞体栄養膜細胞上の Fc 受容体を介して母体から胎児に盛んに移行し，妊娠第二期から活発な移行が始まり，妊娠第三期の終わりまで増大する。妊娠第一期の Fc 受容体の欠如が示唆することは，妊娠第一期の胎児は器官形成期（3 週から 8 週）に IgG クラスのモノクローナル抗体に曝露されないため，IgG クラス抗体への母体内曝露による変異原性及び催奇形作用のリスクは無視できることである [28, 29, 30]。M15-989 試験の中止後，被験者は選択的中絶の約 5 ヵ月後に妊娠し，自然流産した。

表 2.7.4-27. リサンキズマブのクローン病臨床開発プログラムの妊娠の要約

Maternal Exposure Outcomes (N = 20)	Risankizumab	Placebo	Total
Live birth without congenital anomaly	3	3	6
Spontaneous Abortion	2	0	2
Elective termination (fetal defects)	1	0	1
Elective termination with no fetal defects	3	1	4
Ongoing pregnancy	6	0	6
Subject lost to follow up	1	0	1
Total	16	4[a]	20

a. Two of the 4 subjects were randomized to the withdrawal (placeboSC) arm in the maintenance study, M16-000, where the pregnancy events occurred, after previously receiving risankizumab in the induction study. The pregnancy outcomes, as described above, were live birth without congenital anomaly for 1 subject and elective termination with no fetal defects for the second subject.

男性被験者及びその女性パートナーは，治験実施計画書に従い，避妊は必要とされなかった。免疫グロブリンであるリサンキズマブに，遺伝毒性はなく，受胎産物に移行する精液の量は無視できる。結果的に，リサンキズマブのような高分子医薬品は，男性精液中に移行して女性パートナーの健康リスクとはならず，発生する受胎産物に取り込まれて利用されることもない[31]。

リサンキズマブのクローン病臨床データパッケージで，男性被験者のパートナーに父性曝露妊娠が 1 件報告された。妊娠の転帰は以下のとおりである。

- M15-989 試験 – リサンキズマブ群：先天異常なく生児出生 1 件

リサンキズマブのヒトでの母乳移行，授乳中の乳児に対する影響，母乳分泌に対する影響についてデータは存在しない。ヒト IgG はヒトの母乳中に分泌されるが，公表されているデータから，母乳中の抗体は新生児及び乳児の循環血中に大量に移行しないことが示唆されている[32]。

妊娠について，発生毒性試験では催奇形作用は示唆されなかった。利用可能な臨床試験が不十分であり，妊婦に対するリサンキズマブ投与のリスクについて評価することはできない。

2.7.4.5.6 過量投与

リサンキズマブの過量投与の報告はなかった。また，臨床試験期間中に用量制限毒性もみられなかった。

過量投与が起きた場合，副作用の徴候及び症状がないか患者をモニタリングすることが推奨される。副作用を発現した患者には適切な治療を行う必要がある。

2.7.4.5.7 薬物乱用

臨床試験では，薬物乱用又は依存性の報告はなく，薬物乱用に関連するその他の情報も報告されていない。リサンキズマブによる治療が薬物乱用を生じさせる根拠及び予測はない。

2.7.4.5.8 離脱症状及び反跳現象

リサンキズマブのクローン病臨床開発プログラムのいずれの臨床試験でも，離脱症状及び反跳現象の報告はなかった。

2.7.4.5.9 自動車運転及び機械操作に対する影響又は精神機能の障害

リサンキズマブが自動車運転及び機械操作に影響を及ぼす又は精神機能に障害を生じさせる根拠及び予測はない。

2.7.4.6 市販後データ

本邦では，2019 年 3 月 26 日（国際誕生日）に尋常性乾癬，関節症性乾癬，膿疱性乾癬，乾癬性紅皮症を有する成人患者を対象にリサンキズマブ 150 mg 及び 75 mg の SC 投与（0 週，4 週，以降 12 週間隔）が初めて承認された。また，150 mg/mL の PFS 及び自己注射器が日本，米国，及び欧州で承認されている。アッヴィ社は，通常の医薬品安全性監視を通して，新たな潜在的安全性シグナルのモニタリングを継続している。この調査には，市販後報告（文献を含むすべての情報源）からの重篤及び非重篤な事象の報告，並びに臨床試験で発現した重篤な有害事象の週 1 回の評価，米国食品医薬品局（FDA）の有害事象報告システムデータベースから得られたデータマイニングスコアの四半期ごとの評価，特に注目すべき有害事象の結果を要約した項を含む規定期間ごとの定期報告（定期的安全性最新報告，治験安全性最新報告，定期副作用報告等）及び市販後調査が含まれる。

リサンキズマブ 150 mg の安全性は，20[redacted] 年 [redacted] 月 [redacted] 日から 20[redacted] 年 [redacted] 月 [redacted] 日までに収集した市販後報告（自発報告，非自発的な報告及び文献）をもとに評価した。アッヴィ社のグローバル安全性データベースを検索し，29696 の報告から 58850 件の情報を入手し，主に乾癬患者で報告されたものであった。報告の 91.6%（27205/29696）は非重篤な事象であった。また，報告の 95.5%（28358/29696）は非自発的な報告からの情報であり，主に患者サポートプログラムから収集された。最も発現割合が高かった MedDRA の SOC は一般・全身障害および投与部位の状態（全報告数の 36%）であり，その中で報告数が多かった事象は，薬効欠如，疲労及び治療効果短縮であった。

報告の中で発現割合が高かった事象は，乾癬（8.5%），薬効欠如（3.8%），疲労（3.6%），そう痒症（3.3%）及び頭痛（3%）であった。これらの事象はいずれもリサンキズマブの添付文書に提示されているか，一般集団又は乾癬患者でよくみられる事象であった。有効性の欠如

（乾癬及び薬効欠如［PT］）は，発現割合が高かった事象として示しているが，慢性疾患を適応症とする製剤では予想できないものではなかった。

最も発現割合が高かった重篤な有害事象は死亡（0.2%）であった。121 の死亡報告のうち 112 は非自発的な市販後報告であったが，データ品質において限界があることからロバスト解析からは除外した。110 の死亡報告は情報が限定的であり，リサンキズマブとの因果関係を判断することができなかった。11 の死亡報告は重大な合併症による死亡及び自然死であった。年齢の記載があった 71 の報告では，死亡の多くは高齢者集団で認められ，年齢の中央値は 69 歳であった。最も多かった適応症は乾癬（79%）であり，その他の多くは不明（17%）であった。クローン病患者 1 例で死亡が報告されたが，情報が限定的であり，医学的評価ができなかった。乾癬は複数の合併症を伴うことから，死亡のリスクが高くなる可能性があり，コホート研究では重症乾癬患者の全死亡リスクの上昇（ハザード比：1.5，95%信頼区間：1.3–1.7）が報告されている[33]。

2 番目に発現割合が高かった重篤な有害事象は COVID-19（0.17%）であり，次いで入院（0.15%），肺炎（0.14%）及び脳血管発作（0.14%）であった。COVID-19 は，標準の監視活動を通してモニタリングを継続するが，現時点では COVID-19 とリサンキズマブ投与で新たな安全性リスクは特定されていない。COVID-19 パンデミックが継続しており，検査能力が向上していくことを考慮すると，リサンキズマブを投与された患者での報告数が増えることは予想できないことではない。肺炎及び脳血管発作は，発現割合が高い重篤な有害事象であったが，これらの事象の発現はまれであった。これらの事象は重篤な感染症及び MACE に関連するものであり，それぞれ重要な特定されたリスク及び重要な潜在的リスクとしてモニタリングを継続するが，現時点では新たな安全性の懸念は特定されていない。複数の試験で示された心血管系イベントのリスクを上昇させる因子は，乾癬患者では糖尿病，高血圧及び肥満であった[34]。また，中等症から重症の乾癬患者では，心筋梗塞[35]，脳卒中[36]及び心血管系イベントによる死亡[37]のリスクが上昇することが示された。

その他の重篤な有害事象の発現割合は，全件数の 0.2%未満であり，乾癬患者では死亡のリスクを上昇させる可能性のある合併症を有していることが多いことから，これらの結果は予想できないものではない。市販後報告を評価した結果，リサンキズマブの上市により新たな安全性リスクは特定されなかった。

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2.7.4.7 付録

表2.7.4.7-1

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RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 432)	600 mg IV (N = 620)	1200 mg IV (N = 577)	Total (N = 1197)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
Exposure-adjusted event rate:	(PYs = 117.6) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 159.8) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 143.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 303.1) Events (E/100 PYs) [SSA E/100 PYs]		
All TEAEs	876 (744.9) [707.2]	910 (569.5) [551.6]	713 (497.6) [497.3]	1623 (535.5) [540.9]	-155.6 (-216.5, -94.8)	-174.5 (-236.8, -112.3)
TEAEs related to COVID-19	4 (3.4) [4.0]	1 (0.6) [0.6]	0	1 (0.3) [0.3]	-3.5 (-7.7, 0.8)	-4.3 (-8.6, -0.0)
TEAEs related to study drug according to the investigator	188 (159.9) [154.5]	213 (133.3) [132.3]	198 (138.2) [137.1]	411 (135.6) [133.4]	-22.3 (-51.4, 6.8)	-17.5 (-48.2, 13.2)
Severe TEAEs	93 (79.1) [76.1]	42 (26.3) [25.7]	43 (30.0) [30.6]	85 (28.0) [27.9]	-50.3 (-68.3, -32.3)	-39.3 (-58.1, -20.4)
Serious TEAEs	115 (97.8) [93.7]	54 (33.8) [32.7]	30 (20.9) [21.1]	84 (27.7) [27.7]	-61.0 (-81.0, -41.0)	-64.6 (-84.4, -44.9)
TEAEs leading to discontinuation of study drug	51 (43.4) [43.7]	16 (10.0) [9.6]	15 (10.5) [10.7]	31 (10.2) [10.3]	-34.1 (-47.5, -20.8)	-32.4 (-46.5, -18.3)
TEAEs leading to death	5 (4.3) [5.6]	0	1 (0.7) [0.8]	1 (0.3) [0.4]	-5.6 (-10.6, -0.7)	-5.2 (-10.6, 0.3)

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 432)	600 mg IV (N = 620)	1200 mg IV (N = 577)	Total (N = 1197)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
All deaths	2 (1.7) [2.2]	0	1 (0.7) [0.8]	1 (0.3) [0.4]	-2.2 (-5.4, 0.9)	-1.6 (-5.2, 2.1)
Deaths occurring <= 140 days after last dose of study drug	2 (1.7) [2.2]	0	1 (0.7) [0.8]	1 (0.3) [0.4]	-2.2 (-5.4, 0.9)	-1.6 (-5.2, 2.1)
Deaths occurring > 140 days after last dose of study drug	0	0	0	0	0.0	0.0
Deaths related to COVID-19	0	0	0	0	0.0	0.0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 432)	600 mg IV (N = 620)	1200 mg IV (N = 577)	Total (N = 1197)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
Exposure-adjusted incidence rate:	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]		
All TEAEs	274/58.2 (470.8) [445.6]	339/96.0 (353.1) [347.8]	312/89.3 (349.4) [354.8]	651/185.3 (351.3) [353.9]	-97.8 (-163.8, -31.8)	-74.9 (-143.0, -6.7)
TEAEs related to COVID-19	3/116.9 (2.6) [3.0]	1/159.8 (0.6) [0.6]	0/143.3	1/303.1 (0.3) [0.3]	-2.4 (-6.0, 1.3)	-3.1 (-6.8, 0.5)
TEAEs related to study drug according to the investigator	91/98.8 (92.1) [92.5]	117/137.2 (85.3) [84.6]	108/123.9 (87.2) [87.3]	225/261.2 (86.1) [84.7]	-7.8 (-32.8, 17.1)	-6.2 (-32.6, 20.2)
Severe TEAEs	52/103.6 (50.2) [47.2]	32/154.4 (20.7) [20.2]	30/137.5 (21.8) [22.0]	62/291.9 (21.2) [21.1]	-26.9 (-42.0, -11.8)	-22.1 (-37.8, -6.3)
Serious TEAEs	67/100.2 (66.9) [65.5]	41/153.5 (26.7) [26.2]	23/138.9 (16.6) [16.7]	64/292.4 (21.9) [21.8]	-39.4 (-57.7, -21.1)	-43.8 (-61.8, -25.7)
TEAEs leading to discontinuation of study drug	37/104.5 (35.4) [34.0]	13/155.5 (8.4) [7.9]	12/139.3 (8.6) [8.7]	25/294.8 (8.5) [8.5]	-26.1 (-38.3, -13.9)	-23.5 (-36.2, -10.7)
TEAEs leading to death	2/116.9 (1.7) [2.3]	0/159.8	1/143.0 (0.7) [0.8]	1/302.8 (0.3) [0.4]	-2.3 (-5.4, 0.9)	-1.6 (-5.3, 2.1)

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 432)	600 mg IV (N = 620)	1200 mg IV (N = 577)	Total (N = 1197)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
All deaths	2/116.9 (1.7) [2.3]	0/159.8	1/143.1 (0.7) [0.8]	1/302.9 (0.3) [0.4]	-2.3 (-5.4, 0.9)	-1.6 (-5.3, 2.1)
Deaths occurring <= 140 days after last dose of study drug	2/116.9 (1.7) [2.3]	0/159.8	1/143.1 (0.7) [0.8]	1/302.9 (0.3) [0.4]	-2.3 (-5.4, 0.9)	-1.6 (-5.3, 2.1)
Deaths occurring > 140 days after last dose of study drug	0/117.6	0/159.8	0/143.3	0/303.1	0.0	0.0
Deaths related to COVID-19	0/117.6	0/159.8	0/143.3	0/303.1	0.0	0.0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 406)	600 mg IV (N = 572)	1200 mg IV (N = 535)	Total (N = 1107)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
Subjects with Baseline Eligibility SES-CD >= 6 (or >= 4 for Isolated Ileal Disease)						
Exposure-adjusted event rate:	(PYs = 110.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 147.1) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 133.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 280.4) Events (E/100 PYs) [SSA E/100 PYs]		
All TEAEs	819 (742.5) [707.4]	847 (575.8) [557.9]	662 (496.6) [494.3]	1509 (538.2) [545.0]	-149.4 (-212.5, -86.4)	-177.8 (-242.0, -113.6)
TEAEs related to COVID-19	4 (3.6) [4.3]	1 (0.7) [0.7]	0	1 (0.4) [0.3]	-3.6 (-8.1, 0.8)	-4.5 (-9.0, -0.0)
TEAEs related to study drug according to the investigator	175 (158.7) [154.3]	199 (135.3) [134.7]	193 (144.8) [143.2]	392 (139.8) [137.7]	-19.5 (-49.7, 10.7)	-12.6 (-44.6, 19.4)
Severe TEAEs	88 (79.8) [77.3]	32 (21.8) [21.5]	38 (28.5) [28.6]	70 (25.0) [24.9]	-55.8 (-74.3, -37.4)	-42.7 (-62.2, -23.2)
Serious TEAEs	110 (99.7) [95.6]	48 (32.6) [31.7]	25 (18.8) [18.6]	73 (26.0) [26.1]	-63.9 (-84.7, -43.2)	-69.2 (-89.6, -48.8)
TEAEs leading to discontinuation of study drug	49 (44.4) [45.0]	16 (10.9) [10.5]	13 (9.8) [10.0]	29 (10.3) [10.4]	-34.5 (-48.6, -20.5)	-34.4 (-49.1, -19.8)

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 406)	600 mg IV (N = 572)	1200 mg IV (N = 535)	Total (N = 1107)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
Subjects with Baseline Eligibility SES-CD >= 6 (or >= 4 for Isolated Ileal Disease)						
TEAEs leading to death	5 (4.5) [5.9]	0	0	0	-5.9 (-11.0, -0.7)	-6.2 (-11.7, -0.8)
All deaths	2 (1.8) [2.4]	0	0	0	-2.4 (-5.6, 0.9)	-2.5 (-6.0, 1.0)
Deaths occurring <= 140 days after last dose of study drug	2 (1.8) [2.4]	0	0	0	-2.4 (-5.6, 0.9)	-2.5 (-6.0, 1.0)
Deaths occurring > 140 days after last dose of study drug	0	0	0	0	0.0	0.0
Deaths related to COVID-19	0	0	0	0	0.0	0.0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 406)	600 mg IV (N = 572)	1200 mg IV (N = 535)	Total (N = 1107)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
Subjects with Baseline Eligibility SES-CD >= 6 (or >= 4 for Isolated Ileal Disease)						
Exposure-adjusted incidence rate:	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]		
All TEAEs	255/55.4 (460.3) [436.1]	316/87.1 (362.8) [356.4]	293/82.5 (355.2) [358.8]	609/169.7 (358.9) [362.3]	-79.7 (-147.6, -11.8)	-62.4 (-132.2, 7.4)
TEAEs related to COVID-19	3/109.5 (2.7) [3.1]	1/147.1 (0.7) [0.7]	0/133.3	1/280.4 (0.4) [0.3]	-2.5 (-6.3, 1.4)	-3.3 (-7.2, 0.5)
TEAEs related to study drug according to the investigator	84/92.8 (90.5) [91.3]	109/126.0 (86.5) [86.1]	105/114.6 (91.6) [91.4]	214/240.6 (88.9) [87.5]	-5.2 (-31.1, 20.6)	-1.6 (-29.0, 25.9)
Severe TEAEs	48/97.2 (49.4) [47.2]	27/142.5 (18.9) [18.5]	28/128.2 (21.8) [21.8]	55/270.6 (20.3) [20.3]	-28.7 (-44.3, -13.1)	-22.8 (-39.1, -6.4)
Serious TEAEs	62/94.1 (65.9) [64.9]	36/141.5 (25.4) [24.9]	20/129.8 (15.4) [15.4]	56/271.3 (20.6) [20.7]	-40.0 (-58.7, -21.2)	-44.7 (-63.1, -26.3)
TEAEs leading to discontinuation of study drug	35/98.0 (35.7) [34.6]	13/142.8 (9.1) [8.7]	10/129.8 (7.7) [7.8]	23/272.6 (8.4) [8.5]	-25.9 (-38.7, -13.1)	-24.9 (-38.0, -11.7)
TEAEs leading to death	2/109.5 (1.8) [2.4]	0/147.1	0/133.3	0/280.4	-2.4 (-5.7, 0.9)	-2.5 (-6.1, 1.0)

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.1.1.2

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			- 95% CI for Treatment Difference [A]-	
	Placebo IV (N = 406)	600 mg IV (N = 572)	1200 mg IV (N = 535)	Total (N = 1107)	600 mg IV VS Placebo IV	1200 mg IV VS Placebo IV
Subjects with Baseline Eligibility SES-CD >= 6 (or >= 4 for Isolated Ileal Disease)						
All deaths	2/109.5 (1.8) [2.4]	0/147.1	0/133.3	0/280.4	-2.4 (-5.7, 0.9)	-2.5 (-6.0, 1.0)
Deaths occurring <= 140 days after last dose of study drug	2/109.5 (1.8) [2.4]	0/147.1	0/133.3	0/280.4	-2.4 (-5.7, 0.9)	-2.5 (-6.0, 1.0)
Deaths occurring > 140 days after last dose of study drug	0/110.3	0/147.1	0/133.3	0/280.4	0.0	0.0
Deaths related to COVID-19	0/110.3	0/147.1	0/133.3	0/280.4	0.0	0.0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
E/100 PYs = Events per 100 patient-years. SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies: M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies: M15-993, M15-991 and M16-006.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

表2.7.4.7-2

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RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.1.7

Overview of Treatment-Emergent Adverse Events and All Deaths
Among Randomized Subjects
(SA1 Population)

		------ Risankizumab ------			- 95% CI& for Treatment Difference -		Risankizumab Rescue Therapy*
	Placebo SC (N=184) n (%)	180 mg SC (N=179) n (%)	360 mg SC (N=179) n (%)	Total (N=358) n (%)	180 mg SC VS Placebo SC	360 mg SC VS Placebo SC	(N=150) n (%)
Subjects with any treatment-emergent							
Adverse event (AE)	135 (73.4)	128 (71.5)	129 (72.1)	257 (71.8)	-1.9 (-11.1, 7.3)	-1.3 (-10.5, 7.9)	92 (61.3)
AE related to COVID-19	1 (0.5)	1 (0.6)	4 (2.2)	5 (1.4)	0.0 (-1.5, 1.5)	1.7 (-0.7, 4.1)	4 (2.7)
AE related to study drug according to the investigator	46 (25.0)	49 (27.4)	45 (25.1)	94 (26.3)	2.4 (-6.7, 11.4)	0.1 (-8.8, 9.1)	26 (17.3)
Severe AE	23 (12.5)	12 (6.7)	21 (11.7)	33 (9.2)	-5.8 (-11.8, 0.2)	-0.8 (-7.5, 5.9)	12 (8.0)
Serious AE	23 (12.5)	22 (12.3)	24 (13.4)	46 (12.8)	-0.2 (-7.0, 6.6)	0.9 (-6.0, 7.8)	18 (12.0)
AE leading to discontinuation of study drug	6 (3.3)	3 (1.7)	6 (3.4)	9 (2.5)	-1.6 (-4.8, 1.6)	0.1 (-3.6, 3.8)	3 (2.0)
AE leading to death	0	0	0	0	0.0	0.0	0
All deaths							
Deaths occurring <= 140 days after last dose of study drug	0	0	0	0	0.0	0.0	0
Deaths occurring > 140 days after last dose of study drug	0	0	0	0	0.0	0.0	0
Deaths related to COVID-19	0	0	0	0	0.0	0.0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
& 95% CI for treatment difference is based on the normal approximation.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-3

[redacted]20[redacted] 06:26 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.1.7 J

Overview of Treatment-Emergent Adverse Events and All Deaths
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

		------ Risankizumab ------			- 95% CI& for Treatment Difference -		Risankizumab Rescue
	Placebo SC (N=14) n (%)	180 mg SC (N=13) n (%)	360 mg SC (N=13) n (%)	Total (N=26) n (%)	180 mg SC VS Placebo SC	360 mg SC VS Placebo SC	Therapy* (N=13) n (%)
Subjects with any treatment-emergent							
Adverse event (AE)	10 (71.4)	8 (61.5)	11 (84.6)	19 (73.1)	-9.9 (-45.4, 25.6)	13.2 (-17.5, 43.9)	9 (69.2)
AE related to COVID-19	0	0	0	0	0.0	0.0	0
AE related to study drug according to the investigator	1 (7.1)	2 (15.4)	4 (30.8)	6 (23.1)	8.2 (-15.6, 32.0)	23.6 (-4.9, 52.1)	3 (23.1)
Severe AE	2 (14.3)	0	2 (15.4)	2 (7.7)	-14.3 (-32.6, 4.0)	1.1 (-25.7, 27.9)	1 (7.7)
Serious AE	2 (14.3)	0	3 (23.1)	3 (11.5)	-14.3 (-32.6, 4.0)	8.8 (-20.5, 38.1)	3 (23.1)
AE leading to discontinuation of study drug	1 (7.1)	0	0	0	-7.1 (-20.6, 6.3)	-7.1 (-20.6, 6.3)	1 (7.7)
AE leading to death	0	0	0	0	0.0	0.0	0
All deaths							
Deaths occurring <= 140 days after last dose of study drug	0	0	0	0	0.0	0.0	0
Deaths occurring > 140 days after last dose of study drug	0	0	0	0	0.0	0.0	0
Deaths related to COVID-19	0	0	0	0	0.0	0.0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
& 95% CI for treatment difference is based on the normal approximation.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-4

[redacted]20[redacted] 14:35 <[redacted] >

RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.5.1.1

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events
(All Treated Safety Analysis Set)

	Placebo IV/SC (RZB naive) (N = 432) n (%)	RZB 180 mg SC (N = 1096) n (%)	RZB 360 mg SC (N = 533) n (%)	RZB 600 mg IV (N = 688) n (%)
Subjects with:				
All TEAEs	306 (70.8)	656 (59.9)	338 (63.4)	409 (59.4)
Any COVID-19 related TEAEs	7 (1.6)	45 (4.1)	20 (3.8)	1 (0.1)
TEAEs related to study drug per investigator	99 (22.9)	216 (19.7)	121 (22.7)	140 (20.3)
Severe TEAEs	60 (13.9)	87 (7.9)	40 (7.5)	45 (6.5)
Serious TEAEs	80 (18.5)	121 (11.0)	58 (10.9)	55 (8.0)
TEAEs leading to discontinuation of study drug	42 (9.7)	33 (3.0)	15 (2.8)	17 (2.5)
TEAEs leading to death	2 (0.5)	2 (0.2)	0	0
All deaths	2 (0.5)	2 (0.2)	0	0
Deaths occurring <= 140 days after last dose of study drug	2 (0.5)	2 (0.2)	0	0
Deaths occurring > 140 days after last dose of study drug	0	0	0	0
COVID-19 related deaths	0	0	0	0

Note: TEAEs are defined as events with onset after the first dose of study drug and within 140 days after the last dose of study drug, or database cutoff, whichever is earliest. Subjects may be represented in more than one treatment group according to treatments received.
ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
Subjects may be represented in more than one treatment group according to treatments received.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 are counted as severe.
Events with unknown relationship to study drug are being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.5.1.1

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events
(All Treated Safety Analysis Set)

	RZB 1200 mg IV (N = 1023) n (%)	Any RZB SC (N = 1318) n (%)	Any RZB IV (N = 1536) n (%)	Any RZB (N = 1574) n (%)
Subjects with:				
All TEAEs	535 (52.3)	876 (66.5)	899 (58.5)	1214 (77.1)
Any COVID-19 related TEAEs	4 (0.4)	65 (4.9)	5 (0.3)	70 (4.4)
TEAEs related to study drug per investigator	187 (18.3)	314 (23.8)	325 (21.2)	510 (32.4)
Severe TEAEs	60 (5.9)	125 (9.5)	111 (7.2)	217 (13.8)
Serious TEAEs	59 (5.8)	177 (13.4)	122 (7.9)	274 (17.4)
TEAEs leading to discontinuation of study drug	21 (2.1)	48 (3.6)	43 (2.8)	91 (5.8)
TEAEs leading to death	2 (0.2)	2 (0.2)	2 (0.1)	4 (0.3)
All deaths	2 (0.2)	2 (0.2)	2 (0.1)	4 (0.3)
Deaths occurring <= 140 days after last dose of study drug	2 (0.2)	2 (0.2)	2 (0.1)	4 (0.3)
Deaths occurring > 140 days after last dose of study drug	0	0	0	0
COVID-19 related deaths	0	0	0	0

Note: TEAEs are defined as events with onset after the first dose of study drug and within 140 days after the last dose of study drug, or database cutoff, whichever is earliest. Subjects may be represented in more than one treatment group according to treatments received.
ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
Subjects may be represented in more than one treatment group according to treatments received.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 are counted as severe.
Events with unknown relationship to study drug are being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

表2.7.4.7-5

[redacted]20[redacted] 15:46 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.2.3 J

Subjects with Treatment-Emergent Adverse Events by System Organ Class
and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
Any adverse event	10 (62.5)	16 (51.6)	12 (42.9)	28 (47.5)
血液およびリンパ系障害	1 (6.3)	3 (9.7)	2 (7.1)	5 (8.5)
貧血	1 (6.3)	2 (6.5)	2 (7.1)	4 (6.8)
白血球減少症	0	1 (3.2)	0	1 (1.7)
胃腸障害	6 (37.5)	7 (22.6)	3 (10.7)	10 (16.9)
裂肛	0	1 (3.2)	0	1 (1.7)
肛門狭窄	0	0	1 (3.6)	1 (1.7)
大腸炎	0	0	1 (3.6)	1 (1.7)
便秘	0	3 (9.7)	0	3 (5.1)
クローン病	4 (25.0)	1 (3.2)	2 (7.1)	3 (5.1)
下痢	1 (6.3)	0	0	0
胃炎	1 (6.3)	0	0	0
胃食道逆流性疾患	0	1 (3.2)	0	1 (1.7)
イレウス	0	2 (6.5)	0	2 (3.4)
悪心	1 (6.3)	0	0	0
嘔吐	2 (12.5)	1 (3.2)	0	1 (1.7)

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.3_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class
and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
一般・全身障害および投与部位の状態	2 (12.5)	2 (6.5)	2 (7.1)	4 (6.8)
注射部位疼痛	0	1 (3.2)	0	1 (1.7)
末梢腫脹	0	0	1 (3.6)	1 (1.7)
発熱	2 (12.5)	1 (3.2)	1 (3.6)	2 (3.4)
肝胆道系障害	0	2 (6.5)	0	2 (3.4)
胆管結石	0	1 (3.2)	0	1 (1.7)
胆管炎	0	1 (3.2)	0	1 (1.7)
胆石症	0	1 (3.2)	0	1 (1.7)
感染症および寄生虫症	4 (25.0)	9 (29.0)	4 (14.3)	13 (22.0)
肛門膿瘍	0	2 (6.5)	0	2 (3.4)
膀胱炎	0	2 (6.5)	0	2 (3.4)
医療機器関連敗血症	1 (6.3)	0	0	0
陰部ヘルペス	0	1 (3.2)	0	1 (1.7)
帯状疱疹	0	1 (3.2)	0	1 (1.7)
上咽頭炎	1 (6.3)	4 (12.9)	4 (14.3)	8 (13.6)
口腔カンジダ症	1 (6.3)	0	0	0

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.3_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class
and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
感染症および寄生虫症 (Cont.)				
口腔ヘルペス	1 (6.3)	0	1 (3.6)	1 (1.7)
咽頭炎	1 (6.3)	0	0	0
肺炎	0	0	1 (3.6)	1 (1.7)
傷害、中毒および処置合併症	0	1 (3.2)	0	1 (1.7)
挫傷	0	1 (3.2)	0	1 (1.7)
臨床検査	0	1 (3.2)	1 (3.6)	2 (3.4)
アミラーゼ増加	0	0	1 (3.6)	1 (1.7)
リンパ球数減少	0	1 (3.2)	0	1 (1.7)
筋骨格系および結合組織障害	1 (6.3)	0	1 (3.6)	1 (1.7)
関節障害	1 (6.3)	0	0	0
背部痛	0	0	1 (3.6)	1 (1.7)
精神障害	0	2 (6.5)	0	2 (3.4)
感情障害	0	1 (3.2)	0	1 (1.7)
不眠症	0	1 (3.2)	0	1 (1.7)
腎および尿路障害	1 (6.3)	0	0	0
腎尿細管障害	1 (6.3)	0	0	0

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.3_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class
and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
生殖系および乳房障害	1 (6.3)	0	0	0
子宮頚部上皮異形成	1 (6.3)	0	0	0
呼吸器、胸郭および縦隔障害	2 (12.5)	0	0	0
口腔咽頭痛	1 (6.3)	0	0	0
上気道の炎症	1 (6.3)	0	0	0
皮膚および皮下組織障害	0	1 (3.2)	3 (10.7)	4 (6.8)
湿疹	0	0	3 (10.7)	3 (5.1)
痒疹	0	1 (3.2)	0	1 (1.7)

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表2.7.4.7-6

[redacted]20[redacted] 15:46 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.4.4 J

Subjects with Treatment-Emergent Adverse Events with a Reasonable Possibility
of Being Related to Study Drug by System Organ Class and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
Any adverse event	2 (12.5)	6 (19.4)	1 (3.6)	7 (11.9)
胃腸障害	0	1 (3.2)	1 (3.6)	2 (3.4)
肛門狭窄	0	0	1 (3.6)	1 (1.7)
便秘	0	1 (3.2)	0	1 (1.7)
感染症および寄生虫症	1 (6.3)	3 (9.7)	0	3 (5.1)
医療機器関連敗血症	1 (6.3)	0	0	0
帯状疱疹	0	1 (3.2)	0	1 (1.7)
上咽頭炎	0	2 (6.5)	0	2 (3.4)
臨床検査	0	1 (3.2)	0	1 (1.7)
リンパ球数減少	0	1 (3.2)	0	1 (1.7)
精神障害	0	1 (3.2)	0	1 (1.7)
感情障害	0	1 (3.2)	0	1 (1.7)
呼吸器、胸郭および縦隔障害	1 (6.3)	0	0	0
口腔咽頭痛	1 (6.3)	0	0	0

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表2.7.4.7-7

[redacted]20[redacted] 06:26 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.2.1 J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
Any adverse event	10 (71.4)	8 (61.5)	11 (84.6)	19 (73.1)	9 (69.2)
血液およびリンパ系障害	0	1 (7.7)	0	1 (3.8)	0
貧血	0	1 (7.7)	0	1 (3.8)	0
先天性、家族性および遺伝性障害	0	0	0	0	1 (7.7)
聴覚ニューロパチースペクトラム障害	0	0	0	0	1 (7.7)
耳および迷路障害	0	0	1 (7.7)	1 (3.8)	0
頭位性回転性めまい	0	0	1 (7.7)	1 (3.8)	0
眼障害	0	1 (7.7)	0	1 (3.8)	0
アレルギー性結膜炎	0	1 (7.7)	0	1 (3.8)	0
胃腸障害	8 (57.1)	4 (30.8)	8 (61.5)	12 (46.2)	4 (30.8)
上腹部痛	0	0	0	0	1 (7.7)
裂肛	0	1 (7.7)	2 (15.4)	3 (11.5)	0
痔瘻	0	0	0	0	1 (7.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
胃腸障害 (Cont.)					
肛門狭窄	1 (7.1)	0	1 (7.7)	1 (3.8)	1 (7.7)
肛門潰瘍	0	0	1 (7.7)	1 (3.8)	0
アフタ性潰瘍	0	1 (7.7)	1 (7.7)	2 (7.7)	0
クローン病	5 (35.7)	0	0	0	1 (7.7)
齲歯	1 (7.1)	1 (7.7)	2 (15.4)	3 (11.5)	0
下痢	1 (7.1)	0	0	0	0
胃炎	0	0	0	0	1 (7.7)
歯肉痛	0	0	1 (7.7)	1 (3.8)	0
回腸狭窄	1 (7.1)	0	0	0	1 (7.7)
過敏性腸症候群	0	0	1 (7.7)	1 (3.8)	0
悪心	0	1 (7.7)	0	1 (3.8)	0
小腸閉塞	0	0	1 (7.7)	1 (3.8)	0
一般・全身障害および投与部位の状態	2 (14.3)	2 (15.4)	3 (23.1)	5 (19.2)	2 (15.4)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
疲労	0	1 (7.7)	0	1 (3.8)	0
注射部位紅斑	1 (7.1)	0	0	0	1 (7.7)
注射部位疼痛	0	0	1 (7.7)	1 (3.8)	0
注射部位そう痒感	0	0	0	0	1 (7.7)
発熱	1 (7.1)	2 (15.4)	2 (15.4)	4 (15.4)	1 (7.7)
肝胆道系障害	0	1 (7.7)	0	1 (3.8)	0
肝機能異常	0	1 (7.7)	0	1 (3.8)	0
免疫系障害	0	0	0	0	1 (7.7)
季節性アレルギー	0	0	0	0	1 (7.7)
感染症および寄生虫症	6 (42.9)	5 (38.5)	5 (38.5)	10 (38.5)	5 (38.5)
四肢膿瘍	0	1 (7.7)	0	1 (3.8)	0
肛門膿瘍	0	0	1 (7.7)	1 (3.8)	0
バクテリアルトランスロケーション	0	0	0	0	1 (7.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
感染症および寄生虫症 (Cont.)					
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (7.7)
膀胱炎	0	0	1 (7.7)	1 (3.8)	0
毛包炎	1 (7.1)	0	0	0	1 (7.7)
歯肉炎	0	0	1 (7.7)	1 (3.8)	0
インフルエンザ	0	1 (7.7)	0	1 (3.8)	0
上咽頭炎	6 (42.9)	4 (30.8)	3 (23.1)	7 (26.9)	1 (7.7)
口腔ヘルペス	0	0	0	0	1 (7.7)
マイコプラズマ性肺炎	0	0	1 (7.7)	1 (3.8)	0
扁桃炎	0	0	0	0	1 (7.7)
上気道感染	0	1 (7.7)	0	1 (3.8)	0
傷害、中毒および処置合併症	0	0	1 (7.7)	1 (3.8)	1 (7.7)
節足動物咬傷	0	0	1 (7.7)	1 (3.8)	0
靭帯捻挫	0	0	0	0	1 (7.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
臨床検査	0	0	1 (7.7)	1 (3.8)	3 (23.1)
アラニンアミノトランスフェラーゼ増加	0	0	0	0	2 (15.4)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	0	1 (7.7)
γ-グルタミルトランスフェラーゼ増加	0	0	0	0	1 (7.7)
肝機能検査値上昇	0	0	1 (7.7)	1 (3.8)	0
尿潜血陽性	0	0	0	0	1 (7.7)
代謝および栄養障害	1 (7.1)	0	0	0	0
脱水	1 (7.1)	0	0	0	0
筋骨格系および結合組織障害	0	2 (15.4)	3 (23.1)	5 (19.2)	0
関節痛	0	2 (15.4)	1 (7.7)	3 (11.5)	0
四肢痛	0	0	2 (15.4)	2 (7.7)	0
滑液嚢腫	0	0	1 (7.7)	1 (3.8)	0
神経系障害	3 (21.4)	2 (15.4)	0	2 (7.7)	1 (7.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
神経系障害 (Cont.)					
浮動性めまい	1 (7.1)	0	0	0	1 (7.7)
頭痛	1 (7.1)	1 (7.7)	0	1 (3.8)	0
感覚鈍麻	1 (7.1)	0	0	0	0
失神寸前の状態	0	1 (7.7)	0	1 (3.8)	0
精神障害	1 (7.1)	1 (7.7)	2 (15.4)	3 (11.5)	0
適応障害	0	0	1 (7.7)	1 (3.8)	0
不安障害	0	0	1 (7.7)	1 (3.8)	0
不眠症	1 (7.1)	1 (7.7)	0	1 (3.8)	0
呼吸器、胸郭および縦隔障害	1 (7.1)	0	3 (23.1)	3 (11.5)	0
喘息	0	0	1 (7.7)	1 (3.8)	0
咳嗽	0	0	1 (7.7)	1 (3.8)	0
口腔咽頭痛	1 (7.1)	0	1 (7.7)	1 (3.8)	0
アレルギー性鼻炎	0	0	1 (7.7)	1 (3.8)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.2.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
皮膚および皮下組織障害	2 (14.3)	1 (7.7)	1 (7.7)	2 (7.7)	1 (7.7)
アレルギー性皮膚炎	0	0	0	0	1 (7.7)
接触皮膚炎	1 (7.1)	0	0	0	0
湿疹	0	0	1 (7.7)	1 (3.8)	0
結節性紅斑	0	1 (7.7)	0	1 (3.8)	0
脂漏性皮膚炎	1 (7.1)	0	0	0	0
蕁麻疹	0	1 (7.7)	0	1 (3.8)	0
血管障害	1 (7.1)	0	1 (7.7)	1 (3.8)	0
高血圧	1 (7.1)	0	1 (7.7)	1 (3.8)	0
血栓性静脈炎	0	0	1 (7.7)	1 (3.8)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-8

[redacted]20[redacted] 06:26 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.4.2 J

Subjects with Treatment-Emergent Adverse Events with a Reasonable Possibility of Being Related to Study Drug by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
Any adverse event	1 (7.1)	2 (15.4)	4 (30.8)	6 (23.1)	3 (23.1)
胃腸障害	0	0	0	0	1 (7.7)
肛門狭窄	0	0	0	0	1 (7.7)
一般・全身障害および投与部位の状態	1 (7.1)	1 (7.7)	0	1 (3.8)	1 (7.7)
疲労	0	1 (7.7)	0	1 (3.8)	0
注射部位紅斑	1 (7.1)	0	0	0	1 (7.7)
注射部位そう痒感	0	0	0	0	1 (7.7)
感染症および寄生虫症	0	1 (7.7)	2 (15.4)	3 (11.5)	2 (15.4)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (7.7)
上咽頭炎	0	1 (7.7)	2 (15.4)	3 (11.5)	0
扁桃炎	0	0	0	0	1 (7.7)
神経系障害	0	1 (7.7)	0	1 (3.8)	0
頭痛	0	1 (7.7)	0	1 (3.8)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.4.2_J

Subjects with Treatment-Emergent Adverse Events with a Reasonable Possibility of Being Related to Study Drug by System Organ Class and Preferred Term Among Randomized Subjects (SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
精神障害	0	0	1 (7.7)	1 (3.8)	0
不安障害	0	0	1 (7.7)	1 (3.8)	0
呼吸器、胸郭および縦隔障害	0	0	1 (7.7)	1 (3.8)	0
口腔咽頭痛	0	0	1 (7.7)	1 (3.8)	0
皮膚および皮下組織障害	0	1 (7.7)	0	1 (3.8)	1 (7.7)
アレルギー性皮膚炎	0	0	0	0	1 (7.7)
蕁麻疹	0	1 (7.7)	0	1 (3.8)	0
血管障害	0	0	1 (7.7)	1 (3.8)	0
高血圧	0	0	1 (7.7)	1 (3.8)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-9

[redacted]20[redacted] 15:46 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.5.3 J

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class
and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
Any adverse event	2 (12.5)	1 (3.2)	1 (3.6)	2 (3.4)
血液およびリンパ系障害	0	0	1 (3.6)	1 (1.7)
貧血	0	0	1 (3.6)	1 (1.7)
胃腸障害	2 (12.5)	1 (3.2)	0	1 (1.7)
クローン病	2 (12.5)	0	0	0
イレウス	0	1 (3.2)	0	1 (1.7)
生殖系および乳房障害	1 (6.3)	0	0	0
子宮頚部上皮異形成	1 (6.3)	0	0	0

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表2.7.4.7-10

[redacted]20[redacted] 10:57 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.5.1

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
Any adverse event	23 (12.5)	12 (6.7)	21 (11.7)	33 (9.2)	12 (8.0)
血液およびリンパ系障害	1 (0.5)	2 (1.1)	2 (1.1)	4 (1.1)	1 (0.7)
貧血	0	2 (1.1)	2 (1.1)	4 (1.1)	0
鉄欠乏性貧血	0	0	0	0	1 (0.7)
白血球減少症	1 (0.5)	0	0	0	0
心臓障害	1 (0.5)	1 (0.6)	1 (0.6)	2 (0.6)	1 (0.7)
急性心筋梗塞	0	0	1 (0.6)	1 (0.3)	0
心不全	1 (0.5)	0	0	0	0
急性心不全	0	1 (0.6)	0	1 (0.3)	0
うっ血性心不全	0	1 (0.6)	0	1 (0.3)	0
冠動脈穿孔	0	0	0	0	1 (0.7)
虚血性心筋症	0	0	0	0	1 (0.7)
心嚢液貯留	0	0	0	0	1 (0.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.5.1

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
眼障害	1 (0.5)	1 (0.6)	0	1 (0.3)	0
眼痛	0	1 (0.6)	0	1 (0.3)	0
黄斑変性	1 (0.5)	0	0	0	0
胃腸障害	10 (5.4)	5 (2.8)	7 (3.9)	12 (3.4)	4 (2.7)
腹痛	2 (1.1)	0	0	0	0
痔瘻	1 (0.5)	0	1 (0.6)	1 (0.3)	0
肛門狭窄	1 (0.5)	1 (0.6)	0	1 (0.3)	0
便秘	0	0	1 (0.6)	1 (0.3)	0
クローン病	4 (2.2)	0	0	0	4 (2.7)
下痢	1 (0.5)	0	0	0	0
回腸狭窄	1 (0.5)	0	0	0	0
イレウス	0	1 (0.6)	1 (0.6)	2 (0.6)	0
大腸狭窄	1 (0.5)	0	1 (0.6)	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.5.1

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
胃腸障害 (Cont.)					
悪心	1 (0.5)	0	0	0	0
食道食物嵌入	0	1 (0.6)	0	1 (0.3)	0
腹膜障害	0	1 (0.6)	0	1 (0.3)	0
肛門周囲痛	1 (0.5)	0	0	0	0
小腸閉塞	0	0	2 (1.1)	2 (0.6)	1 (0.7)
亜イレウス	0	1 (0.6)	1 (0.6)	2 (0.6)	0
嘔吐	1 (0.5)	0	0	0	0
一般・全身障害および投与部位の状態	0	0	3 (1.7)	3 (0.8)	0
無力症	0	0	1 (0.6)	1 (0.3)	0
高体温症	0	0	1 (0.6)	1 (0.3)	0
発熱	0	0	1 (0.6)	1 (0.3)	0
免疫系障害	0	0	0	0	1 (0.7)
過敏症	0	0	0	0	1 (0.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.5.1

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
感染症および寄生虫症	6 (3.3)	3 (1.7)	6 (3.4)	9 (2.5)	3 (2.0)
肛門膿瘍	2 (1.1)	0	1 (0.6)	1 (0.3)	0
虫垂炎	1 (0.5)	2 (1.1)	0	2 (0.6)	0
細菌性関節炎	0	1 (0.6)	0	1 (0.3)	0
クロストリジウム・ディフィシレ感染	0	0	1 (0.6)	1 (0.3)	1 (0.7)
憩室炎	1 (0.5)	0	0	0	0
赤痢菌性胃腸炎	0	0	0	0	1 (0.7)
感染性胸水	0	0	1 (0.6)	1 (0.3)	0
肝膿瘍	0	0	1 (0.6)	1 (0.3)	0
腰筋膿瘍	1 (0.5)	0	0	0	0
敗血症	0	0	0	0	1 (0.7)
ウイルス感染	0	0	3 (1.7)	3 (0.8)	0
ウイルス性上気道感染	1 (0.5)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.5.1

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
傷害、中毒および処置合併症	1 (0.5)	0	0	0	0
創部炎症	1 (0.5)	0	0	0	0
代謝および栄養障害	1 (0.5)	0	0	0	0
低カルシウム血症	1 (0.5)	0	0	0	0
筋骨格系および結合組織障害	1 (0.5)	1 (0.6)	2 (1.1)	3 (0.8)	0
関節痛	0	1 (0.6)	0	1 (0.3)	0
関節炎	0	0	1 (0.6)	1 (0.3)	0
背部痛	0	0	2 (1.1)	2 (0.6)	0
骨粗鬆症	1 (0.5)	0	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.5)	0	1 (0.6)	1 (0.3)	1 (0.7)
基底細胞癌	1 (0.5)	0	0	0	0
HER2陽性乳癌	0	0	1 (0.6)	1 (0.3)	0
肺腺癌	0	0	0	0	1 (0.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__1.1.5.1

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
神経系障害	1 (0.5)	0	0	0	0
脳梗塞	1 (0.5)	0	0	0	0
呼吸器、胸郭および縦隔障害	1 (0.5)	1 (0.6)	0	1 (0.3)	1 (0.7)
慢性閉塞性肺疾患	1 (0.5)	1 (0.6)	0	1 (0.3)	1 (0.7)
外科および内科処置	1 (0.5)	0	0	0	0
人工流産	1 (0.5)	0	0	0	0
血管障害	0	0	0	0	1 (0.7)
高血圧	0	0	0	0	1 (0.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-11

[redacted]20[redacted] 06:26 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.5.1 J

Subjects with Treatment-Emergent Severe Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
Any adverse event	2 (14.3)	0	2 (15.4)	2 (7.7)	1 (7.7)
胃腸障害	2 (14.3)	0	1 (7.7)	1 (3.8)	0
肛門狭窄	1 (7.1)	0	0	0	0
クローン病	1 (7.1)	0	0	0	0
回腸狭窄	1 (7.1)	0	0	0	0
小腸閉塞	0	0	1 (7.7)	1 (3.8)	0
一般・全身障害および投与部位の状態	0	0	1 (7.7)	1 (3.8)	0
発熱	0	0	1 (7.7)	1 (3.8)	0
感染症および寄生虫症	0	0	0	0	1 (7.7)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (7.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-12

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	P2	92 to 149	57	148	R: FEBRILE SYNDROME S: 一般・全身障害および投与部位の状態 P: 発熱 L: FEBRILE REACTION	E: 150 L: 3 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
	WO	149 to 191	2	150	R: CEREBROSPINAL FLUID LEAKAGE S: 神経系障害 P: 脳脊髄液漏 L: CEREBROSPINAL FLUID LEAKAGE	E: 154 L: 5 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			4	152	R: HEADACHE S: 神経系障害 P: 頭痛 L: HEADACHE	E: 157 L: 6 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
		P1 1 to 59	34	34	R: ANAL FISTULA S: 胃腸障害 P: 痔瘻 L: ANAL FISTULA	E: 100 L: 67 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				34	R: ANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: ANAL ABSCESS	E: 100 L: 67 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
		FU 2 to 107	23	24	R: DIPLOPIA S: 眼障害 P: 複視 L: DIPLOPIA	E: 48 L: 25 days	T: Grade 2 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Persistent or significant disability/incapacity O: RECOVERED/RESOLVED C: No

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV									
[redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg									
		FU	240 to 345	52	291	R: EXCACERBATION CHRON'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 344 & O: Yes L: 54 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: NOT RECOVERED/NOT RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Placebo									
[redacted] Age: 1[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg									
		WOP1	57 to 93	18	74	R: 2 INTERSPHINTERIC ABSCESSES S: 感染症および寄生虫症 P: 直腸膿瘍 L: ANORECTAL ABSCESS	E: 338 & L: 265 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: No

Subject prematurely discontinued study drug.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 3[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 5[redacted].[redacted] kg								
		WOP1 60 to 107	28	87	R: BOWEL PERFORATION S: 胃腸障害 P: 腸管穿孔 L: BOWEL PERFORATION	E: 92 L: 6 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
		P1 1 to 56	49	49	R: WORSENING CHOLELITHIASIS S: 肝胆道系障害 P: 胆石症 L: CHOLELITHIASIS	E: 68 L: 20 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV							
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 58	45	R: INFECTION JAW S: 感染症および寄生虫症 P: 骨髄炎 L: BONE INFECTION NOS	E: 80 L: 36 days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	P2	105 to 156	16	120	R: INTESTINAL OCCLUSION S: 胃腸障害 P: 腸閉塞 L: INTESTINAL OBSTRUCTION	E: 224 L: 105 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Placebo							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	P3	182 to 351	54	235	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: APPENDICITIS	E: 236 L: 2 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	FU	2 to 108	63 64	R: RENAL COLICS S: 腎および尿路障害 P: 腎仙痛 L: RENAL COLIC	E: 65 L: 2 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Placebo							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	FU	2 to 114	26 27	R: PARTIAL BOWEL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: PARTIAL BOWEL OBSTRUCTION	E: 63 L: 37 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
	P2	90 to 175	68 157	R: ABSCESS SURGICAL SITE INFECTION S: 感染症および寄生虫症 P: 切開部位膿瘍 L: INCISION SITE ABSCESS	E: 174 L: 18 days	T: Grade 2 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch -- Name	Epoch -- Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	P1	1 to	14	R: WORSENING CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 22 L: 9 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			29	R: ANAPHYLACTIC REACTION S: 免疫系障害 P: アナフィラキシー反応 L: ANAPHYLACTIC REACTION	E: 29 L: 1 day	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: No

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
		P2 113 to 226	15	127	R: ILEOCEOCAL PERFORATION S: 胃腸障害 P: 腸管穿孔 L: INTESTINAL PERFORATION	E: 127 L: 1 day	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				127	R: ILEAL SUBOCCLUSION S: 胃腸障害 P: 小腸閉塞 L: PARTIAL SMALL INTESTINAL OBSTRUCTION	E: 133 L: 7 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			99	211	R: INDUCED ABORTION S: 外科および内科処置 P: 人工流産 L: INDUCED ABORTION	E: 211 L: 1 day	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: No

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P3	191 to 360	112	302	R: WORSENING DISCAL HERNIA S: 筋骨格系および結合組織障害 P: 椎間板突出 L: HERNIATED DISC	E: 308 L: 7 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	P1	1 to	20	20	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 24 L: 5 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
	P2	99 to 156	3	101	R: PARTIAL SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: PARTIAL SMALL INTESTINAL OBSTRUCTION	E: 102 L: 2 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	WOP1	60 to 95	13	72	R: SMALL BOWEL SUBOCCLUSION S: 胃腸障害 P: 小腸閉塞 L: PARTIAL SMALL INTESTINAL OBSTRUCTION	E: 74 L: 3 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	WOP1	58 to 106	39	96	R: CHRONIC PAIN SYNDROME S: 一般・全身障害および投与部位の状態 P: 疼痛 L: CHRONIC PAIN	E: 458 & O: Yes L: 363 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NOT RECOVERED/NOT RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	P1	1 to 58	57	57	R: WORSENING MORBUS CROHN DISEASE S: 胃腸障害 P: クローン病 L: CROHNS DISEASE AGGRAVATED	E: 210 L: 154 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED WITH SEQUELAE C: Yes

& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	P1	1 to	6	6	R: EXCERBATION OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: CROHNS DISEASE AGGRAVATED	E: 7 L: 2 days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	FU	2 to 108	26	27	R: EXACERBATION OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: CROHNS DISEASE AGGRAVATED	E: 36 L: 10 days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
		P2	101 to 157	53 153 &	R: INTERMITTENT TRANSIENT BLINDNESS IN RT EYE S: 眼障害 P: 一過性失明 L: TRANSIENT BLINDNESS	E: 244 & L: 92 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: No
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg								
		P1	1 to 64	51 51	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: PNEUMONIA	E: 58 L: 8 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo							
[redacted]# Age: 2[redacted] Sex: Male Race: ASIAN Weight: 4[redacted].[redacted] kg							
	P1	1 to	23	R: ABDOMINAL ABSCESS S: 感染症および寄生虫症 P: 腹部膿瘍 L: ABDOMINAL ABSCESS	E: 47 L: 25 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			36	R: HAP (HOSPITAL ACQUIRED PNEUMONIA) S: 感染症および寄生虫症 P: 肺炎 L: NOSOCOMIAL PNEUMONIA	E: 46 L: 11 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted]# Age: 4[redacted] Sex: Male Race: ASIAN Weight: 3[redacted].[redacted] kg								
	P1	1 to 59	10	10	R: SEVERE APHTHOUS STOMATITIS S: 胃腸障害 P: アフタ性潰瘍 L: APHTHOUS STOMATITIS	E: 26 L: 17 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			15	15	R: ANEMIA AGGRAVATED S: 血液およびリンパ系障害 P: 貧血 L: ANEMIA AGGRAVATED	E: 22 L: 8 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
	WOP1	59 to 100	6	64	R: WORSENING OF GENERAL WEAKNESS S: 一般・全身障害および投与部位の状態 P: 無力症 L: WEAKNESS GENERALISED	E: 69 L: 6 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV									
[redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg									
		WOP1	59 to 100	4	62	R: ANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: ANAL ABSCESS	E: 64 L: 3 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Placebo									
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg									
		P1	1 to 58	29	29	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 33 L: 5 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
(Cont.) P1		1 to 58	30	30	R: COMPLETE LEFT PNEUMOTHORAX S: 呼吸器、胸郭および縦隔障害 P: 気胸 L: PNEUMOTHORAX	E: 32 L: 3 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: No
			32	32	R: ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: ANEMIA	E: 57 L: 26 days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: No
			44	44	R: DVT LEFT UPPER LIMB S: 血管障害 P: 深部静脈血栓症 L: DEEP VENOUS THROMBOSIS ARM	E: 270 L: 227 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
(Cont.)	WOP1	58 to 99	21	78	R: WORSENING CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 84 L: 7 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				78	R: DENUTRTION S: 代謝および栄養障害 P: 栄養障害 L: MALNUTRITION	E: 84 L: 7 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			22	79	R: TACHYCARDIA S: 心臓障害 P: 頻脈 L: TACHYCARDIA	E: 81 L: 3 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: No

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
(Cont.)	WOP1	58 to 99	28	85	R: NEUTROPENIA S: 血液およびリンパ系障害 P: 好中球減少症 L: NEUTROPENIA	E: 99 L: 15 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
	P2	99 to 159	1	99	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 101 L: 3 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				99	R: DENUTRTION S: 代謝および栄養障害 P: 栄養障害 L: MALNUTRITION	E: 101 L: 3 days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted]	Age: 2[redacted]	Sex: Female	Race: WHITE	Weight: 5[redacted].[redacted] kg				
(Cont.)	P2	99 to 159	10	108	R: WORSENING OF CRONH'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 119 L: 12 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
[redacted]	Age: 2[redacted]	Sex: Female	Race: WHITE	Weight: 3[redacted].[redacted] kg				
	WOP1	58 to 99	29	86	R: VAGINAL GLAND ABSCESS(EXACT TYPE UNKNOWN) S: 感染症および寄生虫症 P: 膣膿瘍 L: VAGINAL ABSCESS	E: 96 L: 11 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	WOP1	61 to 102	8	68	R: FLARE OF CROHN DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE RELAPSE	E: 80 L: 13 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				68	R: ACUTE KIDNEY INJURY S: 腎および尿路障害 P: 急性腎障害 L: ACUTE KIDNEY INJURY	E: 80 L: 13 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	P1	1 to 64	15	15	R: UNDERNUTRITION S: 代謝および栄養障害 P: 栄養障害 L: UNSPECIFIED NUTRITIONAL DEFICIENCY	E: 99 L: 85 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV								
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg								
	WO	156 to 258	56	211	R: ANO RECTAL PAIN S: 胃腸障害 P: 肛門周囲痛 L: ANORECTAL PAIN	E: 212 L: 2 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			74	229	R: WORSENING CROHN DISEASE S: 胃腸障害 P: クローン病 L: CROHNS DISEASE AGGRAVATED	E: 231 L: 3 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted]# Age: 5[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg								
	P1	1 to	29	29	R: PERFERATED BOWEL S: 胃腸障害 P: 腸管穿孔 L: PERFORATED BOWEL	E: 30 L: 2 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg								
	P2	99 to 156	7	105	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE AGGRAVATED	E: 260 & O: Yes L: 156 days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NOT RECOVERED/NOT RESOLVED C: Yes
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	FU	349 to 363	2	350	R: SUDDEN HEARING LOSS S: 耳および迷路障害 P: 突発性難聴 L: SUDDEN HEARING LOSS	E: 374 L: 25 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: RECOVERED/RESOLVED C: Yes

& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	WO	157 to 261	78 234	R: INTESTINAL SUBOCCLUSION S: 胃腸障害 P: 腸閉塞 L: INTESTINAL OBSTRUCTION	E: 238 L: 5 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 200mg IV								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	P1	1 to	19	19	R: HYPONATREMIA HYPO-OSMOLAR S: 代謝および栄養障害 P: 低ナトリウム血症 L: HYPONATREMIA	E: 22 L: 4 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				19	R: METABOLIC ACIDOSIS S: 代謝および栄養障害 P: 代謝性アシドーシス L: METABOLIC ACIDOSIS	E: 22 L: 4 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				19	R: RENAL FAILURE MILD S: 腎および尿路障害 P: 腎不全 L: RENAL FAILURE	E: 22 L: 4 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 4[redacted].[redacted] kg								
	P1	1 to 58	15	15	R: HYPOMAGNESIUM S: 臨床検査 P: 血中マグネシウム減少 L: MAGNESIUM LOW	E: 26 L: 12 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				15	R: HYPOKALEMIA S: 代謝および栄養障害 P: 低カリウム血症 L: HYPOKALEMIA	E: 26 L: 12 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
				15	R: HYPOPHOSPHATEMIA S: 代謝および栄養障害 P: 低リン酸血症 L: HYPOPHOSPHATEMIA	E: 26 L: 12 days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	P1	1 to	6	6	R: CROHN'S DISEASE FLARE S: 胃腸障害 P: クローン病 L: CROHN'S DISEASE	E: 16 L: 11 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED WITH SEQUELAE C: Yes
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	FU	349 to 365	12	360	R: MIGRAINE S: 神経系障害 P: 片頭痛 L: MIGRAINE	E: 364 L: 5 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Subject prematurely discontinued study drug.

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	P2	99 to 158	1	R: COLLAPSE WITHOUT LOSS OF CONCIOUSNESS S: 血管障害 P: 循環虚脱 L: CIRCULATORY COLLAPSE	E: 99 L: 1 day	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: No
	P3	183 to 352	36	R: LEFT SIDED WEAKNESS S: 神経系障害 P: 不全片麻痺 L: WEAKNESS LEFT OR RIGHT SIDE	E: 302 L: 85 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			141	R: SUBACUTE OBSTRUCTION DUE TO STENOSIS - BOWEL S: 胃腸障害 P: 腸閉塞 L: SUBACUTE INTESTINAL OBSTRUCTION	E: 329 L: 7 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes

Program Source Code: [redacted]

TABLE 14.3__2.15.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Population)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 19.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment	S: Serious AE? O: Outcome C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600mg IV								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	P3	178 to 348	141	318	R: SUICIDE ATTEMPT S: 精神障害 P: 自殺企図 L: SUICIDE ATTEMPT	E: 334 L: 17 days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: Yes
			159	336	R: PSYCHIC DECOMPENSATION S: 精神障害 P: 精神的機能代償不全 L: PSYCHIATRIC DECOMPENSATION	E: 337 L: 2 days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RECOVERED/RESOLVED C: No

Program Source Code: [redacted]

表2.7.4.7-13

[redacted]20[redacted] 01:32 <[redacted]>
RISANKIZUMAB (CROHN'S)
M15-989 ABBREVIATED CLINICAL STUDY REPORT
R&D/19/0019 - CLINICAL/STATISTICAL

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch -- Interval	Rx Day -- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	P2	1 to 1237	636	636	R: VIRAL GASTROENTERITIS S: 感染症および寄生虫症 P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 638 L: 3 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NO U: RECOVERED/RESOLVED A: 3031020
			659	659	R: PELVIC PERITONITIS SECONDARY TO ANAL DILATATION S: 感染症および寄生虫症 P: 腹膜炎 L: Peritonitis	E: 668 L: 10 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DILATATION ANAL RECTAL STENOSIS U: RECOVERED/RESOLVED A: 3031025
				659	S: 傷害、中毒および処置合併症 P: 処置後合併症 L: Post procedural complication	----------	--- S A M E A S A B O V E ---	----------

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	P2	1 to 1058	325	325	R: EPIGASTRALGIA S: 胃腸障害 P: 上腹部痛 L: Epigastralgia	E: 326 L: 2 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: STRESSFULL PERIOD IN PERSONAL LIFE OF PATIENT U: RECOVERED/RESOLVED A: 3056004
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	1 to 446	341	341	R: PERIANAL ABSCESS CONFIRMED ON MRI S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	E: 350 L: 10 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHNS DISEASE U: RECOVERED/RESOLVED A: 7024016

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	FU	103 to	102	204	R: ANASTOMOTIC LEAKAGE S: 傷害、中毒および処置合併症 P: 吻合部漏出 L: Anastomotic leak	E: 220 L: 17 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical event requiring medical or surgical intervention to prevent serious outcome, Life threatening O: COMPLICATION OF SURGERY STENOSIS NEOTERMINAL ILEUM U: RECOVERED/RESOLVED A: 4025005

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
(Cont.)	FU	103 to 105	207		R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 220 L: 14 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: GASTRIC DRAINAGE	S: Yes, Hospitalization or prolonged hospitalization O: COMPLICATION OF REANASTOMOTIC SURGERY U: RECOVERED/RESOLVED A: 4025006

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	FU	59 to 117	175		R: GASTROPARESIS S: 胃腸障害 P: 胃排出不全 L: Gastroparesis	E: 177 L: 3 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: GASTRIC DRAINAGE ON [redacted]-20[redacted]	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome O: COMPLICATION OF BOWELSURGERY U: RECOVERED/RESOLVED A: 4027004

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	1 to 1170	67	67	R: INFECTION TO CAMPYLOBACTER JEJUNI S: 感染症および寄生虫症 P: カンピロバクター感染 L: Campylobacter jejuni infection	E: 77 L: 11 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization U: RECOVERED/RESOLVED A: 3046005

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	P2	1 to 893	648	648	R: CAROTID SINUS HYPERSENSITIVITY, PATIENT EXPERIENCE SYMPTOMS OF LYPOTHYMIA AND DIZINESS S: 神経系障害 P: 頚動脈洞症候群 L: Carotid sinus hypersensitivity	E: 658 L: 11 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PACEMAKER INSERTION DONE ON [redacted].[redacted].20[redacted]	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome O: NO U: RECOVERED/RESOLVED A: 3048013
				648	S: 神経系障害 P: 浮動性めまい L: Dizziness	----------	--- S A M E A S A B O V E	----------
				648	S: 神経系障害 P: 浮動性めまい L: Dizziness	----------	--- S A M E A S A B O V E	----------

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV Q4W / Risankizumab 180 mg SC Q8W								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	89 to 1208	369	457	R: ANKLE BREAKING RIGHT S: 傷害、中毒および処置合併症 P: 足関節部骨折 L: Ankle fracture	E: 623 L: 167 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ABLATION SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: FALL U: RECOVERED/RESOLVED F: Follow-up sufficient A: 3041003
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	P2	89 to 1264	279	367	R: RHINOSEPTOPLASTY DUE TO NASAL OBSTRUCTION S: 呼吸器、胸郭および縦隔障害 P: 鼻閉塞 L: Nasal obstruction	E: 368 L: 2 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization U: RECOVERED/RESOLVED A: 3042013

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	FU	1126 to	7	1132	R: RIGHT BUTTOCK ABSCESS S: 感染症および寄生虫症 P: 皮下組織膿瘍 L: Abscess on buttock	E: 1233 L: 102 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE RELATED U: NOT RECOVERED/NOT RESOLVED A: 1011005

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	P2	1 to 1246	164	164	R: POST SURGICAL ABDOMINAL PAIN S: 傷害、中毒および処置合併症 P: 処置による疼痛 L: Postoperative pain	E: 165 L: 2 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CHOLECYSTECTOMY U: RECOVERED/RESOLVED A: 1012004
			407	407	R: FALL S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 412 L: 6 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: TRIP OVER ELECTRICAL CORD U: RECOVERED/RESOLVED A: 1012007
				407	R: FRACTURED LEFT HIP S: 傷害、中毒および処置合併症 P: 股関節部骨折 L: Fractured hip	E: 412 L: 6 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: TRIP OVER ELECTRICAL CORD U: RECOVERED/RESOLVED A: 1012005

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day	Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted])								
TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	P2	1 to 1009	462	462	R: UMBILICAL HERNIA S: 胃腸障害 P: 臍ヘルニア L: Umbilical hernia	E: 546 L: 85 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: UMBILICAL HERNIA REPAIR SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: NO OTHER CAUSE U: RECOVERED/RESOLVED A: 3064009
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	1 to 386	352	352	R: INTESTINAL STENOSIS (ILEUM) S: 胃腸障害 P: 回腸狭窄 L: Ileal stenosis	E: 443 L: 92 days I: No	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ILEO-CAECAL RESECTION DONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome U: UNKNOWN A: 3065017

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
(Cont.)	FU	387 to	37	423	R: POST-OPERATIVE PERITONITIS (POST ILEOCAECAL RESECTION SURGERY) S: 感染症および寄生虫症 P: 腹膜炎 L: Peritonitis	E: 443 L: 21 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: NO TREATMENT RECEIVED DURING THE HOSPITALIZATION O: ILEO-TRANSVERSAL RESECTION DONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome, Life threatening O: RELEASE OF SUTURES U: RECOVERED/RESOLVED A: 3065019
				423	S: 傷害、中毒および処置合併症 P: 処置後合併症 L: Post procedural complication	----------	--- S A M E A S A B O V E ---	----------

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	P2	1 to 898	293	293	R: PARTIAL INTESTINAL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Partial bowel obstruction	E: 298 L: 6 days I: No	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization U: RECOVERED/RESOLVED F: Follow-up sufficient A: 6012005
			724	724	R: ILEOCECAL VALVE STENOSIS S: 胃腸障害 P: 腸管狭窄 L: Intestinal stenosis	E: 726 L: 3 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ENDOSCOPIC DILATION	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE U: RECOVERED/RESOLVED A: 6012010

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day	Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W									
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg									
		P2	1 to 1175	175	175	R: BURN S: 傷害、中毒および処置合併症 P: 熱傷 L: Burn	E: 262 L: 88 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: GOT BURNED IN AN ACCIENT WHILE WORKING U: RECOVERED/RESOLVED A: 9031001
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg									
		PRE	to -1		1 &	R: WORSENING OF HEMORRHOID S: 胃腸障害 P: 痔核 L: Hemorrhoids aggravated	E: 280 L: 280 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: HE UNDERWENT AN OPERATION(HEMORRHOIDECTOMY) ON [redacted] 20[redacted] WITH MILD ANAL PAIN U: RECOVERED/RESOLVED A: 9033002

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Epoch -- Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	P2	1 to 504	319 319	R: ADRENAL INSUFFICIENCY S: 内分泌障害 P: 副腎機能不全 L: Adrenal insufficiency	E: 503 & L: 185 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: AFTER LONG TERM TREATMENT BY MEDROL U: RECOVERED/RESOLVED F: Follow-up sufficient A: 3003016

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch -- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	P2	1 to 1235	80	80	R: WORSENING OF TACHYCARDIA S: 心臓障害 P: 頻脈 L: Tachycardia aggravated	E: 80 L: 1 day I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome O: UNK U: RECOVERED/RESOLVED A: 3004011
			201	201	R: OVARIAN CYST LEADING TO OVARIECTOMY S: 生殖系および乳房障害 P: 卵巣嚢胞 L: Ovarian cyst	E: 201 L: 1 day I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome O: HORMONAL DISORDER U: RECOVERED/RESOLVED A: 3004004

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch -- Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
(Cont.)	P2	1 to 1235	236 236	R: WORSENING CROHN DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 244 L: 9 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CD U: RECOVERED/RESOLVED A: 3004005
			1035 1035	R: LATE DUMPING SYNDROME S: 胃腸障害 P: ダンピング症候群 L: Dumping syndrome	E: 1036 L: 2 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: REACTIONAL HYPOGLYCEMIA U: RECOVERED/RESOLVED F: Follow-up sufficient A: 3004037

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch -- Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	FU	575 to 652	78	R: SURGICAL TERMINATION OF PREGNANCY DUE TO FOETAL ABNORMALITY S: 外科および内科処置 P: 選択的妊娠中絶 L: Selective abortion	E: 652 L: 1 day I: No	T: Grade 4 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event requiring medical or surgical intervention to prevent serious outcome, Congenital anomaly U: RECOVERED/RESOLVED A: 7011010

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	1 to 839	152	152	R: ELECTIVE HOSPITALIZATION DUE TO ILEOTRANSVERSE STENOSIS S: 胃腸障害 P: 腸管狭窄 L: Intestinal stenosis	E: 157 L: 6 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event requiring medical or surgical intervention to prevent serious outcome O: EFFECT OF CROHN'S DISEASE U: RECOVERED/RESOLVED A: 6034008

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	1 to 952	389	389	R: THORACIC (CHEST) PAIN S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Thoracic pain	E: 449 L: 61 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN CAUSE OF EVENT U: RECOVERED/RESOLVED A: 5061007
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	1 to 1125	175	175	R: ANAPHYLACTIC REACTION S: 免疫系障害 P: アナフィラキシー反応 L: Anaphylactic reaction	E: 175 L: 1 day I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: FERINJECT CAUSED POSSIBLE ANAPHYLACTIC REACTION U: RECOVERED/RESOLVED A: 7052008

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch -- Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W [redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
(Cont.)	P2	1 to 1125	279	R: IRON DEFICIENCY ANAEMIA S: 血液およびリンパ系障害 P: 鉄欠乏性貧血 L: Iron deficiency anaemia	E: 378 L: 100 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization U: RECOVERED/RESOLVED A: 7052012
			552	R: MILD IRON DEFICIENCY ANAEMIA S: 血液およびリンパ系障害 P: 鉄欠乏性貧血 L: Iron deficiency anaemia	E: 576 L: 25 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ELECTIVE ADMISSION FOR ADMINISTRATION OF INTRAVENOUS IRON INFUSION.	S: Yes, Hospitalization or prolonged hospitalization O: ELECTIVE ADMISSION FOR INFUSION. NO CAUSALITY. U: RECOVERED/RESOLVED A: 7052022

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
(Cont.)	P2	1 to 1125	583	583	R: VIRAL GASTROENTERITIS S: 感染症および寄生虫症 P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 584 L: 2 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: HOSPITALISED FOR OVERNIGHT OBSERVATION O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: VIRAL INFECTION. NO CAUSALITY. U: RECOVERED/RESOLVED A: 7052023
			585	585	R: HEAVY PERIODS PV BLEEDING S: 生殖系および乳房障害 P: 月経過多 L: Heavy periods	E: 643 L: 59 days I: No	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: FIBROIDS U: RECOVERED/RESOLVED A: 7052025
			718	718	R: CROHN'S AGGRAVATED S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 726 L: 9 days I: No	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NOT RELATED TO TRIAL MEDICATION. CROHN'S DISEASE U: RECOVERED/RESOLVED A: 7052029

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

TABLE 14.3__2.5.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Epoch -- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Action Taken	S: Serious AE? O: Other Cause of Event U: Outcome F: Follow-up Status A: Serial Number
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
(Cont.)	P2	1 to 1125	853	853	R: MILD IRON DEFICIENCY ANAEMIA S: 血液およびリンパ系障害 P: 鉄欠乏性貧血 L: Iron deficiency anaemia	E: 856 L: 4 days I: No	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ELECTIVE ADMISSION FOR IRON INFUSION	S: Yes, Hospitalization or prolonged hospitalization O: ELECTIVE ADMISSION FOR IRON INFUSION U: NOT RECOVERED/NOT RESOLVED A: 7052031
INV: [redacted] ([redacted]) TRT: Risankizumab 180 mg SC Q8W								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	P2	1 to 1002	686	686	R: CLUSTER HEADACHE S: 神経系障害 P: 群発頭痛 L: Cluster headache	O: Yes I: Yes	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: STRESS U: NOT RECOVERED/NOT RESOLVED A: 3072007

PRE = Screening; P1 = Open label re-induction; P2 = Open label maintenance; FU = Follow-up.

Program Source Code: [redacted]

表2.7.4.7-14

[redacted]20[redacted] 00:59 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV								
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	FU	31 to	18	48	R: WORSENING OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: PREMATURE DISCONTINUATION	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg							
	P1	1 to 79	42 42	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 164 O: No L: 123 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INADEQUATE RESPONSE OF IP A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	FU	30 to 1	30	R: WORSENING OF CROHN DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 72 O: No L: 43 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: VOMITTING A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	FU	30 to 3	32	R: ABSCESS TERMINALES ILEUM S: 感染症および寄生虫症 P: 腸管膿瘍 L: Abscess intestinal	E: 72 O: No L: 41 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NO MORE INFORMATIONS ARE AVAILABLE AT THIS MOMENT A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
	FU	58 to 78	135	R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 152 O: No L: 18 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: LAST STUDY DRUG WAS ON [redacted] [redacted] 20[redacted]	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: LAPAROTOMY; RESECTION OF A PART OF JEJUNUM 40 CM;HEMYCOLECTOMY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg								
	P1	1 to 89	24	24	R: DEEP VENOUS THROMBOSIS WITH BILATERAL PULMONARY EMBOLISM S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 31 O: No L: 8 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: STUDY DRUG ADMINISTRATION POSTPONED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: DISEASE ACTIVITY; USE OF ANTICONCEPTION, OBESITAS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg								
	P1	1 to 89	24	24	R: DEEP VENOUS THROMBOSIS WITH BILATERAL PULMONARY EMBOLISM S: 血管障害 P: 深部静脈血栓症 L: Thrombosis venous deep	E: 31 O: No L: 8 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: STUDY DRUG ADMINISTRATION POSTPONED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: DISEASE ACTIVITY; USE OF ANTICONCEPTION, OBESITAS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 88	35	R: CROHN'S DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 58 O: No L: 24 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: DISEASE UNDER STUDY. CROHN'S DISEASE EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg								
	P1	1 to 57	56	56	R: RIGHT VENTRICULAR OUTFLOW TRACT TACHYCARDIA S: 心臓障害 P: 心室性頻脈 L: Ventricular tachycardia	E: 57 O: No L: 2 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: ARYTHMIA A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	FU	32 to 36	67	R: MIGRATING PERIPHERAL ARTHRALGIA S: 筋骨格系および結合組織障害 P: 関節痛 L: Arthralgia	O: Yes I: Yes	S: SEVERE R: REASONABLE POSSIBILITY A: STUDY DRUG ALREADY WITHDRAWN, LAST DOSE 08/08/19 O: NONE	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: No

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 8[redacted].[redacted] kg							
	P1	1 to 84	57	R: SPONDYLITS WORSENING S: 筋骨格系および結合組織障害 P: 脊椎炎 L: Spondylitis	E: 60 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: MEDICAL HISTORY A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 7[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg								
	P1	1 to 23	18	18	R: WORSENING OF ABDOMEN PAIN, RELATED TO CROHN'S DISEASE S: 胃腸障害 P: 腹痛 L: Abdominal pain aggravated	E: 23 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE AGGRAVATION A: NO REASONABLE POSSIBILITY C: Yes

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	P1	1 to 23	18	18	R: WORSENING OF ABDOMEN PAIN, RELATED TO CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease	E: 23 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE AGGRAVATION A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Placebo IV							
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	FU	24 to 6	29	R: WORSENING OF ABDOMEN PAIN, RELATED TO CROHN'S DISEASE S: 胃腸障害 P: 腹痛 L: Abdominal pain aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE AGGRAVATION A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	P1	1 to 85	53	R: LEPTOSPIROSIS S: 感染症および寄生虫症 P: レプトスピラ症 L: Leptospirosis	E: 65 O: No L: 13 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: POSSIBLE OCCUPATIONAL EXPOSURE TO LEPTOSPIRA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
	FU	2 to 6	7	R: ILEAL PERFORATION ABOVE EXTENSIVE STENOSIS TRACT COMPLICATED BY AN EXTENSIVE NECROSIS S: 胃腸障害 P: 消化管壊死 L: Ileal necrosis	E: 8 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: SURGERY	S: Yes, Death of subject, Hospitalization or prolonged hospitalization O: WORSENING OF DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	2 to 6	7	R: ILEAL PERFORATION ABOVE EXTENSIVE STENOSIS TRACT COMPLICATED BY AN EXTENSIVE NECROSIS S: 胃腸障害 P: 回腸穿孔 L: Ileal perforation	E: 8 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: SURGERY	S: Yes, Death of subject, Hospitalization or prolonged hospitalization O: WORSENING OF DISEASE A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
	FU	2 to 6	7	R: ILEAL PERFORATION ABOVE EXTENSIVE STENOSIS TRACT COMPLICATED BY AN EXTENSIVE NECROSIS S: 胃腸障害 P: 腸管狭窄 L: Intestinal stenosis	E: 8 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: SURGERY	S: Yes, Death of subject, Hospitalization or prolonged hospitalization O: WORSENING OF DISEASE A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	50 to 20	69	R: SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	E: 73 O: No L: 5 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV								
[redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	FU	50 to 49	98		R: ILEUM STRICTURE S: 胃腸障害 P: 回腸狭窄 L: Stricture of ileum	E: 98 O: No L: 1 day I: No	S: SEVERE R: REASONABLE POSSIBILITY A: CURRENTLY NOT ON STUDY DRUG.	S: Yes, Hospitalization or prolonged hospitalization O: PREVIOUS SMALL BOWEL OBSTRUCTION. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P1	1 to 99	85	85	R: COLON PERFORATION S: 胃腸障害 P: 大腸穿孔 L: Colon perforation	E: 85 O: No L: 1 day I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: BOWEL PERFORATION DURING PROCEDURE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 30	7 7	R: RIGHT PERILABIAL CELLULITIS S: 感染症および寄生虫症 P: 女性外陰部蜂巣炎 L: Vulval cellulitis	E: 32 O: No L: 26 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ER VISIT	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV [redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
	P1	1 to 91	53	53	R: CROHN DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 56 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PATIENT WAS HOSPITALIZED FOR WORSENING OF CROHN DISEASE. SYMPTOMS: PYREXIA, DIARRHEA AND SEVERE ABDOMINAL PAIN. PATIENT WAS TREATED WITH MEDROL AND ANTIBIOTICS. DISCHARGE DONE ON [redacted] 20[redacted]. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV [redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 88	46	R: CROHN DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 49 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: EMERGENCY ROOM ON [redacted] 20[redacted] FOR : PYREXIA, ABDOMINAL PAIN AND BLOODY DIARRHEA. PATIENT HOSPITALIZED. CT ABDO AND BLOOD TEST WERE DONE.TERMINAL ILEITIS/COLITIS (RIGHT,TRANSVERSE COLON)OBSERVED. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg							
	FU	33 to 22	54	R: ACUTE PURULENT TONSILLITIS S: 感染症および寄生虫症 P: 扁桃炎 L: Acute tonsillitis	E: 64 O: No L: 11 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: STOP USING	S: Yes, Hospitalization or prolonged hospitalization O: INTESTINAL FISTULA CANNOT BE RULED OUT A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg							
[redacted]	FU	30 to 51	80	R: RASH S: 皮膚および皮下組織障害 P: 発疹 L: Rash	E: 109 O: No L: 30 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg							
[redacted]	FU	30 to 53	82	R: DAMAGE OF HEPATIC FUNCTION S: 肝胆道系障害 P: 肝機能異常 L: Hepatic function disorder	E: 150 O: No L: 69 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	FU	58 to 33	90		R: LOCALISED PERFORATION IN CAECAL REGION S: 胃腸障害 P: 大腸穿孔 L: Cecum perforation	E: 94 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization O: PROBABLE CAUSE IS COLONOSCOPY ON [redacted] 20[redacted] A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 84	23	R: WORSENING OF ANEMIA DUE TO CROHN'S DISEASE S: 血液およびリンパ系障害 P: 貧血 L: Anemia aggravated	E: 27 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: THERE ARE NO OTHER CAUSES OF EVENT A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	2 to 8	9	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: CROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 14[redacted].[redacted] kg							
	P1	1 to 58	24	R: WORSENING ADBOMINAL PAIN S: 胃腸障害 P: 腹痛 L: Abdominal pain aggravated	E: 41 O: No L: 18 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: SUBJECT PRESENTED TO THE ER ON MAY 3 WITH MODERATE ABDOMINAL PAIN AND ADMITTED FOR EVALUATION AND SHE WAS SUBSEQUENTLY FOUND TO BE COV-19 PCR POSITIVE AND GIVEN IV ANTIBIOTIC AND MORPHINE FOR PAIN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	P1	1 to 56	32	R: ACUTE BOWEL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Bowel obstruction	E: 42 O: No L: 11 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY ILEOCOECAL RESECTION	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: CROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
[redacted]	P1	1 to 57	19	19	R: CROHNS DISEASE AGGRAVATION ILEOCOECAL S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 39 O: No L: 21 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: RELATED TO CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	P1	1 to 26	5 5	R: WORSENING CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 25 O: No L: 21 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 1[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	P1	1 to 24	10	10	R: CD FLARE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 36 O: No L: 27 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: NA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 1[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	P1	1 to 57	11	11	R: FOREARM FRACTURE (LEFT FOREARM), FALL DUE TO SPORTS ACTIVITIES S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGICAL THERAPY	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: UNFORTUNATELY FALL A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 1[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	P1	1 to 57	11	11	R: FOREARM FRACTURE (LEFT FOREARM), FALL DUE TO SPORTS ACTIVITIES S: 傷害、中毒および処置合併症 P: 前腕骨折 L: Forearm fracture	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGICAL THERAPY	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: UNFORTUNATELY FALL A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	60 to 20	79	R: NAUSEA, VOMITTING S: 胃腸障害 P: 悪心 L: Nausea	E: 80 O: No L: 2 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: INPATIENT DUE TO COMPLAINTS AORUND BOWEL PREP A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	60 to 20	79	R: NAUSEA, VOMITTING S: 胃腸障害 P: 嘔吐 L: Vomiting	E: 80 O: No L: 2 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: INPATIENT DUE TO COMPLAINTS AORUND BOWEL PREP A: NO REASONABLE POSSIBILITY C: No

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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	64 to [redacted]	10	R: DECREASED VALUE OF HEMOGLOBIN S: 臨床検査 P: ヘモグロビン減少 L: Hemoglobin decreased	E: 75 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: ANEMIA DUE TO IRON DEFICIENCY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	P1	1 to 84	10	R: ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia	E: 11 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: IRON DEFICIENCY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	P1	1 to 84	35	R: WORSENING OF ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia aggravated	E: 37 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg								
	P1	1 to 85	85	85	R: WEAKNESS, DIZZINESS S: 一般・全身障害および投与部位の状態 P: 無力症 L: Weakness	E: 86 O: No L: 2 days I: No	S: UNKNOWN R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DEHYDRATATION AFTER BOWEL PREPARATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg							
	P1	1 to 85	85	85	R: WEAKNESS, DIZZINESS S: 神経系障害 P: 浮動性めまい L: Dizziness	E: 86 O: No L: 2 days I: No	S: UNKNOWN R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DEHYDRATATION AFTER BOWEL PREPARATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 57	57	R: HEPATHOPATHY S: 肝胆道系障害 P: 肝障害 L: Hepatopathy	E: 78 O: No L: 22 days I: No	S: UNKNOWN R: NO REASONABLE POSSIBILITY A: STUDY DRUG POSTPONED	S: Yes, Hospitalization or prolonged hospitalization O: REACTION TO AZATHIOPRIN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 57	37	R: ALLERGIC REACTION DUE TO MUSTARD PLANTS CELERY, SUBJECT HAS A TO MUSTARD PLANTS S: 免疫系障害 P: 食物アレルギー L: Food allergy	E: 38 O: No L: 2 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: SUBJECT ATE SOUP WITH CELERY AND GOT SWOLLEN LIPS, SUBJECT KNOWN ALLERGY TO MUGWORT. SUBJECT WENT TO THE HOSPITAL AND STAYED THERE FOR SURVEILLANCE. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 112	88	R: CALCULUS OF RIGHT URETER S: 腎および尿路障害 P: 尿管結石症 L: Calculus of ureter	E: 98 O: No L: 11 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: UROLITHIASIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 3[redacted] Sex: Female Race: ASIAN Weight: 7[redacted].[redacted] kg								
	FU	51 to 1	51		R: FLARE AND PROGRESSION OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 63 O: No L: 13 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: REQUIRING ILEOCOLONIC RESECTION	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: FLARE OF CHRONS, ABDOMINAL PAIN A: NO REASONABLE POSSIBILITY C: No

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: ASIAN Weight: 7[redacted].[redacted] kg							
	FU	51 to 26	76	R: BOWEL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Bowel obstruction	E: 78 O: No L: 3 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: POST SURGICAL A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	P1	1 to 83	16	16	R: WORSENING OF INTERMITTENT REFRACTORY HYPERTENTION S: 血管障害 P: 高血圧 L: Hypertension worsened	E: 63 O: No L: 48 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: HYERTENTION DUE TO RENAL ISSUE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	P1	1 to 51	20	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 25 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PNEUMONIA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 64	48	R: PYELONEPHRITIS DUE TO OBSTRUCTING NEPHROLITHIASIS S: 感染症および寄生虫症 P: 腎盂腎炎 L: Pyelonephritis	E: 81 O: No L: 34 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PATIENT ADMISSION BLOOD TESTS, RADIOLOGY STUDIES CYSTOSCOPY ANTIBIOTIC TREATMENT	S: Yes, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	P1	1 to 64	48 48	R: PYELONEPHRITIS DUE TO OBSTRUCTING NEPHROLITHIASIS S: 腎および尿路障害 P: 腎結石症 L: Nephrolithiasis	E: 81 O: No L: 34 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PATIENT ADMISSION BLOOD TESTS, RADIOLOGY STUDIES CYSTOSCOPY ANTIBIOTIC TREATMENT	S: Yes, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: No

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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
[redacted]	P1	1 to 65	20	20	R: URINARY TRACT INFECTION S: 感染症および寄生虫症 P: 尿路感染 L: Urinary tract infection	E: 66 O: No L: 47 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: BACTERIAL INFECTION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	P1	1 to 57	30 30	R: CONVULSION SYNCOPE S: 神経系障害 P: 失神 L: Syncope convulsive	E: 30 O: No L: 1 day I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: PT WITH KNOWN HISTORY OF PAROXYSMAL EPILEPSY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	64 to 35	98	R: ELECTIVE ABORTION S: 外科および内科処置 P: 人工流産 L: Elective abortion	E: 98 O: No L: 1 day I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN, STUDY DRUG INTERRUPTED, WAITING FOR RESPONSE FROM STUDY TEAM, IF SUBJECT MAY CONTINUE IN THE STUDY, THE PREGNANCY WAS TERMINATED. O: ABORTION	S: Yes, Important medical event O: CONTRACEPTION FAILURE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	FU	37 to 6	42		R: PERIANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Important medical event O: CD NATURAL HISTORY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 4[redacted] Sex: Male Race: ASIAN Weight: 4[redacted].[redacted] kg								
[redacted]	FU	2 to	21	22	R: CROHN'S DISEASE AGGRAVATED S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 37 O: No L: 16 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: INADEQUATE RESPONSE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	58 to 11	68	R: BLIND ENDED FISTULA WITH BEGINNING SIRS S: 一般・全身障害および投与部位の状態 P: 全身性炎症反応症候群 L: SIRS	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN, UNBLIND SUBJECT	S: Yes, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	58 to 11	68	R: BLIND ENDED FISTULA WITH BEGINNING SIRS S: 筋骨格系および結合組織障害 P: 瘻孔 L: Fistula	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN, UNBLIND SUBJECT	S: Yes, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: ASIAN Weight: 6[redacted].[redacted] kg							
	FU	54 to 12	65	R: EXACERBATION OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 86 O: No L: 22 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization O: THE EVENT CAN BE ATTRIBUTED TO THE PRIMARY DISEASE PROGRESSION. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	P1	1 to 91	14	14	R: FIBROMYALGIA S: 筋骨格系および結合組織障害 P: 線維筋痛 L: Fibromyalgia	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INCREASE OF EXTRAINTESTINAL SYMPTOMS. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	P1	1 to 91	80	R: URETER STONE WITH HYDRONEPHROSIS S: 腎および尿路障害 P: 水腎症 L: Hydronephrosis	E: 86 O: No L: 7 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: NOT KNOWN A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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TABLE 14.3__2.1.11.9

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	P1	1 to 91	80	R: URETER STONE WITH HYDRONEPHROSIS S: 腎および尿路障害 P: 尿管結石症 L: Ureteral calculus	E: 86 O: No L: 7 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: NOT KNOWN A: NO REASONABLE POSSIBILITY C: No

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	30 to [redacted]	8	R: EXACERBATION OF CD S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 44 O: No L: 8 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: EXACERBATION OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	30 to 49	78	R: CROHN'S DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 81 O: No L: 4 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	30 to 58	87	R: CROHN'S DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 92 O: No L: 6 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NATURAL PROGRESSION OF THE DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	30 to 84	113	R: ACUTE PANCREATITIS, UNSPECIFIED S: 胃腸障害 P: 急性膵炎 L: Acute pancreatitis	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PRESUMED ACUTE PANCREATITIS, PRESENTING W/ABDOMINAL PAIN, NAUSEA AND VOMITING, ALONG W/ ELEVATED LIPASE, MEETING DIAGNOSTIC CRITERIA FOR ACUTE PANCREATITIS/MOST LIKELY DRUG INDUCED A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	P1	1 to 54	17	17	R: LOWER RESPIRATORY TRACT INFECTION S: 感染症および寄生虫症 P: 下気道感染 L: Lower respiratory tract infection	E: 23 O: No L: 7 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: EXACERBATION OF ASTHMA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
[redacted]	P1	1 to 54	17	17	R: EXACERBATION OF ASTHMA S: 呼吸器、胸郭および縦隔障害 P: 喘息 L: Exacerbation of asthma	E: 21 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: RESPIRATORY INFECTION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	P1	1 to 79	34	R: CROHN DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 48 O: No L: 15 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	P1	1 to 79	54	R: CROHN DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 94 O: No L: 41 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
	P1	1 to 84	78	78	R: ILEUS OF SMALL INTESTINE S: 胃腸障害 P: イレウス L: Ileus of intestine	E: 88 O: No L: 11 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: THE HISTORY OF REPEATED ILEUS BEFORE THIS STUDY.RECENT OVEREATING. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	61 to 15	75	R: NEPHROLITHIASIS S: 腎および尿路障害 P: 腎結石症 L: Nephrolithiasis	E: 76 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV								
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	FU	55 to 9	63		R: WORSENING OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 65 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: WORSENING OF THE PRESENT CONDITION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	30 to 9	38	R: WORSENING CROHN`S DISEASE SYMPTOMS S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 85 O: No L: 48 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING CROHN`S DISEASE SYMPTOMS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	65 to 27	91	R: SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	E: 94 O: No L: 4 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZED WITH NASOGASTRIC TUBE INSERTED 500ML FLUID BOLUS GIVEN FOR HYPOTENSION	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE RELATED A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	58 to 17	74	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 82 O: No L: 9 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization, Important medical event O: COMPLEX OF REASONS: -OBSTRUCTION OF THE APPENDIX. -EXPOSURE TO AN INFECTIOUS AGENT -VIOLATION OF INTESTINAL INNERVATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 77	68	R: INFLAMMATED NEOTERMINAL ILEUM S: 胃腸障害 P: 末端回腸炎 L: Terminal ileitis	E: 157 O: No L: 90 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg							
	P1	1 to 57	13 13	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 85 O: No L: 73 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INCREASED ACTIVITY OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	P1	1 to 29	16 16	R: ACUTE GASTROENTERITIS S: 感染症および寄生虫症 P: 胃腸炎 L: Acute gastroenteritis	E: 26 O: No L: 11 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	30 to 3	32	R: INTESTINAL OBSTRUCTION DUE TO STENOSIS, WEIGHT LOSS, UNABLE TO KEEP ANYTHING DOWN (VOMITING) S: 胃腸障害 P: 腸閉塞 L: Intestinal obstruction	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	30 to 3	32	R: INTESTINAL OBSTRUCTION DUE TO STENOSIS, WEIGHT LOSS, UNABLE TO KEEP ANYTHING DOWN (VOMITING) S: 胃腸障害 P: 腸管狭窄 L: Intestinal stenosis	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	30 to 3	32	R: INTESTINAL OBSTRUCTION DUE TO STENOSIS, WEIGHT LOSS, UNABLE TO KEEP ANYTHING DOWN (VOMITING) S: 胃腸障害 P: 嘔吐 L: Vomiting	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	30 to 3	32	R: INTESTINAL OBSTRUCTION DUE TO STENOSIS, WEIGHT LOSS, UNABLE TO KEEP ANYTHING DOWN (VOMITING) S: 臨床検査 P: 体重減少 L: Weight loss	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	FU	30 to [redacted]11	40		R: NOSOCOMIAL PNEUMONIAE, SEPSIS DUE TO PNEUMONIAE S: 感染症および寄生虫症 P: 肺炎 L: Nosocomial pneumonia	E: 41 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject, Life threatening, Hospitalization or prolonged hospitalization, Important medical event O: BRONCHOASPIRATION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	30 to [redacted]	11	40	R: NOSOCOMIAL PNEUMONIAE, SEPSIS DUE TO PNEUMONIAE S: 感染症および寄生虫症 P: 肺敗血症 L: Pulmonary sepsis	E: 41 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject, Life threatening, Hospitalization or prolonged hospitalization, Important medical event O: BRONCHOASPIRATION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	61 to 14	74	R: INFLAMMATION OF INTESTINES, ABSCESS OF RIGHT HYPOGATRIUM S: 胃腸障害 P: 胃腸の炎症 L: Intestinal inflammation	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ITRAVENOUS ANTIBIOTICS	S: Yes, Hospitalization or prolonged hospitalization O: NONE C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	61 to 14	74	R: INFLAMMATION OF INTESTINES, ABSCESS OF RIGHT HYPOGATRIUM S: 感染症および寄生虫症 P: 腹壁膿瘍 L: Abdominal wall abscess	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ITRAVENOUS ANTIBIOTICS	S: Yes, Hospitalization or prolonged hospitalization O: NONE C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	P1	1 to 58	17	17	R: WORSENING CROHNS, PANCOLITIS S: 胃腸障害 P: 大腸炎 L: Pancolitis	E: 21 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING CROHNS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	P1	1 to 58	17	17	R: WORSENING CROHNS, PANCOLITIS S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 21 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING CROHNS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: BLACK OR AFRICAN AMERICAN Weight: 4[redacted].[redacted] kg							
[redacted]	FU	2 to 7	8	R: SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 58	39	R: WORSENING DIARRHEA S: 胃腸障害 P: 下痢 L: Diarrhea aggravated	E: 47 O: No L: 9 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	P1	1 to 56	39	39	R: WORSENING MORBUS BECHTEREW S: 筋骨格系および結合組織障害 P: 強直性脊椎炎 L: Bechterew's disease	E: 44 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MRT	S: Yes, Hospitalization or prolonged hospitalization O: THE SUBJECT HAD SEVERE PAIN IN THE ILEOSACRAL AREA AND WAS ADMITTED TO THE HOSPITAL IN UELZEN FOR FURTHER DIAGNOSIS. SUBJECT HAS RECEIVED NOVALGIN AND WAS DISCHARGED ON [redacted] 20[redacted] IN GOOD CONDITION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	P1	1 to 82	7	7 R: WORSENING CROHN'S S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 141 O: No L: 135 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING CROHN'S A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 4[redacted].[redacted] kg							
	P1	1 to 57	1	R: RISE OF AURICULAR TEMP DURING THE INFUSION FROM 37,5 TO 38,5 S: 臨床検査 P: 体温上昇 L: Body temperature increased	E: 2 O: No L: 2 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: THE PATIENT WAS HOSPITALAIZED FOR MONITORING OF TEMPERATURE AND TO STUDY THE CAUSE OF THE FEVER	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
	P1	1 to 82	15 15	R: GASTROINTESTINAL HEMORRHAGE S: 胃腸障害 P: 胃腸出血 L: Gastrointestinal hemorrhage	E: 19 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: HISTORY OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg							
	P1	1 to 90	62 62	R: CHOLANGITIS, COMMON BILE DUCT STONE S: 肝胆道系障害 P: 胆管結石 L: Common bile duct stone	E: 81 O: No L: 20 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: GALLSTONE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 90	62	R: CHOLANGITIS, COMMON BILE DUCT STONE S: 肝胆道系障害 P: 胆管炎 L: Cholangitis	E: 81 O: No L: 20 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: GALLSTONE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 1[redacted] Sex: Male Race: WHITE Weight: 4[redacted].[redacted] kg								
[redacted]	FU	29 to 9	37		R: CROHN DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: ONLY UNDERLYING DIAGNOSIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in 12-Week Induction Period and until the first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the Study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

日本人の症例番号は，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]である。

表2.7.4.7-15

[redacted]20[redacted] 00:59 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL

TABLE 14.3 2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	91 to 148	26	116	R: CROHN'S DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 175 O: No L: 60 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PROGRESION OF CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg							
[redacted]	P2	84 to 140	57 140	R: RETINAL ABLATION OF THE LEFT EYE S: 眼障害 P: 網膜障害 L: Retinal disorder	E: 144 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PHACOEMULSIFICATION WITH INTRAOCULAR LENS IMPLANTATION AND PARS PLANA VITRECTOMY	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: CONCOMITANT DISEASE C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC [redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	P2	92 to 147	20 111	R: SUBACUTE COLON OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Subacute intestinal obstruction	E: 117 O: No L: 7 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: OBSTRUCTION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P2	85 to 141	46 130	R: SUBACUTE OBSTRUCTION COLON S: 胃腸障害 P: 腸閉塞 L: Subacute intestinal obstruction	E: 132 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: CONSTIPATION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 11[redacted].[redacted] kg							
[redacted]	P2	83 to 153	16	98	R: INTRAABDOMINAL HERNIA, SMALL BOWEL ISCHAEMIA, SMALL BOWEL NECROSIS, CLOSED LOOP SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 腹部ヘルニア L: Abdominal hernia	E: 99 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: ADHESIONS FROM PREVIOUS ABDOMINAL SURGERY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term / S: System Organ Class / P: MedDRA 23.1 Preferred Term / L: Lower Level Term	E: Rx Day Ended / O: Ongoing at End of Study? / L: Length / I: Intermittent?	S: Severity / R: Relationship to Study Drug / A: Action Taken with Study Treatment / O: Other Actions Taken	S: Serious AE? / O: Other Cause of Event / A: Abbvie Opinion of Causality / C: Concomitant or Additional Treatment Given?
INV: [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 11[redacted].[redacted] kg							
	P2	83 to 153	16 98	R: INTRAABDOMINAL HERNIA, SMALL BOWEL ISCHAEMIA, SMALL BOWEL NECROSIS, CLOSED LOOP SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 消化管壊死 L: Necrosis bowel	E: 99 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: ADHESIONS FROM PREVIOUS ABDOMINAL SURGERY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 11[redacted].[redacted] kg							
	P2	83 to 153	16 98	R: INTRAABDOMINAL HERNIA, SMALL BOWEL ISCHAEMIA, SMALL BOWEL NECROSIS, CLOSED LOOP SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 腸管虚血 L: Bowel ischaemia	E: 99 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: ADHESIONS FROM PREVIOUS ABDOMINAL SURGERY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 11[redacted].[redacted] kg							
[redacted]	P2	83 to 153	16	98	R: INTRAABDOMINAL HERNIA, SMALL BOWEL ISCHAEMIA, SMALL BOWEL NECROSIS, CLOSED LOOP SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	E: 99 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: ADHESIONS FROM PREVIOUS ABDOMINAL SURGERY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC [redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	137 to [redacted]	84	220	R: PSYCHOLOGICAL DECOMPENSATION S: 精神障害 P: 精神障害 L: Mental disorder	E: 255 O: No L: 36 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALISATION	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: ADJUSTMENT DISORDER A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
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Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	P2	85 to 141	20 104	R: LEFT SIDED URETERIC CALCULI S: 腎および尿路障害 P: 尿管結石症 L: Ureteric calculus	E: 106 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: LEFT URETERIC STENT INSERTION	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: UNKNOWN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	P2	85 to 141	26	110	R: HYPEREMESIS S: 胃腸障害 P: 嘔吐 L: Hyperemesis	E: 111 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: PERIPHERAL VERTIGO A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
P2	90 to 148	33	122	R: UROLITHIASIS S: 腎および尿路障害 P: 尿路結石 L: Urolithiasis	E: 154 O: No L: 33 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: KIDNEY STONE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg							
[redacted]	P2	80 to 134	25	R: SUBILEUS S: 胃腸障害 P: 亜イレウス L: Subileus	E: 183 O: No L: 80 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
	P2	85 to 145	33 117	R: WORSENING OF OBSESSIVE COMPULSIVE DISORDERS S: 精神障害 P: 強迫性障害 L: Obsessional neurosis aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: INTENSIFICATION OF PSYCHOLOGICAL FOLLOW-UP AND PSYCHIATRIC ADVICE	S: Yes, Hospitalization or prolonged hospitalization O: OTHER CAUSE UNKNOWN. HOSPITALISATION TO EVALUATE THE REEL DIAGNOSIS AND THE CAUSE OF EVENT. A: NO REASONABLE POSSIBILITY C: No

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg							
	P2	89 to 148	51	139	R: NOROVIRUS S: 感染症および寄生虫症 P: ノロウイルス性胃腸炎 L: Gastroenteritis norovirus	E: 142 O: No L: 4 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: IV NACL 0,9% 2L/24H	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC [redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P2	85 to 149	44 128	R: PERFORATION OF THE CECUM, PERITONITIS S: 胃腸障害 P: 大腸穿孔 L: Cecum perforation	E: 139 O: No L: 12 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC [redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P2	85 to 149	44 128	R: PERFORATION OF THE CECUM, PERITONITIS S: 感染症および寄生虫症 P: 腹膜炎 L: Peritonitis	E: 139 O: No L: 12 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC [redacted]# Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	112 to &	30	141 R: ILEOCECAL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Intestinal obstruction	E: 154 O: No L: 14 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: RESECTIONI OF TERMINAL ILEUM AND RIGHT SIDE COLECTOMY WITH ILEO-COLO ANASTOMOSIS	S: Yes, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event O: CROHN'S DISEASE INDUCED ILEOCECAL OBSTRUCTION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg							
	P2	91 to 148	19 109	R: ACUTE CHOLECYSTITIS S: 肝胆道系障害 P: 急性胆嚢炎 L: Acute cholecystitis	E: 130 O: No L: 22 days I: Yes	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CHOLELITHIASIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

日本人の症例番号は，[redacted]，[redacted]である。

表2.7.4.7-16

[redacted]20[redacted] 14:14 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M15-991
R&D/20/0587 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P1	1 to 97	37	37	R: CROHN'S EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 41 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	------ Epoch Name	Epoch Interval	---- Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	60 to 40	99	R: BILIARY STENOSIS S: 肝胆道系障害 P: 胆管狭窄 L: Bile duct stricture	E: 114 O: No L: 16 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE POSTPONED O: ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY AND STENT	S: Yes, Hospitalization or prolonged hospitalization O: STRICTURE OF BILIARY DUCT A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	P1	1 to 85	4	R: ENTEROPATHOGENIC E COLI S: 感染症および寄生虫症 P: 大腸菌性胃腸炎 L: Intestinal infection due to enteropathogenic E. coli	E: 13 O: No L: 10 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CONTAMINATED LAKE WATER A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	2 to 5	6	R: CROHN DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 21 O: No L: 16 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: STUDY DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	P1	1 to 57	1	R: BILATERAL PULMONARY EMBOLISM S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 7 O: No L: 7 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN DISEASE COMPLICATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	P1	1 to 84	5	R: COMPLEX ANAL FISTUL S: 胃腸障害 P: 痔瘻 L: Anal fistula	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DRAINAGE C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg							
[redacted]	P1	1 to 78	63	63	R: CROHN'S EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 65 O: No L: 3 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted] Age: 2[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 3[redacted].[redacted] kg								
	PRE	to -1	1 &	R: PROGRESSIVE CACHEXIA S: 代謝および栄養障害 P: 悪液質 L: Cachexia	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	2 to 19	20	R: WORSENING OF CROHNS DISEASE SYMPTOMS S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CT SCAN -NO OBSTRUCTIONS, NO PERFORATION AND NO EVIDENCE OF ACTIVE BOWEL DISEASE. PLAN FOR PATIENT TO HAVE AN MRE AS AN OUT PATIENT	S: Yes, Hospitalization or prolonged hospitalization O: INCREASED DISEASE ACTIVITY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	61 to 13	73	R: CROHN'S FLARE S: 胃腸障害 P: クローン病 L: Crohn's aggravated	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg							
[redacted]	FU	53 to 71	123	R: ABDOMINAL PAIN AND FEVER S: 胃腸障害 P: 腹痛 L: Abdominal pain	E: 128 O: No L: 6 days I: Yes	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg							
	FU	53 to 71	123	R: ABDOMINAL PAIN AND FEVER S: 一般・全身障害および投与部位の状態 P: 発熱 L: Fever	E: 128 O: No L: 6 days I: Yes	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
[redacted]	FU	31 to	25	55	R: WORSENING OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 57 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY (CROHNS DISEASE) A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
	FU	2 to 5	6	R: SEVERE PERIANAL DISEASE WITH DESTRUCTION OF THE ANAL SPHINCTER DUE TO DETERIORATING CROHN'S DISEASE S: 胃腸障害 P: 肛門括約筋無緊張症 L: Anal sphincter atony	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: EXAMINATION UNDER ANAESTHESIA (EUA) DONE ON [redacted] 20[redacted], DIVERTING ILEOSTOMY DONE ON [redacted] 20[redacted], ANOTHER EUA IS PLANNED FOR [redacted] 20[redacted]	S: Yes, Life threatening, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	2 to 5	6	R: SEVERE PERIANAL DISEASE WITH DESTRUCTION OF THE ANAL SPHINCTER DUE TO DETERIORATING CROHN'S DISEASE S: 胃腸障害 P: 肛門直腸障害 L: Anal disorder NOS	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: EXAMINATION UNDER ANAESTHESIA (EUA) DONE ON [redacted] [redacted] 20[redacted], DIVERTING ILEOSTOMY DONE ON [redacted] 20[redacted], ANOTHER EUA IS PLANNED FOR [redacted] 20[redacted]	S: Yes, Life threatening, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
	FU	2 to 5	6	R: SEVERE PERIANAL DISEASE WITH DESTRUCTION OF THE ANAL SPHINCTER DUE TO DETERIORATING CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: EXAMINATION UNDER ANAESTHESIA (EUA) DONE ON [redacted] [redacted] 20[redacted], DIVERTING ILEOSTOMY DONE ON [redacted] 20[redacted], ANOTHER EUA IS PLANNED FOR [redacted] 20[redacted]	S: Yes, Life threatening, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg								
[redacted]	FU	2 to	20	21	R: WORSENING PERIANAL AND GENERALISED SEPSIS AND SEPTICAEMIA S: 胃腸障害 P: 肛門直腸障害 L: Anal disorder NOS	E: 32 O: No L: 12 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: PATIENT HAS ALREADY BEEN WITHDRAWN FROM THE STUDY	S: Yes, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization O: NATURAL PROGRESSION OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	2 to	20 21	R: WORSENING PERIANAL AND GENERALISED SEPSIS AND SEPTICAEMIA S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 32 O: No L: 12 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: PATIENT HAS ALREADY BEEN WITHDRAWN FROM THE STUDY	S: Yes, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization O: NATURAL PROGRESSION OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	2 to 42	43	R: NEUTROPENIC SEPSIS, BONE MARROW SUPPRESSION, BONE MARROW FAILURE S: 血液およびリンパ系障害 P: 骨髄機能不全 L: Bone marrow failure	E: 72 O: No L: 30 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: METHOTREXATE STOPPED. ANTIBIOTICS STARTED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: NEUTROPENIC SEPSIS AND BONE MARROW SUPPRESSION MOST PROBABLY CAUSED BY METHOTREXATE TOXICITY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	2 to 42	43	R: NEUTROPENIC SEPSIS, BONE MARROW SUPPRESSION, BONE MARROW FAILURE S: 血液およびリンパ系障害 P: 骨髄抑制 L: Myelosuppression	E: 72 O: No L: 30 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: METHOTREXATE STOPPED. ANTIBIOTICS STARTED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: NEUTROPENIC SEPSIS AND BONE MARROW SUPPRESSION MOST PROBABLY CAUSED BY METHOTREXATE TOXICITY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	2 to 42	43	R: NEUTROPENIC SEPSIS, BONE MARROW SUPPRESSION, BONE MARROW FAILURE S: 感染症および寄生虫症 P: 好中球減少性敗血症 L: Neutropenic sepsis	E: 72 O: No L: 30 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: METHOTREXATE STOPPED. ANTIBIOTICS STARTED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: NEUTROPENIC SEPSIS AND BONE MARROW SUPPRESSION MOST PROBABLY CAUSED BY METHOTREXATE TOXICITY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: MULTIPLE Weight: 7[redacted].[redacted] kg							
	FU	2 to 42	43	R: ACUTE RENAL FAILURE S: 腎および尿路障害 P: 急性腎障害 L: Acute renal failure	E: 72 O: No L: 30 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: INTRAVENOUS FLUIDS GIVEN, ANTIBIOTICS STARTED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization, Important medical event O: THIS EVENT IS MOST PROBABLY CAUSED BY THE NEUTROPENIC SEPSIS WORSENING DEHYDRATION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	FU	2 to 29	30	R: EXACERBATION OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 31 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	FU	2 to 36	37	R: EXACERBATION OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 41 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
[redacted]	FU	2 to	45	46	R: VIRAL MYOCARDITIS S: 感染症および寄生虫症 P: ウイルス性心筋炎 L: Viral myocarditis	E: 52 O: No L: 7 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN, SUBJECT LAST DOSE OF MEDICATION WAS [redacted]20[redacted] O: SUBJECT WAS NOT TERMINATED DUE TO THE AE. SUBJECT WAS TERMINATED BECAUSE HE UNBLINDED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization O: VIRAL INFECTION A: REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 56	40	R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 43 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: ILEUS CAUSED BY CROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	P1	1 to 62	9	9	R: NAUSEA S: 胃腸障害 P: 悪心 L: Nausea	E: 18 O: No L: 10 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	63 to 15	77	R: WORSENING OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: ACTIVE CROHNS DISEASE, UPPER GI INVOLVEMENT, WEIGHT LOSS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	FU	63 to 84	146	R: UROLITHIASIS S: 腎および尿路障害 P: 尿路結石 L: Urolithiasis	E: 175 O: No L: 30 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	P1	1 to 62	19	R: ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia	E: 20 O: No L: 2 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITAL ADMISSION AND BLOOD TRANSFUSION	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	23 to 3	25	R: WORSENING DISEASE CROHN S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 77 O: No L: 53 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: DUE TO CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 96	19 19	R: CROHN'S DISEAS FLARE UP S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 22 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted]# Age: 3[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 96	69	R: SMALL BOWEL OBSTRUCTION SECONDARY TO CROHN'S DISEASE S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	E: 88 O: No L: 20 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: THE SUBJECT'S VISIT FOR WEEK 12 AND COLONOSCOPY PROCEDURE SCHEDULED FOR [redacted] DIDN'T HAPPEN. SHE WILL BE RESCHEDULED AFTER HER RECOVERY. O: PATIENT WAS HOPITALIZED ON [redacted] AFTER SHE WAS DIAGNOSED WITH SMALL BOWEL OBSTRUCTION AND HAD SURGERY ON [redacted]. SHE HASN'T BEEN DISCHARGED YET.	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: BLACK OR AFRICAN AMERICAN Weight: 6[redacted].[redacted] kg							
	FU	24 to 108	131	R: RECURRENT CROHN'S ILEITIS WITH STRICTURE AND PROXIMAL OBSTRUCTION. S: 胃腸障害 P: クローン病 L: Crohn's ileitis	E: 141 O: No L: 11 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: BLACK OR AFRICAN AMERICAN Weight: 6[redacted].[redacted] kg							
	FU	24 to 108	131	R: RECURRENT CROHN'S ILEITIS WITH STRICTURE AND PROXIMAL OBSTRUCTION. S: 胃腸障害 P: 回腸狭窄 L: Ileal stricture	E: 141 O: No L: 11 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: BLACK OR AFRICAN AMERICAN Weight: 6[redacted].[redacted] kg							
	FU	24 to 108	131	R: RECURRENT CROHN'S ILEITIS WITH STRICTURE AND PROXIMAL OBSTRUCTION. S: 胃腸障害 P: 小腸閉塞 L: Ileal obstruction	E: 141 O: No L: 11 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: BLACK OR AFRICAN AMERICAN Weight: 6[redacted].[redacted] kg							
	FU	24 to 113	136	R: PARALYTIC ILEUS S: 胃腸障害 P: 麻痺性イレウス L: Paralytic ileus	E: 140 O: No L: 5 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RELATED TO PROCEDURE: ILEOCECECTOMY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 71	4	R: TYPICAL ATRIAL UNDULLATION S: 心臓障害 P: 心房粗動 L: Atrial flutter	E: 4 O: No L: 1 day I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: ISHAEMIC HEART DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg								
	FU	60 to	21	80	R: HEMATOCHEZIA S: 胃腸障害 P: 血便排泄 L: Hematochezia	E: 84 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: NO ACTIVE BLEEDING IN THE LARGE INTESTINE. SUSPECTED EXACERBATION OF SMALL BOWEL DISEASE BASED ON PAST HISTORY. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 4[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	FU	2 to 7	8	R: CROHN'S DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 16 O: No L: 9 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: UNDERLYING CONDITION OF CD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
[redacted]	FU	2 to	1	2	R: FLARE OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 23 O: No L: 22 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: WORSENING OF DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV [redacted] Age: 2[redacted] Sex: Male Race: BLACK OR AFRICAN AMERICAN Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 65	24 24	R: ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia	E: 25 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: SEVERE CROHN'S DISEASE MINOR ULCERS WITH MNIR BLEEDING IN ENDOSCOPY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER Weight: 5[redacted].[redacted] kg							
	P1	1 to 99	73	R: CELLULITIS OF SCROTUM S: 感染症および寄生虫症 P: 男性外性器蜂巣炎 L: Cellulitis genital organ (male)	E: 76 O: No L: 4 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CELLULITIS OF SCROTUM AN INCIDENTAL EVENT. APPARENTLY HAS NO KNOW CAUSE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV								
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
[redacted]	P1	1 to 64	64	64	R: FLARE UP OF CROHN DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 196 O: No L: 133 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	58 to 10	67	R: NEPHROLITHIASIS S: 腎および尿路障害 P: 腎結石症 L: Nephrolithiasis	E: 70 O: No L: 4 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PAST HX NEPHROLITHIASIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
	FU	2 to 4	5	R: ARTHRALGIA WORSENING S: 筋骨格系および結合組織障害 P: 関節痛 L: Arthralgia aggravated	E: 8 O: No L: 4 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: THIS IS RELATED FOR EXTRA-INTESTINAL MANIFESTATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	58 to 26	83	R: CROHN'S EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 171 & O: No L: 89 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	P1	1 to 57	17 17	R: CERVICAL HERNIA S: 筋骨格系および結合組織障害 P: 椎間板突出 L: Cervical disc herniation	E: 21 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: MEDICAL HISTORY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
	P1	1 to 89	45 45	R: CROHNS DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 50 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: USE OF ONGOING CON-MEDICATIONS	S: Yes, Hospitalization or prolonged hospitalization O: EXACERBATION OF PRE-EXISTING CROHN'S A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
	P1	1 to 89	53	R: CROHN'S DISEASE FLARE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 58 O: No L: 6 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: C DIFFICILE PCR POSITIVE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	FU	57 to 3	59	R: INTRAABDOMINAL ABSCESS S: 感染症および寄生虫症 P: 腹部膿瘍 L: Intra-abdominal abscess	E: 72 O: No L: 14 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	FU	57 to 23	79	R: POSTOPERATIVE DYSBIOSIS S: 胃腸障害 P: 細菌叢異常 L: Dysbiosis	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event O: SURGICAL INTERVENTION [redacted]20[redacted] A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	2 to 24	25	R: CROHN'S FLARE-UP, PERI-RECTAL ABSCESS S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 34 O: No L: 10 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: LACK OF TREATMENT FOR CROHN'S FOR A PROLONGED PERIOD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
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Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	2 to 24	25	R: CROHN'S FLARE-UP, PERI-RECTAL ABSCESS S: 感染症および寄生虫症 P: 直腸周囲膿瘍 L: Perirectal abscess	E: 34 O: No L: 10 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: LACK OF TREATMENT FOR CROHN'S FOR A PROLONGED PERIOD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	P1	1 to 105	31	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	O: Yes I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: COLITIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	FU	57 to 5	61	R: WORSENING OF ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia aggravated	E: 85 O: No L: 25 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	P1	1 to 55	40	40	R: VIRAL PHARYNGITIS S: 感染症および寄生虫症 P: ウイルス性咽頭炎 L: Viral pharyngitis	E: 43 O: No L: 4 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: VIRAL A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	P1	1 to 64	29	29	R: NOT IDENTIFIED SUSPECT SEPSIS ETHIOLOGY FEVER S: 一般・全身障害および投与部位の状態 P: 発熱 L: Fever	E: 40 O: No L: 12 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: W4 IP ADMINISTRATION WAS DONE 8 DAYS LATER THAN IS ALLOWED VISIT WINDOW. LATE IP DOSING WAS APPROVED BY TA MD O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: SUSPECT UNKNOWN INFECTION A: REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
[redacted]	P1	1 to 64	29	29	R: NOT IDENTIFIED SUSPECT SEPSIS ETHIOLOGY FEVER S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 40 O: No L: 12 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: W4 IP ADMINISTRATION WAS DONE 8 DAYS LATER THAN IS ALLOWED VISIT WINDOW. LATE IP DOSING WAS APPROVED BY TA MD O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: SUSPECT UNKNOWN INFECTION A: REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 600 mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	P1	1 to 84	57	R: ANAEMIA GRADE 3 S: 血液およびリンパ系障害 P: 貧血 L: Anaemia	E: 79 O: No L: 23 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: EXCEREBRATION OF CD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted]# Age: 1[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	53 to 33	85	R: CROHN DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 87 O: No L: 3 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN, HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
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Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted]# Age: 5[redacted] Sex: Female Race: WHITE Weight: 12[redacted].[redacted] kg							
[redacted]	FU	2 to 7	8	R: SQUAMOUS CELL LUNG CARCINOMA S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 肺扁平上皮癌 L: Squamous cell carcinoma of lung	E: 52 O: No L: 45 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: SURGERY WAS PERFORMED ON [redacted] 20[redacted] TO REMOVE THE LESION.	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: LONG AND EXTENSIVE HEAVY TOBACCO ABUSE UP TO 2 PACKS A DAY. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted]# Age: 5[redacted] Sex: Female Race: WHITE Weight: 12[redacted].[redacted] kg							
	FU	2 to 39	40	R: BILATERAL AORTO-ILIAC OCCLUSIVE DISEASE, WORSE ON THE LEFT. S: 血管障害 P: ルリッシュ症候群 L: Aortoiliac occlusive disease	E: 52 O: No L: 13 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: STUDY TREATMENT WAS WITHDRAWN WHEN THE PATIENT WAS DIAGNOSED WITH LUNG CANCER ON [redacted].20[redacted]. O: THE PATIENT RECEIVED LEFT ABOVE KNEE AMPUTATION.	S: Yes, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event O: THIS EVENT WAS A COMPLICATION OF THE PATIENT'S LUNG SURGERY ON [redacted] 20[redacted]. A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted]# Age: 5[redacted] Sex: Female Race: WHITE Weight: 12[redacted].[redacted] kg								
[redacted]	FU	2 to 46	47		R: ACUTE HYPOXEMIC RESPIRATORY FAILURE S: 呼吸器、胸郭および縦隔障害 P: 急性呼吸不全 L: Acute respiratory failure	E: 52 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: THE STUDY DRUG HAS BEEN WITHDRAWN SINCE THE PATIENT WAS DIAGNOSED WITH SQUAMOUS CELL LUNG CARCINOMA.	S: Yes, Death of subject, Life threatening, Hospitalization or prolonged hospitalization, Important medical event O: THIS EVENT WAS A COMPLICATION OF THE PATIENT'S LEFT LEG AMPUTATION SURGERY ON [redacted] 20[redacted]. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P1	1 to 61	25 25	R: PARTIAL OCCLUSION IN ILEON S: 胃腸障害 P: 小腸閉塞 L: Partial obstruction of small intestine	E: 85 O: No L: 61 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: CROHN FLARE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted]# Age: 5[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 7[redacted].[redacted] kg							
	FU	2 to 3	4	R: CROHN'S DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 45 O: No L: 42 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV							
[redacted] Age: 1[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	P1	1 to 85	83	83	R: WORSENING CD FLARE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the 12-Week Induction Period
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	P1	1 to 85	36	R: INCISIONAL HERNIA REPAIR S: 外科および内科処置 P: 瘢痕ヘルニア修復 L: Incisional hernia repair	E: 36 O: No L: 1 day I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: TREATMENT HAS RESUMED O: SURGERY	S: Yes, Important medical event O: PRE-EXISTING INCISIONAL ABDOMINAL HERNIA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Screening; P1 = Induction treatment 1; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

表2.7.4.7-17

[redacted]20[redacted] 14:14 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M15-991
R&D/20/0587 - CLINICAL/STATISTICAL

TABLE 14.3 2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV								
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 4[redacted].[redacted] kg								
	P2	89 to 141	14	102	R: STRICTURE AT ILEUM S: 胃腸障害 P: 回腸狭窄 L: Ileal stricture	E: 104 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RELATED TO STRICTURE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg							
	P2	85 to 141	15 99	R: ABDOMINAL PAIN, NAUSEA S: 胃腸障害 P: 腹痛 L: Abdominal pain	E: 100 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: ACCUTE CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	P2	85 to 141	15 99	R: ABDOMINAL PAIN, NAUSEA S: 胃腸障害 P: 悪心 L: Nausea	E: 100 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: ACCUTE CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	P2	85 to 141	57 141	R: DISEASE PROGRESSION CROHN S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 177 O: No L: 37 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV [redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	149 to 19	167	R: PNEUMONIA ASSOCIATED TO STAPHYLOCOCCUS AUREUS, ACUTE RENAL FAILURE S: 感染症および寄生虫症 P: ブドウ球菌性肺炎 L: Staphylococcus aureus pneumonia	E: 184 O: No L: 18 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: PNEUMONIA ASSOCIATED TO STAPHYLOCOCCUS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	149 to 19	167	R: PNEUMONIA ASSOCIATED TO STAPHYLOCOCCUS AUREUS, ACUTE RENAL FAILURE S: 腎および尿路障害 P: 急性腎障害 L: Acute renal failure	E: 184 O: No L: 18 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: PNEUMONIA ASSOCIATED TO STAPHYLOCOCCUS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	149 to [redacted]&	41	189	R: PULMONARY ASPERGILLUM INFECTION AND SAUREUS PNEUMONIA S: 感染症および寄生虫症 P: 気管支肺アスペルギルス症 L: Pulmonary aspergillosis	E: 250 O: No L: 62 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PULMONARY ASPERGILLUM INFECTION AND S AUREUS PNEUMONIA A: REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	149 to [redacted]	41	189	R: PULMONARY ASPERGILLUM INFECTION AND SAUREUS PNEUMONIA S: 感染症および寄生虫症 P: ブドウ球菌性肺炎 L: Staphylococcus aureus pneumonia	E: 250 O: No L: 62 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PULMONARY ASPERGILLUM INFECTION AND S AUREUS PNEUMONIA A: REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV [redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	89 to [redacted]&	22	R: CROHN'S DISEASE EXACERBATION S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 112 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted]# Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	89 to 26	114	R: JEJUNAL STRICTURE S: 胃腸障害 P: 空腸狭窄 L: Jejunal stenosis	E: 127 O: No L: 14 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: UNDERLYING CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted]# Age: 3[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 7[redacted].[redacted] kg							
[redacted]	FU	98 to 15	112	R: ANASTOMOTIC LEAKAGE S: 傷害、中毒および処置合併症 P: 吻合部漏出 L: Anastomotic leak	E: 141 O: No L: 30 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: POST-OP COMPLICATIONS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 3[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg							
[redacted]	P2	91 to 147	37	127	R: WORSENING OF ANAL STRICTURE S: 胃腸障害 P: 肛門狭窄 L: Anal stricture	E: 129 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC [redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	140 to [redacted]	188	R: INTESTINAL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Intestinal obstruction	E: 194 O: No L: 7 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: N/A O: SMALL BOWEL RESECTION SURGERY	S: Yes, Hospitalization or prolonged hospitalization, Important medical event O: DISEASE WORSENING A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	144 to #	6	R: PERIANAL ABSCESS. S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	E: 151 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PERIANAL DISEASE IS DUE TO CHROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	FU	142 to 2	143	R: WORSENING OF ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: DUE TO HIS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV [redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	FU	142 to 62	203	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 203 O: No L: 1 day I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WAS ALREADY WITHDRAWN IN [redacted] 20[redacted] O: THE SUBJECT WAS OFF STUDY DRUG SINCE [redacted] 20[redacted]	S: Yes, Life threatening, Hospitalization or prolonged hospitalization, Important medical event O: DISEASE RELATED PER PI A: NO REASONABLE POSSIBILITY C: No

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

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(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	150 to 65	214	R: WORSENING UMBILICAL HERNIA S: 胃腸障害 P: 臍ヘルニア L: Umbilical hernia	E: 278 O: No L: 65 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONPROCEDURE	S: Yes, Hospitalization or prolonged hospitalization O: UMBILICAL HERNIA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

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(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV							
[redacted] Age: 6[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 7[redacted].[redacted] kg							
	P2	92 to 149	2 93	R: POST PROCEDURE RECTAL BLEED S: 傷害、中毒および処置合併症 P: 処置後出血 L: Post procedural bleeding	E: 95 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: SUBJECT COMPLETED PROTOCOL REQUIRED COLONOSCOPY ON [redacted] WHICH LED TO EVENT. A: NO REASONABLE POSSIBILITY C: No

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
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Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo IV/Risankizumab 1200 mg IV [redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	P2	85 to 141	9 93	R: CYTOMEGALOVIRUS S: 感染症および寄生虫症 P: サイトメガロウイルス感染 L: Cytomegalovirus infection	E: 100 O: No L: 8 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INMUNOSUPRESION CD RELATED A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC [redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	P2	78 to 115	1	78	R: ABDOMINAL PAIN S: 胃腸障害 P: 腹痛 L: Abdominal pain	E: 79 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: THE ABDOMINAL PAIN IS ASSESSED AS BEING DUE TO COLONOSCOPY PERFORMED YESTERDAY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	P2	78 to 115	1 78	R: FEVER S: 一般・全身障害および投与部位の状態 P: 発熱 L: Fever	E: 79 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: THE FEVER IS ASSESSED AS BEING DUE TO COLONOSCOPY PERFORMED YESTERDAY MOST LIKELY DUE TO BACTERIAL TRANSLOCATION AFTER COLONOSCOPY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	100 to [redacted]	19	118	R: SPONTANEOUS ABORTION S: 妊娠、産褥および周産期の状態 P: 自然流産 L: Spontaneous abortion	E: 141 O: No L: 24 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DILATION AND CURETTAGE SUCTION	S: Yes, Important medical event O: HISTORY OF PREVIOUS SPONTANEOUS ABORTION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV [redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	153 to [redacted]	113 265	R: FISTULIZING CROHN DISEASE WITH EXACERBATION S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 270 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: SEPSIS FROM NECROTIZING FASCITIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	153 to [redacted]	113	R: FISTULIZING CROHN DISEASE WITH EXACERBATION S: 胃腸障害 P: クローン病 L: Fistulizing Crohn's disease	E: 270 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: SEPSIS FROM NECROTIZING FASCITIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.2.11.8

Listing of Subjects with Treatment-Emergent Serious Adverse Event during the Induction Period 2
(SA2 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 1200 mg IV							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	FU	153 to 117	269	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 270 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Death of subject, Life threatening, Persistent or significant disability/Incapacity, Hospitalization or prolonged hospitalization, Important medical event O: FISTULIZING CROHN'S EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment-emergent AEs (TEAEs) for the Induction Period 2 are defined as events that begin either on or after the first dose of the study medication in the Induction Period 2 and until first dose of study drug in the Study M16-000 if the subject is enrolled into the Study M16-000 or within 140 days after the last dose of the study drug in the Induction Period 2 if the subject does not participate in the Study M16-000.
SA2 Population includes all subjects who received at least one dose of study drug during the Induction Period 2.
Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
P2 = Induction treatment 2; FU = Follow-up. # Subject prematurely discontinued. & Date is estimated.

Program Source Code: [redacted]

表2.7.4.7-18

TABLE 14.3 2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	DB	1 to 402	372	372	R: DIVERTICULITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis	E: 375 O: No L: 4 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CT ABDOMEN/PELVIS WITH CONTRAST	S: Yes, Hospitalization or prolonged hospitalization O: DIVERTICULOSIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 399	302	302*	R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 303 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PASSENGER X-RAY WITH CONTRAST AGENT	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING OF CROHNS DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 389	229	229*	R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 248 O: No L: 20 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INADEQUATE RESPONSE OF IP A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
[redacted]	DB	1 to 113	36	36	R: CONGESTIVE HEART FAILURE, COPD EXACERBATION S: 心臓障害 P: うっ血性心不全 L: Congestive heart failure	E: 41 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: COPD EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	DB	1 to 113	36	36	R: CONGESTIVE HEART FAILURE, COPD EXACERBATION S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 41 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: COPD EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	114 to 3	116	R: ACUTE CHF EXACERBATION S: 心臓障害 P: 急性心不全 L: Acute decompensated heart failure	E: 118 O: No L: 3 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: HISTORY OF CHF A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 394	26	26	R: BOWEL OBSTRUCTION (PRETERMINAL ILEUM) S: 胃腸障害 P: 小腸閉塞 L: Small intestinal obstruction	E: 29 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE RELATED A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 392	149	149	R: ANAL ABSCESS WITH EXTENSION ABOVE THE ELEVATOR MUSCLES S: 感染症および寄生虫症 P: 肛門膿瘍 L: Anal abscess	E: 157 O: No L: 9 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	341 to 369*	29	R: DISSEMINATED HISTOPLASMOSIS S: 感染症および寄生虫症 P: 播種性ヒストプラスマ症 L: Disseminated histoplasmosis	O: Yes I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: REFERRAL TO INFECTIOUS DISEASE	S: Yes, Important medical event A: REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 395	32	32	R: TENDINOPATHY S: 筋骨格系および結合組織障害 P: 腱障害 L: Tendinopathy	E: 36 O: No L: 5 days I: Yes	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: DIABETES A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 395	262	262	R: SUBACUTE LOW BACK PAIN S: 筋骨格系および結合組織障害 P: 背部痛 L: Low back pain	E: 263 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: SPONDYLOARTHITIS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 395	263	263	R: CARDIAC SINUS DYSFUNCTION S: 心臓障害 P: 心機能障害 L: Cardiac dysfunction	E: 264 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: THE SEQUELS WERE SIMPLE. AFTER THE ISOPTINE SHUTDOWN EVERYTHING IS BACK TO NORMAL. A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 5[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	DB	1 to 392	241	241	R: OSTEOPOROSIS S: 筋骨格系および結合組織障害 P: 骨粗鬆症 L: Osteoporosis	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CONSIDER OSTEOPOROSIS MEDICAL HISTORY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 6[redacted].[redacted] kg								
	DB	1 to 406	71	71	R: ANAEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anaemia	E: 113 O: No L: 43 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: HAEMMORRHAGIA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted] Age: 1[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	DB	1 to 479	415 415*	R: ILEAL SUBSTENOSIS S: 胃腸障害 P: 回腸狭窄 L: Ileal stenosis	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: THE STUDY DRUG ADMINISTRATION WAS POSTPONED TO [redacted] 20[redacted]. WE MADE NO OTHER CHANGES IN DRUG ADMINISTRATION O: NONE	S: Yes, Important medical event O: WORSENING OF THE STENOSIS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	DB	1 to 387	1	1	R: PERITONEALE SYNDROM S: 胃腸障害 P: 腹膜障害 L: Peritoneal disorder	E: 6 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: COLONOSCOPY ASKING BY PROTOCOLE TO CHECK THE CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
[redacted]	FU	348 to 366	19	R: HIGH GRADE DYSPLASIA ON THE TRANSVERSE COLON (AT THE SURGICAL ANASTOMOSIS) S: 胃腸障害 P: 結腸異形成 L: Colon dysplasia	E: 410 O: No L: 45 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: REFERRED FOR SURGICAL EVALUATION	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE EVOLUTION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	DB	1 to 400	46	46	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 49 O: No L: 4 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION AND SURGERY	S: Yes, Important medical event O: APPENDICITIS, SURGERY REQUIRED A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

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INV: [redacted] TRT: Placebo SC								
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	DB	1 to 174	12	12	R: CARDIAC FAILURE STAGE II S: 心臓障害 P: 心不全 L: Cardiac failure	O: Yes I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: NOT WITHDRAWN AT PRESENT.	S: Yes, Hospitalization or prolonged hospitalization O: PATIENT HAS CARDIAC BACKGROUND. AWAITING ANGIO FOR FURTHER INFORMATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
	FU	175 to &	30	204*	R: ADENOCARCINOMA OF THE LEFT LUNG S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 肺腺癌 L: Adenocarcinoma of lung	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: PATIENT HAS BEEN TAKEN OVER BY RESPIRATORY AND WILL GO ON TO THE RAPID ACCESS LUNG CANCER PATHWAY	S: Yes, Important medical event O: FAMILY HISTORY OF CANCER A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg							
[redacted]	FU	175 to [redacted]	93	267* R: FLARE OF CROHNS S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, DISCONTINUED FROM TRIAL AS PER ABBVIE INSTRUCTION ON THE [redacted]/[redacted]/20[redacted]. COMMENCED ON USTEKINUMAB [redacted]/[redacted]/20[redacted]	S: Yes, Hospitalization or prolonged hospitalization O: FLARE OF CROHNS AS STOPPED RISANKISUMAB DUE TO SAE OF LUNG CANCER. COLITIS INDUCED ALSO FROM IMMUNOTHERAPY. DIARRHOEA KNOWN SIDE EFFECT. A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
	DB	1 to 391	41	41	R: CHEST PAIN S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Chest pain	E: 49 O: No L: 9 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: GASTROESOPHAGEAL REFLUX DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg								
	DB	1 to 392	316	316	R: UTERINE FIBROIDS S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 子宮平滑筋腫 L: Uterine fibroids	E: 317 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: PELVIC PAIN A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

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INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 226	198	198	R: BOWEL PERFORATION S: 胃腸障害 P: 腸管穿孔 L: Bowel perforation	E: 201 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: COLONOSCOPY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	FU	227 to &	115	341*	R: EXACERBATION OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 343 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: ACTIVE CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 10[redacted].3[redacted] kg								
	DB	1 to 387	243	243	R: INTESTINAL OBSTRUCTION S: 胃腸障害 P: 腸閉塞 L: Intestinal obstruction	E: 277 O: No L: 35 days I: No	S: MILD R: REASONABLE POSSIBILITY A: RESCUE VISIT	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	DB	1 to 333	12	12	R: HEPATIC ABSCESS, THORACIC EMPIEMA S: 感染症および寄生虫症 P: 感染性胸水 L: Pyothorax	E: 46 O: No L: 35 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Important medical event O: NOTE THAT ANY OF THE DRUGS (PREDNISOLONE, AZATHIOPRINE, STUDY DRUG) CAN INCREASE THE RISK OF INFECTIONS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	DB	1 to 333	12	12	R: HEPATIC ABSCESS, THORACIC EMPIEMA S: 感染症および寄生虫症 P: 肝膿瘍 L: Liver abscess	E: 46 O: No L: 35 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Important medical event O: NOTE THAT ANY OF THE DRUGS (PREDNISOLONE, AZATHIOPRINE, STUDY DRUG) CAN INCREASE THE RISK OF INFECTIONS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	DB	1 to 393	149	149	R: CHRONIC PAIN SYNDROME S: 一般・全身障害および投与部位の状態 P: 疼痛 L: Chronic pain	E: 155 O: No L: 7 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: US ABDOMEN, MR LIVER, US LEFT SHOULDER, X-RAY LEFT SHOULDER, X-RAY PELVIS, X-RAY THORAX, ELECTROMYOGRAPHY	S: Yes, Hospitalization or prolonged hospitalization O: OBESITY A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 3[redacted] Sex: Female Race: MULTIPLE Weight: 6[redacted].[redacted] kg								
	DB	1 to 386	128	128	R: MYCOPLASMA PNEUMONIA S: 感染症および寄生虫症 P: マイコプラズマ性肺炎 L: Mycoplasmal pneumonia	E: 170 O: No L: 43 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: BLOODWORK, CT	S: Yes, Hospitalization or prolonged hospitalization O: MYCOPLASMA PNEUMONIA IS AN INCIDENTAL EVENT. SEASONALITY. A: REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 330	62	62	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 65 O: No L: 4 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INFLAMED APPENDIX A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	331 to 73	403*	R: WORSENING CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 413 O: No L: 11 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 392	143	143	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 145 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: LAB TESTS, ECHO ABDOMEN, APPENDECTOMY	S: Yes, Hospitalization or prolonged hospitalization O: NO REASONABLE POSSIBILITY, INFECTION OF THE APPENDIX CAN HAPPEN TO ANYONE, NO PREDISPOSITION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg								
	DB	1 to 390	131	131	R: WORSENING OF OBESITY S: 代謝および栄養障害 P: 肥満 L: Obesity	E: 133 O: No L: 3 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: ELECTIVE ADMISSION TO LAPAROSCOPIC SLEEVE GASTRECTOMY PLANNED FOR MORBID OBESITY TREATMENT A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 398	1	1	R: LUMBOISHIALGIA LAT SIN. S: 神経系障害 P: 坐骨神経痛 L: Lumboischialgia	O: Yes I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: SYMPTOMATIC THERAPY OF DIAREA, ANALGETICS	S: Yes, Hospitalization or prolonged hospitalization O: DORSAL PROTRUSION OF VERTEBAL DISCUS L5-S1 A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 398	16	16	R: DIARRHEA S: 胃腸障害 P: 下痢 L: Diarrhea	E: 36 O: No L: 21 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION ON [redacted] 20[redacted]	S: Yes, Hospitalization or prolonged hospitalization O: USE OF ANELGETICS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 398	43	43	R: EXARBATION OF CD S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 57 O: No L: 15 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION AND INTRODUCTION OF BUDESONIDE IN THE CD THERAPY	S: Yes, Hospitalization or prolonged hospitalization O: EXARBATION OF CD DUE TO POSSIBALY OF INEFFECTIVE DRUG A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg								
	DB	1 to 389	189	189	R: ANAL FISTULA S: 胃腸障害 P: 痔瘻 L: Anal fistula	E: 197 O: No L: 9 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: FISTULECTOMY.SETON	S: Yes, Hospitalization or prolonged hospitalization O: CD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	DB	1 to 170	99	99	R: FLARE OF CROHN DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 101 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: ILEAL STENOSIS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	FU	171 to [redacted]	25	195	R: SUB-OCCLUSIVE SYNDROME S: 胃腸障害 P: 亜イレウス L: Subocclusive syndrome	E: 226 O: No L: 32 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Important medical event O: PERITONITIS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
[redacted]	FU	171 to [redacted]	25	R: PERITONITIS S: 感染症および寄生虫症 P: 腹膜炎 L: Peritonitis	E: 226 O: No L: 32 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: RELATED TO CROHN DESEASE. NONE OTHER CAUSE DEFINED. C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	FU	171 to 81	251		R: HYPERTHERMIA S: 一般・全身障害および投与部位の状態 P: 高体温症 L: Hyperthermia	E: 252 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: INTRAPERITONEAL FISTULA IN LEFT ILIAC FOSSA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 392	61	61	R: ACUTE BACK PAIN S: 筋骨格系および結合組織障害 P: 背部痛 L: Acute back pain	E: 71 O: No L: 11 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: LOMBALGIA INFLAMMATORY INVOLVEMENT A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	DB	1 to 392	79	R: ARTHRITIS OF LEFT KNEE S: 筋骨格系および結合組織障害 P: 関節炎 L: Knee arthritis	E: 84 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: INFLAMMATORY RHUMATISM BEGINNER CHORINIC WITH PERIPHERAL MANIFESTATION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg							
	DB	1 to 392	79	R: ACUTE DORSALGIA S: 筋骨格系および結合組織障害 P: 背部痛 L: Dorsalgia	E: 84 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: INFLAMMATORY RHUMATISM BEGINNER CHORINIC WITH PERIPHERAL MANIFESTATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	DB	1 to 393	249	249	R: RIGHT URETERAL CALCULUS S: 腎および尿路障害 P: 尿管結石症 L: Ureteral calculus	E: 251 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CYSTOSCOPY WITH URETERAL STENT PLACEMENT	S: Yes, Hospitalization or prolonged hospitalization O: H/O KIDNEY STONES A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 389	5	5	R: PARTIAL SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: Partial small intestinal obstruction	E: 7 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC [redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	DB	1 to 324	8	R: CROHN'S FLARE S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 113 O: No L: 106 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S FLARE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg							
	FU	325 to	23 347	R: ANAL STRICTURE S: 胃腸障害 P: 肛門狭窄 L: Anal stricture	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: COLONIC AND ANAL STRICTURE. PROGRAMMED COLECTOMY.	S: Yes, Hospitalization or prolonged hospitalization O: PROGRESSION OF UNDERLYING DISEASE ANAL STRICTURE. A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted]# Age: 3[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg							
[redacted]	DB	1 to 230	27	R: VIRAL INFECTION S: 感染症および寄生虫症 P: ウイルス感染 L: Viral infection	E: 58 O: No L: 32 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: VIRAL INFECTION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	DB	1 to 405	90 90	R: VIRAL INFECTION S: 感染症および寄生虫症 P: ウイルス感染 L: Viral infection	E: 113 O: No L: 24 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	219 to 80	298*	R: WORSENING OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 328 O: No L: 31 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: PROGRESSION OF UNDERLYING DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted]# Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
[redacted]	FU	225 to [redacted]	8	232*	R: ILEAL STENOSIS S: 胃腸障害 P: 回腸狭窄 L: Ileal stenosis	E: 235 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC [redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
	DB	1 to 400	255 255	R: FRACTURE OF THE PHALANX OF THE PROXIMAL SECOND FINGER OF THE RIGHT HAND S: 傷害、中毒および処置合併症 P: 手骨折 L: Fractured finger	E: 259 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Important medical event O: FINGER INJURY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	DB	1 to 394	52	R: GLUTEAL ABCESS S: 感染症および寄生虫症 P: 四肢膿瘍 L: Gluteal abscess	E: 52 O: No L: 1 day I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ABCESS INCISION	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 394	172	172	R: GLUTEALABSCESS S: 感染症および寄生虫症 P: 四肢膿瘍 L: Gluteal abscess	E: 173 O: No L: 2 days I: No	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 394	268	268	R: ANALFISTULAE S: 胃腸障害 P: 痔瘻 L: Anal fistula	E: 269 O: No L: 2 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: THERAPY WITH STEM CELLS	S: Yes, Hospitalization or prolonged hospitalization O: DUE TO MORBUS CROHN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 7[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 385	360	360	R: BASAL CELL CARCINOMA TO RIGHT TEMPLE OF HEAD S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 基底細胞癌 L: Basal cell carcinoma	E: 498 O: No L: 139 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: BIOPSY, BASAL CELL REMOVAL COMPLETED	S: Yes, Important medical event O: SUN EXPOSURE, AGE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	DB	1 to 392	333 333	R: HYDRADENITIS SUPURATIVA S: 皮膚および皮下組織障害 P: 汗腺炎 L: Hidradenitis suppurativa	E: 348 O: No L: 16 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: THE PATIENT HAS A MILD FORM OF HYDRADENITIS SINCE 2016 WITH OCCASIONAL EXACERBATIONS,, THERAPEUTIC ANTIBIOTICS, NO DISEASE PROGRESSION, AND NO KNOWN RISK FACTORS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 392	382	382	R: PERIANAL FISTULA S: 胃腸障害 P: 痔瘻 L: Perianal fistula	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
[redacted]	FU	288 to 4	291		R: WORSENING OF CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 302 O: No L: 12 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: YERSINIA ENTEROCOLITICA SUPERINFECTION WAS ONLY POSSIBLE CAUSE OF EVENT WHICH WAS NOT CONFIRMED A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 278	74	74	R: SUBILEUS S: 胃腸障害 P: 亜イレウス L: Subileus	E: 205 O: No L: 132 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: XRAY CHEST AND ABDOMEN	S: Yes, Hospitalization or prolonged hospitalization O: DIET MISTAKE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 278	206	206	R: WORSENED SUBILEUS S: 胃腸障害 P: 亜イレウス L: Subileus	E: 209 O: No L: 4 days I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: UNDERLYING DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	DB	1 to 278	236 236	R: WORSENED SUBILEUS S: 胃腸障害 P: 亜イレウス L: Subileus	E: 243 O: No L: 8 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: UNDERLYING DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted]# Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 278	242	242	R: ENDOMETRIOSIS OF SMALL BOWEL S: 生殖系および乳房障害 P: 子宮内膜症 L: Endometriosis of intestine	E: 249 O: No L: 8 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: FIBROPTIC STENOSIS OF THE TERMINAL ILEUM A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 382	35	35	R: EXACERBATION COPD S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 42 O: No L: 8 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: LABORATORY TESTING, CHEST XRAY, ECG, OXYGEN ADMINISTERED	S: Yes, Hospitalization or prolonged hospitalization O: PI: COPD GOLD III WORSENING TO EXACERBATION(POSSIBLE VIRAL CAUS). SUBJECT EXPERIENCES EXACERBATIONS MOSTLY WHEN IT'S WINTER A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 382	134	134	R: EXACERBATION COPD S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 139 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: X-THORAX, LAB TESTING, URINE CULTURE, SPUTUM CULTURE	S: Yes, Hospitalization or prolonged hospitalization O: PI: COPD GOLD III WORSENING TO EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 382	169	169	R: EXACERBATION COPD S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 180 O: No L: 12 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: OXYGEN	S: Yes, Hospitalization or prolonged hospitalization O: PI: COPD GOLD III WORSENING TO EXACERBATION. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 382	234	234*	R: EXACERBATION COPD S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 239 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: OXYGEN	S: Yes, Hospitalization or prolonged hospitalization O: PI: COPD GOLD IIII WORSENING TO EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
[redacted]	DB	1 to 382	249	249*	R: EXACERBATION COPD S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 254 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: OXYGEN	S: Yes, Hospitalization or prolonged hospitalization O: EXACERBATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted]# Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	FU	2 to	21	22	R: ACUTE EXACERBATION OF CROHNS DISEASE S: 胃腸障害 P: クローン病 L: Crohns disease aggravated	E: 99 O: No L: 78 days I: No	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Important medical event O: FEVER, INCREASING COMPLAINTS DUE TO CROWNS DISEASE, INCREASING NUMBER OF LIQUID STOOLS PER DAY(ECAZERBATION) A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 12[redacted].[redacted] kg							
	DB	1 to 396	316 316*	R: SMALL BOWEL OBSTRUCTION S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	E: 321 O: No L: 6 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION, ABDOMINAL/PELVIC CT SCAN, LABORATORY ANALYSIS OF BLOOD AND URINE	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE FLARE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 12[redacted].[redacted] kg								
	DB	1 to 396	386	386*	R: CROHN'S FLARE S: 胃腸障害 P: クローン病 L: Crohn's aggravated	E: 389 O: No L: 4 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CHRONIC STRICTURE AT THE ILEOCECAL VALUE AND TERMINAL ILEUM REGION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 4[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	DB	1 to	131	131*	R: CLOSTRIDIUM DIFFICILE INFECTION S: 感染症および寄生虫症 P: クロストリジウム・ディフィシレ感染 L: Clostridium difficile infection	E: 140 O: No L: 10 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
(SA1 Population)

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 8[redacted].[redacted] kg								
	DB	1 to 421	215	215	R: POSITIVE HER 2 LEFT BREAST CANCER S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: HER2陽性乳癌 L: HER2 positive breast cancer	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: WILL HAVE RADIATION AND SURGERY	S: Yes, Important medical event O: ENVIRONMENTAL FACTORS AND CHANCE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 385	296	296	R: WORSENING ACL TEAR LEFT KNEE S: 傷害、中毒および処置合併症 P: 靱帯断裂 L: Anterior cruciate ligament tear	E: 298 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ACL RECONSTRUCTION	S: Yes, Hospitalization or prolonged hospitalization O: ACL TEAR A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted]# Age: 2[redacted] Sex: Male Race: ASIAN Weight: 4[redacted].[redacted] kg								
[redacted]	FU	55 to	37	91	R: WORSENING OF CROHN'S DESEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 103 O: No L: 13 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization O: THE EVENT OCCURRED LONG AFTER THE INITIATION OF THE STUDY DRUG. CROHN'S DISEASE RELAPSE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	DB	1 to 399	312	312*	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 328 O: No L: 17 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: TUBO OVARIAN ABSCESS IS THE LIKELY CAUSE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	DB	1 to 399	312	312*	R: LEFT TUBO-OVARIAN ABSCESS S: 感染症および寄生虫症 P: 卵管卵巣膿瘍 L: Tubo-ovarian abscess	O: Yes I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: SUBJECT HAS LONGSTANDING HISTORY OF GYNAECOLOGICAL CONDITIONS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 1[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	FU	175 to 8	182*	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 229 O: No L: 48 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 399	144	144*	R: SHIGA-TOXIN GASTROENTERITIS S: 感染症および寄生虫症 P: 赤痢菌性胃腸炎 L: Gastroenteritis shigella	E: 151 O: No L: 8 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 2[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 12[redacted].[redacted] kg							
	FU	58 to 72	129	R: TERMINATION OF PREGNANCY S: 外科および内科処置 P: 人工流産 L: Termination of pregnancy	E: 129 O: No L: 1 day I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: STOPPED DUE TO PREGNANCY O: TERMINATION OF PREGNANCY	S: Yes, Important medical event O: ELECTIVE TERMINATION OF PREGNANCY A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg								
	DB	1 to 388	46	46	R: KIDNEY STONE S: 腎および尿路障害 P: 腎結石症 L: Kidney stone	E: 94 O: No L: 49 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: KINDEY STENT	S: Yes, Important medical event O: MEDICAL HISTORY OF RECURRING KIDNEY STONES A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg							
[redacted]	DB	1 to 391	127 127	R: SIGMOIDAL COLON STENOSIS S: 胃腸障害 P: 大腸狭窄 L: Colon stenosis	E: 137 O: No L: 11 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Important medical event O: WORSENING OF MORBUS CROHN A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 3[redacted] Sex: Female Race: BLACK OR AFRICAN AMERICAN Weight: 14[redacted].[redacted] kg								
	DB	1 to 394	296	296	R: VENTRAL HERNIA S: 胃腸障害 P: 腹部ヘルニア L: Ventral hernia	E: 298 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: VENTRAL HERNIA REPAIR WITH MESH	S: Yes, Hospitalization or prolonged hospitalization O: RECURRENT VENTRAL HERNIA A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 390	280	280*	R: ISCHEMIC CARDIOMYOPATHY S: 心臓障害 P: 虚血性心筋症 L: Ischemic cardiomyopathy	E: 314 O: No L: 35 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ON 11/25/19 SUBJECT HAD ELECTIVE LEFT HEART CATH WITH 2 STENTS TO RIGHT CORONARY ARTERY.	S: Yes, Important medical event O: CORONARY ARTERY DISEASE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 390	313	313*	R: PERICARDIAL EFFUSION S: 心臓障害 P: 心嚢液貯留 L: Pericardial effusion	E: 314 O: No L: 2 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: EMERGENT PERICARDIOCENTESIS	S: Yes, Important medical event O: CARDIAC TAMPONADE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 11[redacted].[redacted] kg								
	DB	1 to 391	352	352	R: PERIANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization O: UNDERLYING DISEASE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 388	4	4	R: URINARY TRACT INFECTION S: 感染症および寄生虫症 P: 尿路感染 L: Urinary tract infection	E: 8 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: TWO DAYS POST URETEROSCOPY ([redacted]20[redacted]) A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 482	389	389	R: RT. PSOAS MUSCLE ABSCESS S: 感染症および寄生虫症 P: 腰筋膿瘍 L: Psoas abscess	E: 422 O: No L: 34 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: WEEK 64 ADMINISTRATION WAS DELAYED(TARGET DATE: [redacted], ACTUAL DATE: [redacted]) O: CROHN'S DISEASE PROGRESSION	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC							
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg							
[redacted]	FU	2 to 11	12	R: TERMINAL ILEUM INCOMPLETE ILEUS S: 胃腸障害 P: 小腸閉塞 L: Small intestinal obstruction	E: 19 O: No L: 8 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Important medical event O: DISEASE ASSOCIATED ILEUS A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 2[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	DB	1 to 401	56	56	R: SUPRAVENTRICULAR TACHYCARDIA S: 心臓障害 P: 上室性頻脈 L: Supraventricular tachycardia	E: 58 O: No L: 3 days I: Yes	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: PRECORDIAL PAIN A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 392	280	280	R: INFLAMMATION OF WOUND RIGHT MIDDLE FINGER S: 傷害、中毒および処置合併症 P: 創部炎症 L: Inflammation of wound	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CULTURES TAKEN;LAVAGE OF BITE WOUND	S: Yes, Important medical event O: CAT BITE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
	DB	1 to 387	67	67	R: STENOSIS OF THE ANAL S: 胃腸障害 P: 肛門狭窄 L: Anal stenosis	E: 79 O: No L: 13 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: COMPLICATIONS OF CROHN'S DISEASE C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
[redacted]	DB	1 to 387	67	67	R: STENOSIS OF THE TERMINAL ILEUM S: 胃腸障害 P: 回腸狭窄 L: Stenosis ileum	E: 79 O: No L: 13 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: COMPLICATIONS OF CROHN'S DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
	DB	1 to 387	164	164*	R: STENOSIS OF THE TERMINAL ILEUM S: 胃腸障害 P: 回腸狭窄 L: Stenosis ileum	E: 214 O: No L: 51 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: THIS ADVERSE EVENT MAY HAVE BEEN CAUSED BY THE CONDITION OF CROHN'S DISEASE. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
	DB	1 to 387	303	303*	R: STENOSIS OF THE TERMINAL ILEUM S: 胃腸障害 P: 回腸狭窄 L: Stenosis ileum	E: 305 O: No L: 3 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: THIS ADVERSE EVENT MAY HAVE BEEN CAUSED BY PROGRESSIVELY DISEASE PROPERTY AND THEREBY THE CLINICAL CONDITION OF CROHN'S DISEASE. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 343	100	100	R: WORSENING OF FISTULA (LOW TRANSSPHINCTER) S: 胃腸障害 P: 痔瘻 L: Trans-sphincteric fistula	O: Yes I: No	S: SEVERE R: REASONABLE POSSIBILITY A: HOSPITALIZATION	S: Yes, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted] Age: 2[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
	DB	1 to 343	100 100	R: PERIANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	E: 137 O: No L: 38 days I: No	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGICAL DRAINING	S: Yes, Important medical event A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg								
	DB	1 to 387	322	322	R: NON ST-ELEVATION MYOCARDIAL INFRACTION S: 心臓障害 P: 急性心筋梗塞 L: Non ST segment elevation myocardial infarction	E: 326 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: HISTORY OF SMOKING A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 390	203	203	R: COLON SYMPTOMATIC STRICTURING S: 胃腸障害 P: 大腸狭窄 L: Colonic stricture	E: 205 O: No L: 3 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: HOSPITALIZATION DUE TO BALLOON DILATATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 390	356	356	R: COLON SYMPTOMATIC STRICTURE S: 胃腸障害 P: 大腸狭窄 L: Colonic stricture	E: 359 O: No L: 4 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: BALLOON DILATATION	S: Yes, Hospitalization or prolonged hospitalization O: HOSPITALIZATION DUE TO BALLOON DILATATION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 2[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 390	389	389	R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 392 O: No L: 4 days I: Yes	S: SEVERE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	DB	1 to 404	54	R: WORSENING OF ANAEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: BLOOD TRANSFUSION	S: Yes, Important medical event O: CHRONIC DISEASE ANAEMIA A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 389	55	55	R: CROHNS' DISEASE AGGRAVATION S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 69 O: No L: 15 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE AGGRAVATION. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 10[redacted].[redacted] kg								
	DB	1 to 394	14	14	R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 23 O: No L: 10 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: IT IS RELATED TO CROHN'S DISEASE. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	------ Epoch Name	Interval	---- Rx Day Day	of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 10[redacted].[redacted] kg								
	DB	1 to 394	86	86	R: ILEUS S: 胃腸障害 P: イレウス L: Ileus	E: 115 O: No L: 30 days I: Yes	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CRHON'S DISEASE AGGRAVATION A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg							
	DB	1 to 273	242 242	R: WORSENING CROHN'S DISEASE S: 胃腸障害 P: クローン病 L: Crohn's disease aggravated	E: 243 O: No L: 2 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SURGERY AND DRAINING FISTULA	S: Yes, Important medical event O: CROHN DISEASE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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Among Randomized Subjects
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg								
	DB	1 to 273	253	253	R: POST-DEFECATORY PROCTALGIA S: 胃腸障害 P: 肛門周囲痛 L: Proctalgia	E: 257 O: No L: 5 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING THE OTHER AE, PAIN IN THE ANAL AREA A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

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INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg								
	FU	274 to	42	315	R: DIVERTICULITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: CROHN DISEASE A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
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Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 10[redacted].[redacted] kg								
[redacted]	FU	274 to &	64	337	R: WORSENING OF DIVERTICULITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis aggravated	O: Yes I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: HOSPITALIZATION	S: Yes, Hospitalization or prolonged hospitalization O: FISTUALIZATION OF THE SIGMOID ORIGIN IS THE CAUSE OF THE WORSENING OF DIVERTICULITIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 5[redacted].[redacted] kg								
	DB	1 to 392	122	122	R: SMALL BOWEL OBSTRUTION S: 胃腸障害 P: 小腸閉塞 L: Small bowel obstruction	E: 134 O: No L: 13 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Important medical event O: WORTHNING OF CD A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 4[redacted].[redacted] kg								
	DB	1 to 392	365	365	R: PYREXIA S: 一般・全身障害および投与部位の状態 P: 発熱 L: Pyrexia	E: 393 O: No L: 29 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: SUSPECTED ASPIRATION PNEUMONIA DUE TO ORAL ENDOSCOPIC SMALL BOWEL ENDOSCOPY. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
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Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 4[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	DB	1 to 421	320	320*	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: COVID−19 L: COVID-19	E: 330 O: No L: 11 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: COVID-19 INFECTION FROM POSSIBLE WORKPLACE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg								
	DB	1 to 399	168	168	R: VIRAL INFECTION S: 感染症および寄生虫症 P: ウイルス感染 L: Viral infection	E: 170 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: INFECTION A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	DB	1 to 397	250	250	R: RIGHT MIDDLE CEREBRAL ARTERY TERRITORY INFARCT S: 神経系障害 P: 脳梗塞 L: Middle cerebral artery infarct	E: 275 O: No L: 26 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SUBJECT HOSPITALIZED	S: Yes, Important medical event O: ATHEROSCLEROTIC DISEASE RESULTING IN CORONARY ARTERY STENOSIS CAUSING MCA STROKE A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 11[redacted].[redacted] kg								
	DB	1 to 390	350	350	R: COMMUNITY ACQUIRED PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Community acquired pneumonia	E: 354 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SUBJECT SEEKED EMERGENCY CARE ON 5 [redacted]2[redacted] DUE TO EXPERIENCING DIFFICULTY BREATHING AND CHEST PAIN. SUBJECT WAS ADMITTED INTO HOSPITAL FOR PNEUMONIA. DISCHARGED [redacted]20[redacted]	S: Yes, Important medical event O: CHEST PAIN AND DIFFICULTY BREATHING RELATED TO PNEUMONIA. NO KNOWN CAUSE A: REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 11[redacted].[redacted] kg							
[redacted]	DB	1 to 390	350	R: MILD ACUTE KIDNEY INJURY S: 腎および尿路障害 P: 急性腎障害 L: Acute kidney injury	E: 354 O: No L: 5 days I: No	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: TELMISARTAN STARTED IN HOSPITAL BUT SITE HAS NO SOURCE DOCUMENTS WITH DOSING AND START DATE STOP DATE. HOSPITAL DOCUMENTS ONLY STATES THE IT WAS INTERRUPTED AND SUBJECT WENT HOME RESTARTING	S: Yes, Hospitalization or prolonged hospitalization O: LIKELY DUE TO MEDICATIONS GIVEN IN HOSPITAL A: NO REASONABLE POSSIBILITY C: No

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	DB	1 to 392	325	325	R: PERI-ANAL FISTULA S: 胃腸障害 P: 痔瘻 L: Anal fistula	O: Yes I: Yes	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: CROHN'S DISEASE - HISTORY OF PREVIOUS PERIANAL FISTULA A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Placebo SC							
[redacted]# Age: 2[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg							
	DB	1 to 169	127 127	R: VIRAL UPPER RESPIRATORY INFECTION S: 感染症および寄生虫症 P: ウイルス性上気道感染 L: Viral upper respiratory tract infection	E: 136 O: No L: 10 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, AZATHIOPRIN TEMPORARILY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization O: DECREASED IMMUNE SYSTEM POSSIBLE DUE TO USE OF AZATHIOPRIN A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 360 mg SC								
[redacted] Age: 3[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	DB	1 to 386	175	175	R: CONSTIPATION S: 胃腸障害 P: 便秘 L: Constipation	E: 177 O: No L: 3 days I: No	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Important medical event O: ACUTE CONSTIPATION AND KNOWN STENOSIS AT TERMINAL ILEUM A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC							
[redacted] Age: 3[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg							
[redacted]	DB	1 to 389	50	50	R: COLONIC STRICTURE S: 胃腸障害 P: 大腸狭窄 L: Colonic stricture	O: Yes I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: PATIENT REPORTED SYMPTOMS OF WORSENING CROHN'S DISEASE. PATIENT HOSPITALIZED SINCE [redacted]20[redacted] DUE TO SYMPTOMS AND DILATION OF COLON STRICTURE DUE TO SCAR TISSUE PROCEDURE. A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

TABLE 14.3__2.1.11.9

Listing of Subjects with Treatment-Emergent Serious Adverse Event
Among Randomized Subjects
(SA1 Population)

Subject Number	Epoch Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality C: Concomitant or Additional Treatment Given?
INV: [redacted], [redacted] ([redacted]) TRT: Risankizumab 180 mg SC								
[redacted] Age: 5[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	DB	1 to 409	378	378	R: VIRAL GASTROENTERITIS S: 感染症および寄生虫症 P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 382 O: No L: 5 days I: No	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: VIRAL GASTROENTERITIS A: NO REASONABLE POSSIBILITY C: Yes

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1. Rx day is defined as the number of days since (positive values) or prior (negative values) to the first dose of study drug during the study.
Important Medical Event = Important medical event requiring medical or surgical intervention to prevent serious outcome (includes spontaneous and elective abortion).
PRE = Pre treatment; DB = Blinded treatment; OL = Open label treatment; FU = Follow-up.
# Subject prematurely discontinued. & Date is estimated. * Records after rescue medication.

Program Source Code: [redacted]

日本人の症例番号は, [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted]である。

表2.7.4.7-19

[redacted]20[redacted] 09:14 <[redacted]>
RISANKIZUMAB (ABBV-066)
STUDY M19-128
R&D/21/0311 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.1

Listing of Treatment-Emergent Serious Adverse Events
(Safety Analysis Set) - Substudy 1

Japanese

Subject Number	----- Name	Epoch Interval	---- Day	RX Day/ Time of Onset@	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: RX Day/Time Ended O: Ongoing at the End of study L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Concomitant Medication or Therapy Started?	S: Serious AE? O: Other Cause of Event

** No data in this segment or part of this table. **

@ Time relative to most recent dose in [].

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Listing of Treatment-Emergent Serious Adverse Events
(Safety Analysis Set) - Substudy 1

All Subjects

Subject Number	----- Name	Epoch	---- Interval Day	RX Day/ Time of Onset@	R: Reported Term S: System Organ Class P: MedDRA 23.1 Preferred Term L: Lower Level Term	E: RX Day/Time Ended O: Ongoing at the End of study L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Concomitant Medication or Therapy Started?	S: Serious AE? O: Other Cause of Event
INV: [redacted], [redacted] ([redacted]) TRT: RISANKIZUMAB 90 MG PFS X 4 SC INJECTIONS								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:7[redacted].[redacted] KG							
	FUP	2 TO	28	29 12:00 [674:53]	R: DEPRESSION S: 精神障害 P: うつ病 L: DEPRESSION	E: 128/9:00 L: 100 DAYS I: SINGLE EVENT	T: 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED C: Y	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION

FUP = Follow-up.
@ Time relative to most recent dose in [].

Program Source Code: [redacted]

表2.7.4.7-20

[redacted]20[redacted] 18:32 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
Any adverse event	67 (15.5) [15.0]	41 (6.6) [6.5]	23 (4.0) [4.0]	64 (5.3) [5.4]
血液およびリンパ系障害	4 (0.9) [0.7]	2 (0.3) [0.4]	3 (0.5) [0.6]	5 (0.4) [0.4]
貧血	3 (0.7) [0.6]	2 (0.3) [0.4]	3 (0.5) [0.6]	5 (0.4) [0.4]
骨髄機能不全	1 (0.2) [0.2]	0	0	0
骨髄抑制	1 (0.2) [0.2]	0	0	0
好中球減少症	1 (0.2) [0.1]	0	0	0
心臓障害	1 (0.2) [0.1]	2 (0.3) [0.3]	0	2 (0.2) [0.2]
心房粗動	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
頻脈	1 (0.2) [0.1]	0	0	0
心室性頻脈	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
胃腸障害	52 (12.0) [11.5]	18 (2.9) [2.8]	6 (1.0) [1.0]	24 (2.0) [2.0]
腹痛	3 (0.7) [0.8]	0	0	0
痔瘻	1 (0.2) [0.1]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
胃腸障害 (Cont.)				
肛門括約筋無緊張症	1 (0.2) [0.2]	0	0	0
肛門直腸障害	1 (0.2) [0.2]	0	0	0
アフタ性潰瘍	1 (0.2) [0.1]	0	0	0
大腸炎	1 (0.2) [0.3]	0	0	0
クローン病	40 (9.3) [8.9]	7 (1.1) [1.1]	3 (0.5) [0.5]	10 (0.8) [0.8]
下痢	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
細菌叢異常	1 (0.2) [0.2]	0	0	0
胃腸出血	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
胃腸の炎症	1 (0.2) [0.3]	0	0	0
消化管壊死	1 (0.2) [0.3]	0	0	0
血便排泄	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
回腸穿孔	1 (0.2) [0.3]	0	0	0
回腸狭窄	1 (0.2) [0.2]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
胃腸障害 (Cont.)				
イレウス	0	3 (0.5) [0.5]	0	3 (0.3) [0.2]
麻痺性イレウス	1 (0.2) [0.2]	0	0	0
腸閉塞	3 (0.7) [0.7]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
腸管穿孔	1 (0.2) [0.1]	0	0	0
腸管狭窄	2 (0.5) [0.6]	0	0	0
大腸穿孔	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
悪心	1 (0.2) [0.2]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
急性膵炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
小腸閉塞	3 (0.7) [0.7]	2 (0.3) [0.3]	1 (0.2) [0.2]	3 (0.3) [0.2]
末端回腸炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
嘔吐	1 (0.2) [0.3]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
一般・全身障害および投与部位の状態	3 (0.7) [0.6]	0	2 (0.3) [0.4]	2 (0.2) [0.2]
無力症	2 (0.5) [0.4]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
一般・全身障害および投与部位の状態 (Cont.)				
発熱	1 (0.2) [0.2]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
全身性炎症反応症候群	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肝胆道系障害	1 (0.2) [0.1]	3 (0.5) [0.5]	1 (0.2) [0.2]	4 (0.3) [0.3]
胆管狭窄	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
胆管結石	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
胆管炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
胆石症	1 (0.2) [0.1]	0	0	0
肝機能異常	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
肝障害	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
免疫系障害	1 (0.2) [0.1]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
アナフィラキシー反応	1 (0.2) [0.1]	0	0	0
食物アレルギー	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
感染症および寄生虫症	16 (3.7) [3.6]	6 (1.0) [0.9]	4 (0.7) [0.7]	10 (0.8) [0.9]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
腹部膿瘍	2 (0.5) [0.3]	0	0	0
腹壁膿瘍	1 (0.2) [0.3]	0	0	0
腸管膿瘍	1 (0.2) [0.3]	0	0	0
肛門膿瘍	2 (0.5) [0.4]	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
虫垂炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
男性外性器蜂巣炎	1 (0.2) [0.2]	0	0	0
胃腸炎	1 (0.2) [0.3]	0	0	0
大腸菌性胃腸炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
レプトスピラ症	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
下気道感染	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
好中球減少性敗血症	1 (0.2) [0.2]	0	0	0
骨髄炎	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
直腸周囲膿瘍	1 (0.2) [0.2]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
肺炎	2 (0.5) [0.4]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肺敗血症	1 (0.2) [0.3]	0	0	0
腎盂腎炎	1 (0.2) [0.3]	0	0	0
直腸膿瘍	1 (0.2) [0.1]	0	0	0
敗血症	1 (0.2) [0.2]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
扁桃炎	1 (0.2) [0.3]	0	0	0
尿路感染	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
膣膿瘍	1 (0.2) [0.1]	0	0	0
ウイルス性心筋炎	1 (0.2) [0.2]	0	0	0
ウイルス性咽頭炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
女性外陰部蜂巣炎	1 (0.2) [0.3]	0	0	0
傷害、中毒および処置合併症	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
転倒	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
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SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
傷害、中毒および処置合併症 (Cont.)				
前腕骨折	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
臨床検査	1 (0.2) [0.3]	1 (0.2) [0.1]	2 (0.3) [0.3]	3 (0.3) [0.3]
血中マグネシウム減少	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
体温上昇	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
ヘモグロビン減少	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
体重減少	1 (0.2) [0.3]	0	0	0
代謝および栄養障害	2 (0.5) [0.3]	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
悪液質	1 (0.2) [0.2]	0	0	0
低カリウム血症	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
低リン酸血症	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
栄養障害	1 (0.2) [0.1]	0	0	0
筋骨格系および結合組織障害	2 (0.5) [0.5]	4 (0.6) [0.6]	1 (0.2) [0.2]	5 (0.4) [0.4]
強直性脊椎炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
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Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
筋骨格系および結合組織障害 (Cont.)				
関節痛	1 (0.2) [0.2]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
線維筋痛	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
瘻孔	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
椎間板突出	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
脊椎炎	1 (0.2) [0.3]	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肺扁平上皮癌	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
神経系障害	2 (0.5) [0.6]	0	0	0
浮動性めまい	1 (0.2) [0.3]	0	0	0
失神	1 (0.2) [0.3]	0	0	0
腎および尿路障害	3 (0.7) [0.7]	2 (0.3) [0.3]	2 (0.3) [0.4]	4 (0.3) [0.3]
急性腎障害	1 (0.2) [0.2]	0	0	0
尿路結石	1 (0.2) [0.2]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
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Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
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System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
腎および尿路障害 (Cont.)				
水腎症	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
腎結石症	1 (0.2) [0.3]	0	2 (0.3) [0.4]	2 (0.2) [0.2]
尿管結石症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
呼吸器、胸郭および縦隔障害	1 (0.2) [0.1]	1 (0.2) [0.2]	3 (0.5) [0.6]	4 (0.3) [0.3]
急性呼吸不全	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
喘息	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
気胸	1 (0.2) [0.1]	0	0	0
肺塞栓症	0	0	2 (0.3) [0.4]	2 (0.2) [0.2]
皮膚および皮下組織障害	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
発疹	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
外科および内科処置	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
人工流産	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
瘢痕ヘルニア修復	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
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SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.4

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
血管障害	1 (0.2) [0.1]	1 (0.2) [0.2]	2 (0.3) [0.4]	3 (0.3) [0.2]
深部静脈血栓症	1 (0.2) [0.1]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
高血圧	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
ルリッシュ症候群	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
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SSA = Study size adjusted.

Program Source Code: [redacted]

表2.7.4.7-21

[redacted]20[redacted] 15:46 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3 2.1.1.3 J

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class
and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
Any adverse event	3 (18.8)	3 (9.7)	0	3 (5.1)
胃腸障害	3 (18.8)	2 (6.5)	0	2 (3.4)
クローン病	3 (18.8)	1 (3.2)	0	1 (1.7)
イレウス	0	1 (3.2)	0	1 (1.7)
肝胆道系障害	0	1 (3.2)	0	1 (1.7)
胆管結石	0	1 (3.2)	0	1 (1.7)
胆管炎	0	1 (3.2)	0	1 (1.7)

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表2.7.4.7-22

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RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
Any adverse event	23 (12.5)	22 (12.3)	24 (13.4)	46 (12.8)	18 (12.0)
血液およびリンパ系障害	0	1 (0.6)	1 (0.6)	2 (0.6)	0
貧血	0	1 (0.6)	1 (0.6)	2 (0.6)	0
心臓障害	1 (0.5)	2 (1.1)	2 (1.1)	4 (1.1)	1 (0.7)
急性心筋梗塞	0	0	1 (0.6)	1 (0.3)	0
心機能障害	0	0	1 (0.6)	1 (0.3)	0
心不全	1 (0.5)	0	0	0	0
急性心不全	0	1 (0.6)	0	1 (0.3)	0
うっ血性心不全	0	1 (0.6)	0	1 (0.3)	0
虚血性心筋症	0	0	0	0	1 (0.7)
心嚢液貯留	0	0	0	0	1 (0.7)
上室性頻脈	0	1 (0.6)	0	1 (0.3)	0
胃腸障害	10 (5.4)	8 (4.5)	11 (6.1)	19 (5.3)	10 (6.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
胃腸障害 (Cont.)					
腹部ヘルニア	1 (0.5)	0	0	0	0
痔瘻	2 (1.1)	0	3 (1.7)	3 (0.8)	0
肛門狭窄	1 (0.5)	1 (0.6)	0	1 (0.3)	0
結腸異形成	1 (0.5)	0	0	0	0
便秘	0	0	1 (0.6)	1 (0.3)	0
クローン病	4 (2.2)	2 (1.1)	2 (1.1)	4 (1.1)	6 (4.0)
下痢	0	1 (0.6)	0	1 (0.3)	0
回腸狭窄	1 (0.5)	0	0	0	3 (2.0)
イレウス	0	1 (0.6)	1 (0.6)	2 (0.6)	1 (0.7)
腸閉塞	1 (0.5)	0	0	0	0
腸管穿孔	0	1 (0.6)	0	1 (0.3)	0
大腸狭窄	0	2 (1.1)	1 (0.6)	3 (0.8)	0
腹膜障害	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
胃腸障害 (Cont.)					
肛門周囲痛	1 (0.5)	0	0	0	0
小腸閉塞	0	1 (0.6)	3 (1.7)	4 (1.1)	1 (0.7)
亜イレウス	0	1 (0.6)	1 (0.6)	2 (0.6)	0
一般・全身障害および投与部位の状態	0	2 (1.1)	2 (1.1)	4 (1.1)	0
胸痛	0	1 (0.6)	0	1 (0.3)	0
高体温症	0	0	1 (0.6)	1 (0.3)	0
疼痛	0	1 (0.6)	0	1 (0.3)	0
発熱	0	0	1 (0.6)	1 (0.3)	0
感染症および寄生虫症	7 (3.8)	5 (2.8)	8 (4.5)	13 (3.6)	6 (4.0)
四肢膿瘍	0	0	1 (0.6)	1 (0.3)	0
肛門膿瘍	2 (1.1)	0	1 (0.6)	1 (0.3)	0
虫垂炎	1 (0.5)	2 (1.1)	0	2 (0.6)	0
COVID－19	0	0	0	0	1 (0.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
感染症および寄生虫症 (Cont.)					
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (0.7)
憩室炎	2 (1.1)	0	0	0	0
赤痢菌性胃腸炎	0	0	0	0	1 (0.7)
ウイルス性胃腸炎	0	1 (0.6)	0	1 (0.3)	0
播種性ヒストプラスマ症	0	0	0	0	1 (0.7)
感染性胸水	0	0	1 (0.6)	1 (0.3)	0
肝膿瘍	0	0	1 (0.6)	1 (0.3)	0
腹膜炎	0	0	1 (0.6)	1 (0.3)	0
肺炎	0	1 (0.6)	0	1 (0.3)	0
マイコプラズマ性肺炎	0	0	1 (0.6)	1 (0.3)	0
腰筋膿瘍	1 (0.5)	0	0	0	0
敗血症	0	0	0	0	2 (1.3)
卵管卵巣膿瘍	0	0	0	0	1 (0.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
感染症および寄生虫症 (Cont.)					
尿路感染	0	1 (0.6)	0	1 (0.3)	0
ウイルス感染	0	0	3 (1.7)	3 (0.8)	0
ウイルス性上気道感染	1 (0.5)	0	0	0	0
傷害、中毒および処置合併症	1 (0.5)	1 (0.6)	1 (0.6)	2 (0.6)	0
手骨折	0	1 (0.6)	0	1 (0.3)	0
創部炎症	1 (0.5)	0	0	0	0
靭帯断裂	0	0	1 (0.6)	1 (0.3)	0
代謝および栄養障害	0	1 (0.6)	0	1 (0.3)	0
肥満	0	1 (0.6)	0	1 (0.3)	0
筋骨格系および結合組織障害	1 (0.5)	0	2 (1.1)	2 (0.6)	0
関節炎	0	0	1 (0.6)	1 (0.3)	0
背部痛	0	0	2 (1.1)	2 (0.6)	0
骨粗鬆症	1 (0.5)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
筋骨格系および結合組織障害 (Cont.)					
腱障害	0	0	1 (0.6)	1 (0.3)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.5)	1 (0.6)	1 (0.6)	2 (0.6)	1 (0.7)
基底細胞癌	1 (0.5)	0	0	0	0
HER2陽性乳癌	0	0	1 (0.6)	1 (0.3)	0
肺腺癌	0	0	0	0	1 (0.7)
子宮平滑筋腫	0	1 (0.6)	0	1 (0.3)	0
神経系障害	1 (0.5)	1 (0.6)	0	1 (0.3)	0
脳梗塞	1 (0.5)	0	0	0	0
坐骨神経痛	0	1 (0.6)	0	1 (0.3)	0
腎および尿路障害	1 (0.5)	2 (1.1)	0	2 (0.6)	0
急性腎障害	0	1 (0.6)	0	1 (0.3)	0
腎結石症	1 (0.5)	0	0	0	0
尿管結石症	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
生殖系および乳房障害	0	1 (0.6)	0	1 (0.3)	0
子宮内膜症	0	1 (0.6)	0	1 (0.3)	0
呼吸器、胸郭および縦隔障害	1 (0.5)	1 (0.6)	0	1 (0.3)	1 (0.7)
慢性閉塞性肺疾患	1 (0.5)	1 (0.6)	0	1 (0.3)	1 (0.7)
皮膚および皮下組織障害	1 (0.5)	0	0	0	0
汗腺炎	1 (0.5)	0	0	0	0
外科および内科処置	1 (0.5)	0	0	0	0
人工流産	1 (0.5)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

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表2.7.4.7-23

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RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
Any adverse event	31 (19.3)	33 (19.5)	35 (21.0)	68 (20.3)	24 (27.5)
血液およびリンパ系障害	0	1 (0.6)	1 (0.6)	2 (0.6)	0
貧血	0	1 (0.6)	1 (0.6)	2 (0.6)	0
心臓障害	1 (0.6)	3 (1.8)	2 (1.2)	5 (1.5)	2 (2.3)
急性心筋梗塞	0	0	1 (0.6)	1 (0.3)	0
心機能障害	0	0	1 (0.6)	1 (0.3)	0
心不全	1 (0.6)	0	0	0	0
急性心不全	0	1 (0.6)	0	1 (0.3)	0
うっ血性心不全	0	1 (0.6)	0	1 (0.3)	0
虚血性心筋症	0	0	0	0	1 (1.1)
心嚢液貯留	0	0	0	0	1 (1.1)
上室性頻脈	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
胃腸障害	12 (7.5)	14 (8.3)	13 (7.8)	27 (8.0)	12 (13.8)
腹部ヘルニア	1 (0.6)	0	0	0	0
痔瘻	2 (1.2)	0	3 (1.8)	3 (0.9)	0
肛門狭窄	1 (0.6)	1 (0.6)	0	1 (0.3)	0
結腸異形成	1 (0.6)	0	0	0	0
便秘	0	0	1 (0.6)	1 (0.3)	0
クローン病	4 (2.5)	2 (1.2)	2 (1.2)	4 (1.2)	6 (6.9)
下痢	0	1 (0.6)	0	1 (0.3)	0
回腸狭窄	1 (0.6)	0	0	0	4 (4.6)
イレウス	0	1 (0.6)	2 (1.2)	3 (0.9)	1 (1.1)
腸閉塞	1 (0.6)	0	0	0	0
腸管穿孔	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
胃腸障害 (Cont.)					
大腸狭窄	0	3 (1.8)	1 (0.6)	4 (1.2)	0
腹膜障害	0	1 (0.6)	0	1 (0.3)	0
肛門周囲痛	1 (0.6)	0	0	0	0
小腸閉塞	0	1 (0.6)	3 (1.8)	4 (1.2)	1 (1.1)
亜イレウス	0	3 (1.8)	1 (0.6)	4 (1.2)	0
一般・全身障害および投与部位の状態	0	2 (1.2)	2 (1.2)	4 (1.2)	0
胸痛	0	1 (0.6)	0	1 (0.3)	0
高体温症	0	0	1 (0.6)	1 (0.3)	0
疼痛	0	1 (0.6)	0	1 (0.3)	0
発熱	0	0	1 (0.6)	1 (0.3)	0
感染症および寄生虫症	8 (5.0)	5 (3.0)	10 (6.0)	15 (4.5)	7 (8.0)
四肢膿瘍	0	0	2 (1.2)	2 (0.6)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
感染症および寄生虫症 (Cont.)					
肛門膿瘍	2 (1.2)	0	1 (0.6)	1 (0.3)	0
虫垂炎	1 (0.6)	2 (1.2)	0	2 (0.6)	0
COVID-19	0	0	0	0	1 (1.1)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (1.1)
憩室炎	3 (1.9)	0	0	0	0
赤痢菌性胃腸炎	0	0	0	0	1 (1.1)
ウイルス性胃腸炎	0	1 (0.6)	0	1 (0.3)	0
播種性ヒストプラスマ症	0	0	0	0	1 (1.1)
感染性胸水	0	0	1 (0.6)	1 (0.3)	0
肝膿瘍	0	0	1 (0.6)	1 (0.3)	0
腹膜炎	0	0	1 (0.6)	1 (0.3)	0
肺炎	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
感染症および寄生虫症 (Cont.)					
マイコプラズマ性肺炎	0	0	1 (0.6)	1 (0.3)	0
腰筋膿瘍	1 (0.6)	0	0	0	0
敗血症	0	0	0	0	2 (2.3)
卵管卵巣膿瘍	0	0	0	0	1 (1.1)
尿路感染	0	1 (0.6)	0	1 (0.3)	0
ウイルス感染	0	0	3 (1.8)	3 (0.9)	0
ウイルス性上気道感染	1 (0.6)	0	0	0	0
傷害、中毒および処置合併症	1 (0.6)	1 (0.6)	1 (0.6)	2 (0.6)	0
手骨折	0	1 (0.6)	0	1 (0.3)	0
創部炎症	1 (0.6)	0	0	0	0
靭帯断裂	0	0	1 (0.6)	1 (0.3)	0
代謝および栄養障害	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
代謝および栄養障害 (Cont.)					
肥満	0	1 (0.6)	0	1 (0.3)	0
筋骨格系および結合組織障害	1 (0.6)	0	5 (3.0)	5 (1.5)	0
関節炎	0	0	1 (0.6)	1 (0.3)	0
背部痛	0	0	3 (1.8)	3 (0.9)	0
骨粗鬆症	1 (0.6)	0	0	0	0
腱障害	0	0	1 (0.6)	1 (0.3)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.6)	1 (0.6)	1 (0.6)	2 (0.6)	1 (1.1)
基底細胞癌	1 (0.6)	0	0	0	0
HER2陽性乳癌	0	0	1 (0.6)	1 (0.3)	0
肺腺癌	0	0	0	0	1 (1.1)
子宮平滑筋腫	0	1 (0.6)	0	1 (0.3)	0
神経系障害	1 (0.6)	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
神経系障害 (Cont.)					
脳梗塞	1 (0.6)	0	0	0	0
坐骨神経痛	0	1 (0.6)	0	1 (0.3)	0
腎および尿路障害	1 (0.6)	2 (1.2)	0	2 (0.6)	0
急性腎障害	0	1 (0.6)	0	1 (0.3)	0
腎結石症	1 (0.6)	0	0	0	0
尿管結石症	0	1 (0.6)	0	1 (0.3)	0
生殖系および乳房障害	0	1 (0.6)	0	1 (0.3)	0
子宮内膜症	0	1 (0.6)	0	1 (0.3)	0
呼吸器、胸郭および縦隔障害	3 (1.9)	1 (0.6)	0	1 (0.3)	2 (2.3)
慢性閉塞性肺疾患	3 (1.9)	1 (0.6)	0	1 (0.3)	2 (2.3)
皮膚および皮下組織障害	1 (0.6)	0	0	0	0
汗腺炎	1 (0.6)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.1.4

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
外科および内科処置	1 (0.6)	0	0	0	0
人工流産	1 (0.6)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-24

[redacted]20[redacted] 06:26 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3 2.1.1.3 J

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
Any adverse event	2 (14.3)	0	3 (23.1)	3 (11.5)	3 (23.1)
胃腸障害	2 (14.3)	0	1 (7.7)	1 (3.8)	2 (15.4)
肛門狭窄	1 (7.1)	0	0	0	0
クローン病	1 (7.1)	0	0	0	1 (7.7)
回腸狭窄	1 (7.1)	0	0	0	1 (7.7)
小腸閉塞	0	0	1 (7.7)	1 (3.8)	0
一般・全身障害および投与部位の状態	0	0	1 (7.7)	1 (3.8)	0
発熱	0	0	1 (7.7)	1 (3.8)	0
感染症および寄生虫症	0	0	1 (7.7)	1 (3.8)	1 (7.7)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (7.7)
マイコプラズマ性肺炎	0	0	1 (7.7)	1 (3.8)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-25

[redacted]20[redacted] 06:26 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.1.4 J

Treatment-Emergent Serious Adverse Events per 100 Patient-Years (PYs) by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) (PYs=11.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=13) (PYs=11.8) Events (E/100PYs)	Risankizumab 360 mg SC (N=13) (PYs=11.3) Events (E/100PYs)	Risankizumab Total (N=26) (PYs=23.0) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=13) (PYs=9.0) Events (E/100PYs)
Any adverse event	3 (26.3)	0	3 (26.6)	3 (13.0)	4 (44.6)
胃腸障害	3 (26.3)	0	1 (8.9)	1 (4.3)	3 (33.5)
肛門狭窄	1 (8.8)	0	0	0	0
クローン病	1 (8.8)	0	0	0	1 (11.2)
回腸狭窄	1 (8.8)	0	0	0	2 (22.3)
小腸閉塞	0	0	1 (8.9)	1 (4.3)	0
一般・全身障害および投与部位の状態	0	0	1 (8.9)	1 (4.3)	0
発熱	0	0	1 (8.9)	1 (4.3)	0
感染症および寄生虫症	0	0	1 (8.9)	1 (4.3)	1 (11.2)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (11.2)
マイコプラズマ性肺炎	0	0	1 (8.9)	1 (4.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-26

[redacted]20[redacted] 18:32 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.1.3.9

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
Any adverse event	37 (8.6) [8.2]	13 (2.1) [2.0]	12 (2.1) [2.1]	25 (2.1) [2.1]
胃腸障害	29 (6.7) [6.1]	4 (0.6) [0.7]	5 (0.9) [0.9]	9 (0.8) [0.8]
腹部腫瘤	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肛門括約筋無緊張症	1 (0.2) [0.2]	0	0	0
肛門直腸障害	1 (0.2) [0.2]	0	0	0
大腸炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
クローン病	24 (5.6) [5.0]	3 (0.5) [0.5]	3 (0.5) [0.5]	6 (0.5) [0.5]
下痢	1 (0.2) [0.3]	0	0	0
消化管壊死	1 (0.2) [0.3]	0	0	0
回腸穿孔	1 (0.2) [0.3]	0	0	0
腸閉塞	1 (0.2) [0.1]	0	0	0
腸管狭窄	1 (0.2) [0.3]	0	0	0
大腸狭窄	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.9

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
胃腸障害 (Cont.)				
大腸潰瘍	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
直腸炎	1 (0.2) [0.2]	0	0	0
小腸閉塞	2 (0.5) [0.5]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
嘔吐	1 (0.2) [0.3]	0	0	0
一般・全身障害および投与部位の状態	1 (0.2) [0.3]	2 (0.3) [0.3]	2 (0.3) [0.4]	4 (0.3) [0.4]
疾患進行	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
骨盤腔内腫瘤	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
発熱	1 (0.2) [0.3]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
全身性炎症反応症候群	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肝胆道系障害	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
肝機能異常	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
免疫系障害	0	0	2 (0.3) [0.4]	2 (0.2) [0.2]
薬物過敏症	0	0	2 (0.3) [0.4]	2 (0.2) [0.2]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.9

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
感染症および寄生虫症	8 (1.9) [1.9]	0	0	0
腹部膿瘍	3 (0.7) [0.6]	0	0	0
肛門膿瘍	1 (0.2) [0.3]	0	0	0
直腸周囲膿瘍	1 (0.2) [0.2]	0	0	0
肺炎	2 (0.5) [0.6]	0	0	0
肺敗血症	1 (0.2) [0.3]	0	0	0
ウイルス性心筋炎	1 (0.2) [0.2]	0	0	0
傷害、中毒および処置合併症	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
注入に伴う反応	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
臨床検査	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
ホルモン値異常	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
代謝および栄養障害	1 (0.2) [0.2]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.9

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
代謝および栄養障害 (Cont.)				
脱水	1 (0.2) [0.2]	0	0	0
筋骨格系および結合組織障害	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
関節痛	1 (0.2) [0.2]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
瘻孔	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肺扁平上皮癌	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
精神障害	1 (0.2) [0.3]	0	0	0
失見当識	1 (0.2) [0.3]	0	0	0
皮膚および皮下組織障害	1 (0.2) [0.3]	3 (0.5) [0.4]	1 (0.2) [0.2]	4 (0.3) [0.3]
水疱	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
掌蹠膿疱症	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
そう痒症	1 (0.2) [0.3]	0	0	0
発疹	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.9

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
皮膚および皮下組織障害 (Cont.)				
斑状丘疹状皮疹	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
そう痒性皮疹	1 (0.2) [0.3]	0	0	0
蕁麻疹	1 (0.2) [0.3]	0	0	0
外科および内科処置	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
人工流産	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表2.7.4.7-27

[redacted]20[redacted] 15:46 <[redacted] >

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-006
R&D/20/1216 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.3.4 J

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term during the 12-Week Induction Period
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N=16) n (%)	Risankizumab 600 mg IV (N=31) n (%)	Risankizumab 1200 mg IV (N=28) n (%)	Risankizumab Total (N=59) n (%)
Any adverse event	2 (12.5)	0	0	0
胃腸障害	2 (12.5)	0	0	0
クローン病	2 (12.5)	0	0	0
下痢	1 (6.3)	0	0	0
嘔吐	1 (6.3)	0	0	0
一般・全身障害および投与部位の状態	1 (6.3)	0	0	0
発熱	1 (6.3)	0	0	0

Note: Treatment emergent AEs (TEAEs) for the 12-Week Induction Period are defined as events that begin either on or after the first dose of the study drug in the 12-Week Induction Period and until the first dose of study drug in the study M16-000 if the subject is enrolled into the study M16-000 or until first dose of study drug in Induction Period 2 if the subject is enrolled into Induction Period 2, or within 140 days after the last dose administration of the study drug in 12-Week Induction Period if the subject does not participate in the study M16-000 or the Induction Period 2.
SA1 Population includes all subjects who received at least one dose of study drug during the 12-Week Induction Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表2.7.4.7-28

[redacted]20[redacted] 10:57 <[redacted] >

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.3.3

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
Any adverse event	6 (3.3)	3 (1.7)	6 (3.4)	9 (2.5)	3 (2.0)
胃腸障害	4 (2.2)	1 (0.6)	5 (2.8)	6 (1.7)	1 (0.7)
肛門狭窄	0	1 (0.6)	0	1 (0.3)	0
結腸異形成	1 (0.5)	0	0	0	0
クローン病	3 (1.6)	0	2 (1.1)	2 (0.6)	1 (0.7)
直腸狭窄	0	0	1 (0.6)	1 (0.3)	0
小腸閉塞	0	0	1 (0.6)	1 (0.3)	0
亜イレウス	0	0	1 (0.6)	1 (0.3)	0
一般・全身障害および投与部位の状態	0	0	1 (0.6)	1 (0.3)	0
高体温症	0	0	1 (0.6)	1 (0.3)	0
感染症および寄生虫症	1 (0.5)	0	1 (0.6)	1 (0.3)	0
クロストリジウム・ディフィシレ感染	0	0	1 (0.6)	1 (0.3)	0
憩室炎	1 (0.5)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.3.3

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term Among Randomized Subjects (SA1 Population)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
臨床検査	0	1 (0.6)	0	1 (0.3)	0
アラニンアミノトランスフェラーゼ増加	0	1 (0.6)	0	1 (0.3)	0
血中ビリルビン増加	0	1 (0.6)	0	1 (0.3)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (0.6)	1 (0.3)	1 (0.7)
HER2陽性乳癌	0	0	1 (0.6)	1 (0.3)	0
肺腺癌	0	0	0	0	1 (0.7)
骨転移	0	0	0	0	1 (0.7)
精神障害	0	1 (0.6)	0	1 (0.3)	0
易刺激性	0	1 (0.6)	0	1 (0.3)	0
皮膚および皮下組織障害	1 (0.5)	0	0	0	1 (0.7)
アレルギー性皮膚炎	0	0	0	0	1 (0.7)
蕁麻疹	1 (0.5)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-29

[redacted]20[redacted] 06:26 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.3.3 J

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term
Among Randomized Subjects
(SA1 Population - Japan Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo SC (N=14) n (%)	Risankizumab 180 mg SC (N=13) n (%)	Risankizumab 360 mg SC (N=13) n (%)	Risankizumab Total (N=26) n (%)	Risankizumab Rescue Therapy* (N=13) n (%)
Any adverse event	1 (7.1)	0	0	0	1 (7.7)
胃腸障害	1 (7.1)	0	0	0	0
クローン病	1 (7.1)	0	0	0	0
皮膚および皮下組織障害	0	0	0	0	1 (7.7)
アレルギー性皮膚炎	0	0	0	0	1 (7.7)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
Subjects are counted once in each row, regardless of the number of events they may have had.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-30

[redacted]20[redacted] 10:56 <[redacted] >

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.4.1

Subjects with Treatment-Emergent Adjudicated CV Events by Adjudicated Term
Among Randomized Subjects
(SA1 Population)

Category Adjudicated Term	Placebo SC (N=184) n (%)	Risankizumab 180 mg SC (N=179) n (%)	Risankizumab 360 mg SC (N=179) n (%)	Risankizumab Total (N=358) n (%)	Risankizumab Rescue Therapy* (N=150) n (%)
Any adjudicated CV event	1 (0.5)	0	1 (0.6)	1 (0.3)	0
MACE	1 (0.5)	0	1 (0.6)	1 (0.3)	0
Cardiovascular Death	0	0	0	0	0
Non-fatal Myocardial Infarction	0	0	1 (0.6)	1 (0.3)	0
Non-fatal Stroke	1 (0.5)	0	0	0	0
Extended MACE	1 (0.5)	0	1 (0.6)	1 (0.3)	0
Cardiovascular Death	0	0	0	0	0
Non-fatal Myocardial Infarction	0	0	1 (0.6)	1 (0.3)	0
Non-fatal Stroke	1 (0.5)	0	0	0	0
Hospitalization for Unstable Angina	0	0	0	0	0
Coronary Revascularization Procedures	0	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-31

[redacted]20[redacted] 18:32 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.1.4.1.3

Number and Percentage of Subjects with Treatment-Emergent Serious Infections
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
Any adverse event	16 (3.7) [3.6]	6 (1.0) [0.9]	4 (0.7) [0.7]	10 (0.8) [0.9]
感染症および寄生虫症	16 (3.7) [3.6]	6 (1.0) [0.9]	4 (0.7) [0.7]	10 (0.8) [0.9]
腹部膿瘍	2 (0.5) [0.3]	0	0	0
腹壁膿瘍	1 (0.2) [0.3]	0	0	0
腸管膿瘍	1 (0.2) [0.3]	0	0	0
肛門膿瘍	2 (0.5) [0.4]	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
虫垂炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
男性外性器蜂巣炎	1 (0.2) [0.2]	0	0	0
胃腸炎	1 (0.2) [0.3]	0	0	0
大腸菌性胃腸炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
レプトスピラ症	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
下気道感染	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
好中球減少性敗血症	1 (0.2) [0.2]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.3

Number and Percentage of Subjects with Treatment-Emergent Serious Infections
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
骨髄炎	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
直腸周囲膿瘍	1 (0.2) [0.2]	0	0	0
肺炎	2 (0.5) [0.4]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肺敗血症	1 (0.2) [0.3]	0	0	0
腎盂腎炎	1 (0.2) [0.3]	0	0	0
直腸膿瘍	1 (0.2) [0.1]	0	0	0
敗血症	1 (0.2) [0.2]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
扁桃炎	1 (0.2) [0.3]	0	0	0
尿路感染	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
膣膿瘍	1 (0.2) [0.1]	0	0	0
ウイルス性心筋炎	1 (0.2) [0.2]	0	0	0
ウイルス性咽頭炎	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
女性外陰部蜂巣炎	1 (0.2) [0.3]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表2.7.4.7-32

[redacted]20[redacted] 10:56 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.5.7

Treatment-Emergent Serious Infection, TB, Opportunistic Infections and Herpes Zoster per 100 Patient-Years (PYs)
by Preferred Term - Serious Infection
Among Randomized Subjects
(SA1 Population)

		Risankizumab			Risankizumab Rescue
	Placebo SC	180 mg SC	360 mg SC	Total	Therapy*
	(N=184)	(N=179)	(N=179)	(N=358)	(N=150)
	(PYs=160.4)	(PYs=169.3)	(PYs=166.4)	(PYs=335.7)	(PYs=87.2)
MedDRA 23.1 Preferred Term	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)
Any adverse event	8 (5.0)	5 (3.0)	10 (6.0)	15 (4.5)	7 (8.0)
四肢膿瘍	0	0	2 (1.2)	2 (0.6)	0
肛門膿瘍	2 (1.2)	0	1 (0.6)	1 (0.3)	0
虫垂炎	1 (0.6)	2 (1.2)	0	2 (0.6)	0
COVID－19	0	0	0	0	1 (1.1)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (1.1)
憩室炎	3 (1.9)	0	0	0	0
赤痢菌性胃腸炎	0	0	0	0	1 (1.1)
ウイルス性胃腸炎	0	1 (0.6)	0	1 (0.3)	0
播種性ヒストプラスマ症	0	0	0	0	1 (1.1)
感染性胸水	0	0	1 (0.6)	1 (0.3)	0
肝膿瘍	0	0	1 (0.6)	1 (0.3)	0
腹膜炎	0	0	1 (0.6)	1 (0.3)	0
肺炎	0	1 (0.6)	0	1 (0.3)	0
マイコプラズマ性肺炎	0	0	1 (0.6)	1 (0.3)	0
腰筋膿瘍	1 (0.6)	0	0	0	0
敗血症	0	0	0	0	2 (2.3)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.5.7

Treatment-Emergent Serious Infection, TB, Opportunistic Infections and Herpes Zoster per 100 Patient-Years (PYs)
by Preferred Term - Serious Infection
Among Randomized Subjects
(SA1 Population)

MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
卵管卵巣膿瘍	0	0	0	0	1 (1.1)
尿路感染	0	1 (0.6)	0	1 (0.3)	0
ウイルス感染	0	0	3 (1.8)	3 (0.9)	0
ウイルス性上気道感染	1 (0.6)	0	0	0	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-33

[redacted]20[redacted] 10:56 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.5.9

Treatment-Emergent Serious Infection, TB, Opportunistic Infections and Herpes Zoster per 100 Patient-Years (PYs)
by Preferred Term - Opportunistic Infections Excluding TB and Herpes Zoster
Among Randomized Subjects
(SA1 Population)

		Risankizumab			Risankizumab Rescue
	Placebo SC	180 mg SC	360 mg SC	Total	Therapy*
	(N=184)	(N=179)	(N=179)	(N=358)	(N=150)
	(PYs=160.4)	(PYs=169.3)	(PYs=166.4)	(PYs=335.7)	(PYs=87.2)
MedDRA 23.1 Preferred Term	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)
Any adverse event	0	1 (0.6)	1 (0.6)	2 (0.6)	1 (1.1)
アエロモナス感染	0	0	1 (0.6)	1 (0.3)	0
播種性ヒストプラスマ症	0	0	0	0	1 (1.1)
口腔真菌感染	0	1 (0.6)	0	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
CMQ code is 80000189.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-34

[redacted]20[redacted] 09:18 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.5.4.1.14

Treatment-Emergent Malignant Tumours in Exposure-Adjusted Incidence Rate Per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(All Treated Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV/SC (RZB naive) (N = 432) n/PYs (n/100 PYs)	RZB 180 mg SC (N = 1096) n/PYs (n/100 PYs)	RZB 360 mg SC (N = 533) n/PYs (n/100 PYs)	RZB 600 mg IV (N = 688) n/PYs (n/100 PYs)
Any adverse event	0/199.4	7/1102.6 (0.6)	2/441.8 (0.5)	0/200.8
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0/199.4	7/1102.6 (0.6)	2/441.8 (0.5)	0/200.8
基底細胞癌	0/199.4	1/1104.1 (<0.1)	0/442.6	0/200.8
乳癌	0/199.4	1/1104.3 (<0.1)	0/442.6	0/200.8
消化器癌	0/199.4	1/1104.1 (<0.1)	0/442.6	0/200.8
ＨＥＲ２陽性乳癌	0/199.4	0/1104.4	1/442.1 (0.2)	0/200.8
浸潤性乳癌	0/199.4	1/1104.1 (<0.1)	0/442.6	0/200.8
肺腺癌	0/199.4	1/1104.3 (<0.1)	1/442.3 (0.2)	0/200.8
骨転移	0/199.4	0/1104.4	1/442.4 (0.2)	0/200.8
乳頭様甲状腺癌	0/199.4	1/1104.0 (<0.1)	0/442.6	0/200.8
肺扁平上皮癌	0/199.4	0/1104.4	0/442.6	0/200.8
表在拡大型黒色腫、病期不明	0/199.4	1/1104.1 (<0.1)	0/442.6	0/200.8

Note: Subjects may be represented in more than one treatment group according to treatments received.
TEAEs are defined as events with onset after the first dose of study drug and within 140 days after the last dose of study drug, or database cutoff, whichever is earliest.
ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
n/100 PYs = Number of subjects with at least one event per 100 patient-years.

Program Source Code: [redacted]

TABLE 2.4__1.5.4.1.14

Treatment-Emergent Malignant Tumours in Exposure-Adjusted Incidence Rate Per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(All Treated Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	RZB 1200 mg IV (N = 1023) n/PYs (n/100 PYs)	Any RZB SC (N = 1318) n/PYs (n/100 PYs)	Any RZB IV (N = 1536) n/PYs (n/100 PYs)	Any RZB (N = 1574) n/PYs (n/100 PYs)
Any adverse event	2/298.8 (0.7)	9/1542.5 (0.6)	2/511.7 (0.4)	11/2049.7 (0.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2/298.8 (0.7)	9/1542.5 (0.6)	2/511.7 (0.4)	11/2049.7 (0.5)
基底細胞癌	1/299.1 (0.3)	1/1546.7 (<0.1)	1/512.1 (0.2)	2/2056.7 (<0.1)
乳癌	0/299.3	1/1545.6 (<0.1)	0/512.2	1/2057.5 (<0.1)
消化器癌	0/299.3	1/1546.7 (<0.1)	0/512.2	1/2058.7 (<0.1)
ＨＥＲ２陽性乳癌	0/299.3	1/1545.9 (<0.1)	0/512.2	1/2057.9 (<0.1)
浸潤性乳癌	0/299.3	1/1546.8 (<0.1)	0/512.2	1/2058.7 (<0.1)
肺腺癌	0/299.3	2/1546.6 (0.1)	0/512.2	2/2058.2 (<0.1)
骨転移	0/299.3	1/1546.8 (<0.1)	0/512.2	1/2058.7 (<0.1)
乳頭様甲状腺癌	0/299.3	1/1546.6 (<0.1)	0/512.2	1/2058.6 (<0.1)
肺扁平上皮癌	1/298.9 (0.3)	0/1547.0	1/511.8 (0.2)	1/2058.9 (<0.1)
表在拡大型黒色腫、病期不明	0/299.3	1/1546.8 (<0.1)	0/512.2	1/2058.4 (<0.1)

Note: Subjects may be represented in more than one treatment group according to treatments received.
TEAEs are defined as events with onset after the first dose of study drug and within 140 days after the last dose of study drug, or database cutoff, whichever is earliest.
ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
n/100 PYs = Number of subjects with at least one event per 100 patient-years.

Program Source Code: [redacted]

表2.7.4.7-35

[redacted]20[redacted] 18:49 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.5 1.1.4.1

Number and Percentage of Subjects Meeting Criteria for Liver-related Elevations
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			-Treatment Comparison (95% CI)[A]-	
Criteria	Placebo IV (N = 432) n/N_OBS (%) [SSA %]	600 mg IV (N = 620) n/N_OBS (%) [SSA %]	1200 mg IV (N = 577) n/N_OBS (%) [SSA %]	Total (N = 1197) n/N_OBS (%) [SSA %]	600 mg IV - Placebo	1200 mg IV - Placebo
ALT >= 3 x ULN	4/422 (0.9) [0.9]	9/616 (1.5) [1.4]	5/573 (0.9) [0.9]	14/1189 (1.2) [1.1]	0.5 [-0.7, 1.8]	-0.0 [-1.2, 1.2]
ALT >= 5 x ULN	3/422 (0.7) [0.6]	3/616 (0.5) [0.5]	2/573 (0.3) [0.3]	5/1189 (0.4) [0.4]	-0.1 [-0.9, 0.8]	-0.3 [-1.1, 0.5]
ALT >= 10 x ULN	0/422	2/616 (0.3) [0.3]	0/573	2/1189 (0.2) [0.2]	0.3 [-0.1, 0.7]	0.0
ALT >= 20 x ULN	0/422	1/616 (0.2) [0.2]	0/573	1/1189 (<0.1) [<0.1]	0.2 [-0.1, 0.5]	0.0
AST >= 3 x ULN	3/423 (0.7) [0.7]	6/615 (1.0) [1.0]	4/573 (0.7) [0.7]	10/1188 (0.8) [0.8]	0.3 [-0.8, 1.4]	-0.0 [-1.1, 1.0]
AST >= 5 x ULN	1/423 (0.2) [0.2]	3/615 (0.5) [0.5]	0/573	3/1188 (0.3) [0.2]	0.3 [-0.4, 1.0]	-0.2 [-0.6, 0.2]
AST >= 10 x ULN	0/423	1/615 (0.2) [0.2]	0/573	1/1188 (<0.1) [<0.1]	0.2 [-0.1, 0.5]	0.0
AST >= 20 x ULN	0/423	1/615 (0.2) [0.2]	0/573	1/1188 (<0.1) [<0.1]	0.2 [-0.1, 0.5]	0.0

x ULN = Times upper limit of the normal range.
ALT = Alanine Aminotransferase (U/L); AST = Aspartate Aminotransferase (U/L); ALP = Alkaline Phosphatase (U/L); TBL = Bilirubin (mcmol/L).
Note: ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies, M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies : M15-993, M15-991 and M16-006.
N_OBS indicates the number of subjects with at least one post-baseline values for the respective parameter.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.5__1.1.4.1

Number and Percentage of Subjects Meeting Criteria for Liver-related Elevations
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

		Risankizumab			Treatment Comparison (95% CI) [A]	
Criteria	Placebo IV (N = 432) n/N_OBS (%) [SSA %]	600 mg IV (N = 620) n/N_OBS (%) [SSA %]	1200 mg IV (N = 577) n/N_OBS (%) [SSA %]	Total (N = 1197) n/N_OBS (%) [SSA %]	600 mg IV - Placebo	1200 mg IV - Placebo
TBL >= 2 x ULN	2/424 (0.5) [0.5]	9/619 (1.5) [1.3]	4/572 (0.7) [0.8]	13/1191 (1.1) [1.1]	0.8 [-0.3, 2.0]	0.2 [-0.8, 1.3]
Alkaline phosphatase >= 1.5 x ULN	10/424 (2.4) [2.1]	14/619 (2.3) [2.2]	9/572 (1.6) [1.6]	23/1191 (1.9) [1.9]	0.1 [-1.7, 1.9]	-0.4 [-2.1, 1.3]
ALT and/or AST >= 3 x ULN and TBL >= 1.5 x ULN	0/423	4/616 (0.6) [0.6]	1/572 (0.2) [0.2]	5/1188 (0.4) [0.4]	0.6 [0.0, 1.3]	0.2 [-0.2, 0.6]
ALT and/or AST >= 3 x ULN and TBL >= 2 x ULN	0/423	2/616 (0.3) [0.3]	1/572 (0.2) [0.2]	3/1188 (0.3) [0.2]	0.3 [-0.1, 0.7]	0.2 [-0.2, 0.6]

x ULN = Times upper limit of the normal range.
ALT = Alanine Aminotransferase (U/L); AST = Aspartate Aminotransferase (U/L); ALP = Alkaline Phosphatase (U/L); TBL = Bilirubin (mcmol/L).
Note: ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
SSA estimates for 1200mg and the 1200mg IV - Placebo treatment difference and 95% CI are based on two studies, M15-991 and M16-006. SSA estimates for Placebo, 600mg IV and treatment difference and 95% CI are based on all three studies : M15-993, M15-991 and M16-006.
N_OBS indicates the number of subjects with at least one post-baseline values for the respective parameter.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

表2.7.4.7-36

[redacted]20[redacted] 18:32 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.1.4.1.13

Number and Percentage of Subjects with Treatment-Emergent Hepatic Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
Any adverse event	7 (1.6) [1.7]	10 (1.6) [1.6]	8 (1.4) [1.4]	18 (1.5) [1.4]
肝胆道系障害	1 (0.2) [0.3]	6 (1.0) [0.9]	3 (0.5) [0.5]	9 (0.8) [0.7]
薬物性肝障害	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
肝機能異常	1 (0.2) [0.3]	3 (0.5) [0.5]	1 (0.2) [0.2]	4 (0.3) [0.3]
肝脾腫大	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
肝毒性	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肝障害	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
臨床検査	5 (1.2) [1.1]	5 (0.8) [0.8]	5 (0.9) [0.9]	10 (0.8) [0.8]
アラニンアミノトランスフェラーゼ増加	1 (0.2) [0.3]	0	2 (0.3) [0.3]	2 (0.2) [0.2]
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
血中アルカリホスファターゼ増加	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
血中ビリルビン増加	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
γ-グルタミルトランスフェラーゼ増加	1 (0.2) [0.1]	3 (0.5) [0.5]	1 (0.2) [0.2]	4 (0.3) [0.3]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.13

Number and Percentage of Subjects with Treatment-Emergent Hepatic Events
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
臨床検査 (Cont.)				
肝酵素異常	1 (0.2) [0.2]	0	0	0
肝酵素上昇	1 (0.2) [0.3]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
肝機能検査異常	1 (0.2) [0.2]	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
トランスアミナーゼ上昇	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
代謝および栄養障害	1 (0.2) [0.3]	0	0	0
低アルブミン血症	1 (0.2) [0.3]	0	0	0

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表2.7.4.7-37

[redacted]20[redacted] 10:57 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 4.1.7

Number and Percentage of Subjects Meeting Criteria for Liver-Related Elevations
Among Randomized Subjects
(SA1 Population)

Criteria	Placebo SC (N=184) n/N_OBS (%)	Risankizumab 180 mg SC (N=179) n/N_OBS (%)	Risankizumab 360 mg SC (N=179) n/N_OBS (%)	Risankizumab Total (N=358) n/N_OBS (%)	Risankizumab Rescue Therapy* (N=150) n/N_OBS (%)
ALT >= 3 x ULN	1/175 (0.6)	1/172 (0.6)	3/173 (1.7)	4/345 (1.2)	1/134 (0.7)
ALT >= 5 x ULN	0/175	0/172	2/173 (1.2)	2/345 (0.6)	0/134
ALT >= 10 x ULN	0/175	0/172	0/173	0/345	0/134
ALT >= 20 x ULN	0/175	0/172	0/173	0/345	0/134
AST >= 3 x ULN	2/175 (1.1)	0/171	2/173 (1.2)	2/344 (0.6)	1/133 (0.8)
AST >= 5 x ULN	1/175 (0.6)	0/171	1/173 (0.6)	1/344 (0.3)	0/133
AST >= 10 x ULN	0/175	0/171	0/173	0/344	0/133
AST >= 20 x ULN	0/175	0/171	0/173	0/344	0/133
TBL >= 2 x ULN	3/176 (1.7)	1/172 (0.6)	5/173 (2.9)	6/345 (1.7)	1/134 (0.7)
Alkaline phosphatase >= 1.5 x ULN	4/176 (2.3)	1/172 (0.6)	0/173	1/345 (0.3)	1/134 (0.7)

Note: SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
x ULN = Times upper limit of the normal range.
N_OBS indicates the number of subjects with both baseline and post-baseline values for the respective parameter.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1.
All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column.
All events happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__4.1.7

Number and Percentage of Subjects Meeting Criteria for Liver-Related Elevations
Among Randomized Subjects
(SA1 Population)

Criteria	Placebo SC (N=184) n/N_OBS (%)	Risankizumab 180 mg SC (N=179) n/N_OBS (%)	Risankizumab 360 mg SC (N=179) n/N_OBS (%)	Risankizumab Total (N=358) n/N_OBS (%)	Risankizumab Rescue Therapy* (N=150) n/N_OBS (%)
ALT and/or AST >= 3 x ULN and TBL >= 1.5 x ULN	0/175	1/172 (0.6)	0/173	1/345 (0.3)	0/133
ALT and/or AST >= 3 x ULN and TBL >= 2 x ULN	0/175	0/172	0/173	0/345	0/133

Note: SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
x ULN = Times upper limit of the normal range.
N_OBS indicates the number of subjects with both baseline and post-baseline values for the respective parameter.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1.
All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column.
All events happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-38

[redacted]20[redacted] 10:56 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3 2.1.9.7

Treatment-Emergent Hepatic Event per 100 Patient-Years (PYs) by Preferred Term
Among Randomized Subjects
(SA1 Population)

MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
Any adverse event	4 (2.5)	8 (4.7)	9 (5.4)	17 (5.1)	6 (6.9)
アラニンアミノトランスフェラーゼ増加	1 (0.6)	4 (2.4)	0	4 (1.2)	3 (3.4)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	0	1 (1.1)
血中アルカリホスファターゼ増加	0	0	1 (0.6)	1 (0.3)	0
血中ビリルビン増加	0	1 (0.6)	0	1 (0.3)	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	1 (1.1)
肝機能異常	0	1 (0.6)	0	1 (0.3)	0
脂肪肝	0	2 (1.2)	2 (1.2)	4 (1.2)	1 (1.1)
肝腫大	0	0	1 (0.6)	1 (0.3)	0
高ビリルビン血症	1 (0.6)	0	2 (1.2)	2 (0.6)	0
低アルブミン血症	0	0	1 (0.6)	1 (0.3)	0
肝機能検査異常	1 (0.6)	0	0	0	0
肝機能検査値上昇	1 (0.6)	0	1 (0.6)	1 (0.3)	0
尿中ビリルビン増加	0	0	1 (0.6)	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-39

[redacted]20[redacted] 14:59 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.5 1.5.4.1

Number and Percentage of Subjects Meeting Criteria for Liver-related Elevations
(All Treated Safety Analysis Set)

Criteria	Placebo IV/SC (RZB naive) (N = 432) n/N_OBS (%)	RZB 180 mg SC (N = 1096) n/N_OBS (%)	RZB 360 mg SC (N = 533) n/N_OBS (%)	RZB 600 mg IV (N = 688) n/N_OBS (%)
ALT >= 3 x ULN	4/424 (0.9)	6/886 (0.7)	5/481 (1.0)	10/684 (1.5)
ALT >= 5 x ULN	3/424 (0.7)	0/886	1/481 (0.2)	3/684 (0.4)
ALT >= 10 x ULN	0/424	0/886	0/481	2/684 (0.3)
ALT >= 20 x ULN	0/424	0/886	0/481	1/684 (0.1)
AST >= 3 x ULN	3/425 (0.7)	8/885 (0.9)	5/477 (1.0)	6/683 (0.9)
AST >= 5 x ULN	1/425 (0.2)	3/885 (0.3)	1/477 (0.2)	3/683 (0.4)
AST >= 10 x ULN	0/425	0/885	0/477	1/683 (0.1)
AST >= 20 x ULN	0/425	0/885	0/477	1/683 (0.1)

xULN = Times upper limit of the normal range.
ALT = Alanine Aminotransferase (U/L); AST = Aspartate Aminotransferase (U/L); ALP = Alkaline Phosphatase (U/L); TBL = Bilirubin (mcmol/L).
Note: ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
Subjects may be represented in more than one treatment group according to treatments received.
The denominator N_OBS is defined as the number of subjects with at least one post-baseline value for the respective parameter.

Program Source Code: [redacted]

TABLE 2.5__1.5.4.1

Number and Percentage of Subjects Meeting Criteria for Liver-related Elevations
(All Treated Safety Analysis Set)

Criteria	RZB 1200 mg IV (N = 1023) n/N OBS (%)	Any RZB SC (N = 1318) n/N OBS (%)	Any RZB IV (N = 1536) n/N OBS (%)	Any RZB (N = 1574) n/N OBS (%)
ALT >= 3 x ULN	7/873 (0.8)	11/1173 (0.9)	17/1453 (1.2)	27/1538 (1.8)
ALT >= 5 x ULN	4/873 (0.5)	1/1173 (<0.1)	7/1453 (0.5)	8/1538 (0.5)
ALT >= 10 x ULN	0/873	0/1173	2/1453 (0.1)	2/1538 (0.1)
ALT >= 20 x ULN	0/873	0/1173	1/1453 (<0.1)	1/1538 (<0.1)
AST >= 3 x ULN	5/870 (0.6)	13/1172 (1.1)	11/1451 (0.8)	24/1535 (1.6)
AST >= 5 x ULN	0/870	4/1172 (0.3)	3/1451 (0.2)	7/1535 (0.5)
AST >= 10 x ULN	0/870	0/1172	1/1451 (<0.1)	1/1535 (<0.1)
AST >= 20 x ULN	0/870	0/1172	1/1451 (<0.1)	1/1535 (<0.1)

xULN = Times upper limit of the normal range.
ALT = Alanine Aminotransferase (U/L); AST = Aspartate Aminotransferase (U/L); ALP = Alkaline Phosphatase (U/L); TBL = Bilirubin (mcmol/L).
Note: ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
Subjects may be represented in more than one treatment group according to treatments received.
The denominator N_OBS is defined as the number of subjects with at least one post-baseline value for the respective parameter.

Program Source Code: [redacted]

TABLE 2.5__1.5.4.1

Number and Percentage of Subjects Meeting Criteria for Liver-related Elevations
(All Treated Safety Analysis Set)

Criteria	Placebo IV/SC (RZB naive) (N = 432) n/N_OBS (%)	RZB 180 mg SC (N = 1096) n/N_OBS (%)	RZB 360 mg SC (N = 533) n/N_OBS (%)	RZB 600 mg IV (N = 688) n/N_OBS (%)
TBL >= 2 x ULN	2/425 (0.5)	8/891 (0.9)	7/480 (1.5)	10/687 (1.5)
Alkaline phosphatase >= 1.5 x ULN	11/425 (2.6)	7/889 (0.8)	3/481 (0.6)	17/687 (2.5)
ALT and/or AST >= 3 x ULN and TBL >= 1.5 x ULN	0/425	1/891 (0.1)	0/480	4/684 (0.6)
ALT and/or AST >= 3 x ULN and TBL >= 2 x ULN	0/425	0/891	0/480	2/684 (0.3)

xULN = Times upper limit of the normal range.
ALT = Alanine Aminotransferase (U/L); AST = Aspartate Aminotransferase (U/L); ALP = Alkaline Phosphatase (U/L); TBL = Bilirubin (mcmol/L).
Note: ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
Subjects may be represented in more than one treatment group according to treatments received.
The denominator N_OBS is defined as the number of subjects with at least one post-baseline value for the respective parameter.

Program Source Code: [redacted]

TABLE 2.5__1.5.4.1

Number and Percentage of Subjects Meeting Criteria for Liver-related Elevations
(All Treated Safety Analysis Set)

Criteria	RZB 1200 mg IV (N = 1023) n/N OBS (%)	Any RZB SC (N = 1318) n/N OBS (%)	Any RZB IV (N = 1536) n/N OBS (%)	Any RZB (N = 1574) n/N OBS (%)
TBL >= 2 x ULN	8/870 (0.9)	15/1176 (1.3)	17/1452 (1.2)	26/1538 (1.7)
Alkaline phosphatase >= 1.5 x ULN	12/870 (1.4)	9/1177 (0.8)	28/1452 (1.9)	31/1538 (2.0)
ALT and/or AST >= 3 x ULN and TBL >= 1.5 x ULN	1/870 (0.1)	1/1176 (<0.1)	5/1451 (0.3)	6/1538 (0.4)
ALT and/or AST >= 3 x ULN and TBL >= 2 x ULN	1/870 (0.1)	0/1176	3/1451 (0.2)	3/1538 (0.2)

xULN = Times upper limit of the normal range.
ALT = Alanine Aminotransferase (U/L); AST = Aspartate Aminotransferase (U/L); ALP = Alkaline Phosphatase (U/L); TBL = Bilirubin (mcmol/L).
Note: ISS4 includes all subjects that have received at least one dose of study drug from all Phase 2 and 3 CD studies and associated periods and Sub-studies: M15-993 (Periods 1, 2 and 3), M15-989, M15-991 (Periods 1 and 2), M16-006 (Periods 1 and 2), and M16-000 (Sub-Studies 1, 2 and 3).
Subjects may be represented in more than one treatment group according to treatments received.
The denominator N_OBS is defined as the number of subjects with at least one post-baseline value for the respective parameter.

Program Source Code: [redacted]

表2.7.4.7-40

[redacted]20[redacted] 18:32 <[redacted]>
RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL

TABLE 2.4 1.1.4.1.10

Number and Percentage of Subjects with Treatment-Emergent Hypersensitivity
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
Any adverse event	21 (4.9) [4.3]	30 (4.8) [4.7]	30 (5.2) [5.3]	60 (5.0) [5.1]
眼障害	1 (0.2) [0.1]	0	0	0
眼瞼腫脹	1 (0.2) [0.1]	0	0	0
免疫系障害	4 (0.9) [0.7]	2 (0.3) [0.3]	3 (0.5) [0.6]	5 (0.4) [0.5]
アナフィラキシー反応	1 (0.2) [0.1]	0	0	0
薬物過敏症	0	0	2 (0.3) [0.4]	2 (0.2) [0.2]
過敏症	3 (0.7) [0.6]	2 (0.3) [0.3]	1 (0.2) [0.2]	3 (0.3) [0.3]
感染症および寄生虫症	1 (0.2) [0.1]	0	0	0
膿疱性皮疹	1 (0.2) [0.1]	0	0	0
傷害、中毒および処置合併症	3 (0.7) [0.6]	3 (0.5) [0.5]	1 (0.2) [0.2]	4 (0.3) [0.3]
注入に伴う反応	3 (0.7) [0.6]	3 (0.5) [0.5]	1 (0.2) [0.2]	4 (0.3) [0.3]
生殖系および乳房障害	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
陰嚢皮膚炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.10

Number and Percentage of Subjects with Treatment-Emergent Hypersensitivity
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
呼吸器、胸郭および縦隔障害	1 (0.2) [0.2]	2 (0.3) [0.3]	2 (0.3) [0.4]	4 (0.3) [0.3]
アレルギー性気管支炎	1 (0.2) [0.2]	0	0	0
気管支痙攣	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
アレルギー性鼻炎	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
皮膚および皮下組織障害	15 (3.5) [3.3]	23 (3.7) [3.6]	23 (4.0) [4.1]	46 (3.8) [3.9]
皮膚炎	1 (0.2) [0.2]	2 (0.3) [0.4]	0	2 (0.2) [0.2]
アレルギー性皮膚炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
乾癬様皮膚炎	0	1 (0.2) [0.1]	0	1 (<0.1) [0.1]
湿疹	3 (0.7) [0.6]	3 (0.5) [0.5]	6 (1.0) [1.0]	9 (0.8) [0.7]
結節性紅斑	2 (0.5) [0.3]	2 (0.3) [0.3]	3 (0.5) [0.6]	5 (0.4) [0.4]
発疹	5 (1.2) [1.2]	15 (2.4) [2.3]	8 (1.4) [1.4]	23 (1.9) [1.9]
斑状皮疹	1 (0.2) [0.3]	0	0	0
斑状丘疹状皮疹	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.10

Number and Percentage of Subjects with Treatment-Emergent Hypersensitivity
by Primary MedDRA System Organ Class and Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

System Organ Class MedDRA 23.1 Preferred Term	Placebo IV (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
皮膚および皮下組織障害 (Cont.)				
そう痒性皮疹	2 (0.5) [0.5]	0	0	0
小水疱性皮疹	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
蕁麻疹	2 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.5) [0.6]	4 (0.3) [0.4]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表2.7.4.7-41

[redacted]20[redacted] 10:56 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.7.2

Treatment-Emergent Hypersensitivity Reaction per 100 Patient-Years (PYs) by Preferred Term
Among Randomized Subjects
(SA1 Population)

		Risankizumab			Risankizumab Rescue
	Placebo SC	180 mg SC	360 mg SC	Total	Therapy*
	(N=184)	(N=179)	(N=179)	(N=358)	(N=150)
	(PYs=160.4)	(PYs=169.3)	(PYs=166.4)	(PYs=335.7)	(PYs=87.2)
MedDRA 23.1 Preferred Term	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)	Events (E/100PYs)
Any adverse event	19 (11.8)	21 (12.4)	21 (12.6)	42 (12.5)	13 (14.9)
アレルギー性浮腫	0	0	2 (1.2)	2 (0.6)	0
アレルギー性結膜炎	0	1 (0.6)	0	1 (0.3)	0
皮膚炎	0	1 (0.6)	1 (0.6)	2 (0.6)	0
アレルギー性皮膚炎	1 (0.6)	1 (0.6)	0	1 (0.3)	1 (1.1)
接触皮膚炎	2 (1.2)	1 (0.6)	0	1 (0.3)	1 (1.1)
薬疹	0	0	0	0	1 (1.1)
湿疹	4 (2.5)	5 (3.0)	2 (1.2)	7 (2.1)	1 (1.1)
結節性紅斑	1 (0.6)	1 (0.6)	0	1 (0.3)	1 (1.1)
過敏症	1 (0.6)	0	5 (3.0)	5 (1.5)	1 (1.1)
注射部位過敏反応	0	0	3 (1.8)	3 (0.9)	0
注射部位発疹	0	0	1 (0.6)	1 (0.3)	1 (1.1)
注射部位蕁麻疹	0	1 (0.6)	1 (0.6)	2 (0.6)	0
口唇腫脹	1 (0.6)	0	0	0	0
口囲皮膚炎	0	1 (0.6)	0	1 (0.3)	0
発疹	5 (3.1)	1 (0.6)	3 (1.8)	4 (1.2)	4 (4.6)
紅斑性皮疹	1 (0.6)	2 (1.2)	1 (0.6)	3 (0.9)	1 (1.1)

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
SMQ code is 20000214.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

TABLE 14.3__2.1.7.2

Treatment-Emergent Hypersensitivity Reaction per 100 Patient-Years (PYs) by Preferred Term
Among Randomized Subjects
(SA1 Population)

MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
そう痒性皮疹	1 (0.6)	1 (0.6)	0	1 (0.3)	0
アレルギー性鼻炎	0	1 (0.6)	1 (0.6)	2 (0.6)	1 (1.1)
蕁麻疹	2 (1.2)	4 (2.4)	1 (0.6)	5 (1.5)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
SMQ code is 20000214.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

表2.7.4.7-42

[redacted]20[redacted] 10:38 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
INTEGRATED SUMMARY OF SAFETY
R&D/20/1177 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 2.4 1.1.7.3

Subjects with Treatment-Emergent Adverse Events Identified by Injection Site Reaction CMQ
by Preferred Term
(Placebo-Controlled 12-Week Induction Period Safety Analysis Set)

MedDRA 23.1 Preferred Term	Placebo (N = 432) n (%) [SSA%]	Risankizumab 600 mg IV (N = 620) n (%) [SSA%]	Risankizumab 1200 mg IV (N = 577) n (%) [SSA%]	Risankizumab Total (N = 1197) n (%) [SSA%]
Any adverse event	5 (1.2) [1.0]	5 (0.8) [0.8]	12 (2.1) [2.0]	17 (1.4) [1.4]
注入に伴う反応	3 (0.7) [0.6]	3 (0.5) [0.5]	1 (0.2) [0.2]	4 (0.3) [0.3]
注入部位内出血	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
注入部位蜂巣炎	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
注入部位紅斑	0	1 (0.2) [0.2]	0	1 (<0.1) [<0.1]
注入部位血管外漏出	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
注入部位刺激感	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
注入部位疼痛	1 (0.2) [0.2]	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
注入部位腫脹	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.3) [0.3]	3 (0.3) [0.2]
注射部位内出血	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
注射部位紅斑	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]
注射部位疼痛	0	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]
注射部位知覚異常	0	0	1 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: TEAEs are events occurring after the first dose of study drug and within 140 days after the last administration of study drug and within 140 days after the last administration of study drug in Induction Period 1, or until the first dose of study drug in Induction Period 2 or Study M16-000.
ISS1 includes all subjects that have received at least one dose of study drug in the 12-week induction Period 1 from the two global Phase 3 studies: M15-991 and M16-006, as well as the subjects from the Phase 2 study M15-993 who received placebo or risankizumab 600mg IV for the 12-week induction period.
CMQ code is 80000019.
SSA = Study size adjusted.

Program Source Code: [redacted]

表2.7.4.7-43

[redacted]20[redacted] 10:56 <[redacted]>

RISANKIZUMAB (CROHN'S DISEASE)
STUDY M16-000 SUB-STUDY 1
R&D/21/0085 - CLINICAL/STATISTICAL

TABLE 14.3 2.1.10.2

Treatment-Emergent Injection Site Reaction per 100 Patient-Years (PYs) by Preferred Term
Among Randomized Subjects
(SA1 Population)

MedDRA 23.1 Preferred Term	Placebo SC (N=184) (PYs=160.4) Events (E/100PYs)	Risankizumab 180 mg SC (N=179) (PYs=169.3) Events (E/100PYs)	Risankizumab 360 mg SC (N=179) (PYs=166.4) Events (E/100PYs)	Risankizumab Total (N=358) (PYs=335.7) Events (E/100PYs)	Risankizumab Rescue Therapy* (N=150) (PYs=87.2) Events (E/100PYs)
Any adverse event	13 (8.1)	16 (9.5)	23 (13.8)	39 (11.6)	18 (20.6)
注射部位内出血	1 (0.6)	0	0	0	0
注射部位紅斑	6 (3.7)	9 (5.3)	12 (7.2)	21 (6.3)	6 (6.9)
注射部位過敏反応	0	0	3 (1.8)	3 (0.9)	0
注射部位硬結	1 (0.6)	0	0	0	0
注射部位結節	0	1 (0.6)	0	1 (0.3)	0
注射部位疼痛	2 (1.2)	0	1 (0.6)	1 (0.3)	3 (3.4)
注射部位そう痒感	0	0	0	0	1 (1.1)
注射部位発疹	0	0	1 (0.6)	1 (0.3)	1 (1.1)
注射部位反応	2 (1.2)	4 (2.4)	1 (0.6)	5 (1.5)	7 (8.0)
注射部位腫脹	1 (0.6)	0	3 (1.8)	3 (0.9)	0
注射部位蕁麻疹	0	1 (0.6)	1 (0.6)	2 (0.6)	0
注射部位小水疱	0	1 (0.6)	0	1 (0.3)	0
注射部位熱感	0	0	1 (0.6)	1 (0.3)	0

Note: Treatment emergent AEs (TEAEs) for M16-000 sub-study 1 are defined as events that begin either on or after the first dose of the study drug in the sub-study 1 and within 140 days after the last dose administration of the study drug in the sub-study 1 for subjects who do not participate in the sub-study 3 or until first dose of study drug in the sub-study 3 if the subject is enrolled into the sub-study 3.
SA1 Population includes all subjects who received at least one dose of study drug in the sub-study 1.
CMQ code is 80000019.
E/100PYs = Events per 100 patient-years.
* Risankizumab rescue therapy is one dose of open-label 1200 mg IV followed by 360 mg SC through the end of the sub-study 1. All events happened after receiving risankizumab rescue therapy regardless the previous treatments are presented in this column. AEs happened before receiving risankizumab rescue therapy will be presented in their original treatment group.

Program Source Code: [redacted]

2.7.5 参考文献

参考文献は，各セクションの末尾に記載した。

M16-324 試験

治験の標題： A Randomized Open-Label Single Dose Study to Evaluate the Effect of Rate and Volume of Administration on the Bioavailability of Risankizumab Following Subcutaneous (SC) Dosing in Healthy Volunteers	
施設数 / 実施国名： 1 / 米国	
治験責任医師： [redacted], MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年[redacted] 月[redacted] 日 最後の被験者の最終来院日：20[redacted] 年[redacted] 月[redacted] 日	開発のフェーズ：I
目的： 本試験の目的は，皮下（以下「SC」）投与後のリサンキズマブのバイオアベイラビリティに及ぼす投与速度及び投与液量の影響を評価することであった。SC 投与後のリサンキズマブの安全性及び忍容性も評価した。	
被験者数 (計画時と解析時) ： 計画例数：48，登録例数：48，完了例数：47，安全性及び薬物動態評価例数：48	
診断と主要な組入れ基準： 健康成人男性被験者	
治験方法： 本試験は，リサンキズマブの相対的バイオアベイラビリティ及び注射部位関連疼痛の程度を評価する第 I 相，単回投与，4-Arm，非盲検，無作為化，並行群間比較試験であった。投与後の注射部位からの治験薬の漏出についても評価した。4 つの Arm は各群 12 名で構成され，入院開始時の事前検査当日の体重により層別して登録した。 対照レジメンとして Arm 1 では，シリンジを用いて，液剤 2.4 mL（リサンキズマブ 216 mg）を 0.8 mL ずつ 3 回それぞれ 10 秒以内に SC 投与した。試験レジメンとして Arm 2 及び 3 では，シリンジポンプを用いて液剤 2.4 mL（リサンキズマブ 216 mg）をそれぞれ 3 分間及び 6 分間で SC 投与し，Arm 4 では，シリンジを用いて液剤 2 mL（リサンキズマブ 180 mg）を 10 秒以内に SC 投与した。 薬物動態解析及び抗薬物抗体（以下「ADA」）測定のための血液試料を薬物投与後約 3336 時間（140 日目）まで経時的に採取した。	

被験薬，用量，投与液濃度，製造元，投与方法及びバッチ番号：

Study Drug	Risankizumab (ABBV-066)
Pharmaceutical formulation	Solution for injection in pre-filled syringe
Unit Strength	90 mg/mL
Manufacturer	Boehringer-Ingelheim Pharma GmbH & Co. KG
Mode of Administration	SC injection
Bulk Lot ID	[redacted]

治療期間：

Arm ごとに規定したとおり，リサンキズマブ液剤 90 mg/mL を用いて被験者にリサンキズマブを単回投与した。

評価基準：

薬物動態：

最高血漿中濃度（以下「C_{max}」），最高血漿中濃度到達時間（以下「T_{max}」），時間 0 から最終測定可能時間までの血漿中濃度 - 時間曲線下面積（以下「AUC_t」），時間 0 から無限大時間までの血漿中濃度 - 時間曲線下面積（以下「AUC_{inf}」），用量で標準化した C_{max}（以下「C_{max}/Dose」），用量で標準化した AUC_t（以下「AUC_t/Dose」），用量で標準化した AUC_{inf}（以下「AUC_{inf}/Dose」），終末相消失半減期（以下「$t_{1/2}$」）及び見かけのクリアランス（以下「CL/F」）。

免疫原性：

ADA 抗体価

安全性：

有害事象，バイタルサイン，心電図，臨床検査及び局所忍容性

統計手法：

薬物動態：

C_{max} 及び AUC の自然対数並びに T_{max} に対して共分散分析（ANCOVA）を行った。レジメン（Arm 1，Arm 2 及び Arm 3）は固定因子とし，体重は共変量とした。C_{max} 及び AUC の自然対数の解析から得られた 90%信頼区間を用いた 2 つの片側検定法により，対照レジメンに対する各試験レジメンのバイオアベイラビリティを評価した。Arm 1 及び Arm 4 のみで用量で標準化した薬物動態（以下「PK」）パラメータに関して同様の解析を実施した。

安全性：

臨床検査値及びバイタルサインについて，ベースライン値，投与後値及びベースラインからの変化量の要約を示した。

注射部位関連疼痛評価：

投与後の各評価時点における疼痛評価データをレジメン別に要約し，連続変数（疼痛スコア）については要約統計量を算出し，カテゴリー変数については各カテゴリーの被験者数及び割合を示した。反復測定分析を疼痛スコアデータに対して実施した。

薬剤漏出：

注射後の薬物漏出（重量）の記述統計量をレジメン別に示した。

結果 / 結論：

薬物動態の結果：

Arm 1 から Arm 4 の 2 つの片側検定の 90%信頼区間（以下「CI」）を示す。

Regimens Test vs. Reference	Pharmacokinetic Parameter (units)	Central Values[a]		Relative Bioavailability	
		Test	Reference	Point Estimate[b]	90% CI[c]
Arm 2: 216 mg administered (2.4 mL) over 3 minutes with syringe pump vs. Arm 1: 216 mg administered as three 0.8 mL SC injections	C_{max} (µg/mL)	15.11	15.60	0.968	0.810 – 1.157
	AUC_t (µg•day/mL)	658	609	1.079	0.926 – 1.258
	AUC_{inf} (µg•day/mL)	691	628	1.100	0.932 – 1.299
Arm 3: 216 mg administered (2.4 mL) over 6 minutes with syringe pump vs. Arm 1: 216 mg administered as three 0.8 mL SC injections	C_{max} (µg/mL)	15.61	15.60	1.001	0.837 – 1.196
	AUC_t (µg•day/mL)[d]	535	609	0.878	0.750 – 1.026
	AUC_{inf} (µg•day/mL)[d]	552	628	0.878	0.741 – 1.041
Arm 4: 180 mg administered as single 2 mL injection vs. Arm 1: 216 mg administered as three 0.8 mL SC injections	C_{max}/Dose (µg/mL)/mg	0.08	0.07	1.149	0.935 – 1.412
	AUC_t/Dose (µg•day/mL)/mg	3.22	2.83	1.137	1.002 – 1.290
	AUC_{inf}/Dose (µg•day/mL)/mg	3.34	2.92	1.145	1.007 – 1.301

a. Antilogarithm of the least squares means for logarithms.

b. Antilogarithm of the difference (test minus reference) of the least squares means for logarithms.

c. Antilogarithm of the endpoints of confidence intervals for the difference of logarithms means.

d. Subject [redacted] prematurely discontinued from the study and was not included in this analysis.

免疫原性の結果：

全ての Arm を通じて，ベースライン及び投与時に出現した ADA 発現率はそれぞれ 8.3%–25%及び 0%–50%であった。ADA 陽性被験者におけるリサンキズマブの曝露量は ADA 陰性被験者と同程度であったことから，リサンキズマブの曝露量は ADA の発現により影響を受けないことが示された。リサンキズマブを投与された ADA 陽性被験者では，過敏症又は輸注反応は認められなかった。

安全性の結果：

検討したレジメンの被験者の忍容性は良好であった。試験期間中，臨床的に重要なバイタルサイン又は臨床検査値の結果は認められなかった。報告された有害事象に一定の傾向は認められず，本試験から新たな安全性の問題は特定されなかった。ADA 陽性被験者に注射部位反応，局所忍容性の問題又はアナフィラキシーは認められなかった。

結論：

健康被験者にリサンキズマブを単回 SC 投与したときの PK プロファイルは，4 つの Arm 間でおおむね同様であった。3 分間又は 6 分間 SC 投与後の曝露量は，0.8 mL を 3 回 SC ボーラス投与した対照 Arm と同程度であった。リサンキズマブ 180 mg を単回 SC 投与したときの用量で標準化した曝露量は，対照 Arm と比較してわずかに高かった（15%）。しかし，この曝露量のわずかな差は，被験者数が少ないこと及び並行群間試験であることに起因した可能性がある。

全ての Arm を通じて，ベースライン及び投与時に出現した ADA 発現率はそれぞれ 8.3%–25%及び 0%–50%であ

り，PK 又は安全性に明らかな影響は認められなかった。検討したレジメンの被験者の忍容性は良好であった。試験期間中，臨床的に重要なバイタルサイン又は臨床検査値の結果は認められなかった。報告された有害事象に一定の傾向は認められず，本試験から新たな安全性の問題は特定されなかった。ADA 陽性被験者に注射部位反応，局所忍容性の問題又はアナフィラキシーは認められなかった。

M19-128 試験

治験の標題： A Phase 1, Pharmacokinetic Comparability Study of Intravenous and Subcutaneous Administration of Risankizumab in Healthy Subjects	
施設数 / 実施国名：8 施設 / 米国	
治験責任医師： [redacted], MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年[redacted] 月[redacted] 日 最後の被験者の最終来院日：20[redacted] 年[redacted] 月[redacted] 日	開発のフェーズ：I
目的： Substudy 1：リサンキズマブ 360 mg を単回皮下（以下「SC」）投与したときの第 III 相試験に用いた 90 mg プレフィルドシリンジ（以下「PFS」）に対する市販予定の 360 mg オンボディデリバリーシステム（以下「OBDS」）の相対的バイオアベイラビリティを評価した。更に，180 mg OBDS を単回 SC 投与したときのリサンキズマブの薬物動態を評価した。 Substudy 2：リサンキズマブ 1800 mg を単回静脈内（以下「IV」）投与したときの第 III 相試験に用いた 300 mg 液剤バイアルに対する市販予定の 600 mg 液剤バイアルの相対的バイオアベイラビリティを評価する。	
被験者数 (計画時と解析時) ： Substudy 1：計画例数：282，登録例数：287，完了例数：269，安全性評価例数：286，薬物動態評価例数：258 Substudy 2：計画例数：106，登録例数：107，完了例数：95，安全性評価例数：107，薬物動態評価例数：98	
診断と主要な組入れ基準： 18 歳以上 60 歳以下の健康な男女とした。Substudy 1 では，グループ 1 及び 2 に各グループ 8 例の日本人被験者を組み入れた。	
治験方法： 2 つの substudy からなる単回投与，ランダム化，非盲検，多施設共同試験。 Substudy 1：被験者に PFS 又は OBDS のいずれかを用いてリサンキズマブを腹部に SC 投与した。 ● グループ 1：リサンキズマブ 360 mg SC 投与（4 × 90 mg PFS）（対照，N = 127，N = 8 の日本人含む） ● グループ 2：リサンキズマブ 360 mg OBDS × 1 SC 投与（150 mg/mL，2.4 mL）（試験，N = 129，N = 8 の日本人含む) ● グループ 3：リサンキズマブ 180 mg OBDS × 1 SC 投与（150 mg/mL，1.2 mL）（N = 30) Substudy 2：被験者にリサンキズマブ 1800 mg を IV 投与した。 ● グループ 4：リサンキズマブ 1800 mg IV 投与 – 6 × 300 mg 液剤バイアル（90 mg/mL）（対照，N = 53） ● グループ 5：リサンキズマブ 1800 mg IV 投与 – 3 × 600 mg 液剤バイアル（60 mg/mL）（試験，N = 54） Substudy 1 では，非日本人被験者を 4:4:1 の比でそれぞれグループ 1，2 及び 3 にランダムに割り付けた。Substudy 1 に組み入れられた最初の日本人被験者 16 例を 1:1 の比でグループ 1 及び 2 にランダムに割り付けた。追加で組み入れられた日本人被験者を 4:4:1 の比で 3 グループに割り付けた。Substudy 2 に組み入れられたすべての被験者を 1:1 の比でランダムに割り付けた。 薬物動態，抗薬物抗体（以下「ADA」）及び中和抗体（「NAb」）の測定用血液検体を 113 日間にわたって経時的に採取した。	

被験薬，用量 / 含量 / 濃度投与方法及びロット番号：

	Risankizumab Formulations				
	Group 1	Group 2	Group 3	Group 4	Group 5
Dose	360 mg	360 mg	180 mg	1800 mg	1800 mg
Unit Strength	90 mg/mL	150 mg/mL	150 mg/mL	90 mg/mL	60 mg/mL
Mode of Administration	SC Injection PFS	SC Injection OBDS	SC Injection OBDS	IV Infusion	IV Infusion
Bulk Lot ID	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Packaged Lot ID	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

治療期間：

被験者にリサンキズマブを単回 SC 又は IV 投与した。

評価基準：

薬物動態：

最高血清中濃度（以下「C_{max}」），最高血清中濃度到達時間（以下「T_{max}」），消失半減期（以下「$t_{1/2}$」），見かけのクリアランス（以下「CL/F」，SC 投与），クリアランス（以下「CL」，IV 投与），時間 0 から最終測定可能時間までの血清中濃度 - 時間曲線下面積（以下「AUC_t」），及び時間 0 から無限大時間までの血清中濃度 - 時間曲線下面積（以下「AUC_{inf}」）

免疫原性：

ADA 発現率を投与群別に要約し，各被験者のそれぞれの来院時の ADA 抗体価を表にまとめた。

安全性：

有害事象（以下「AE」），身体検査，バイタルサイン，心電図，及び臨床検査

統計手法：

薬物動態：

Substudy 1：グループ 1 及び 2 のデータから得られた C_{max} 及び AUC の自然対数に対して，共分散分析を実施した。90%信頼区間（以下「CI」）は，対数変換したグループの主要評価項目の差の CI の上限及び下限の冪乗により得た。C_{max} 及び AUC の自然対数の解析から得られた 90% CI の真数が 0.80 から 1.25 の範囲内である場合に，360 mg OBDS と 90 mg PFS 製剤は生物学的に同等であると判定した。グループ 2 及び 3 のデータから得られた用量で標準化した C_{max} 及び AUC の自然対数に対して同様の解析を行い，360 mg OBDS に対する 180 mg OBDS のバイオアベイラビリティを評価した。

Substudy 2：

Substudy 2 でも同様の解析を実施し，リサンキズマブ 300 mg 液剤バイアルに対する 600 mg 液剤バイアルのバイオアベイラビリティを評価した。C_{max} 及び AUC の自然対数の解析から得られた 90%CI の真数が 0.80 から 1.25 の範囲内である場合に，生物学的に同等であると判定した。

免疫原性：

ADA 発現率を投与グループ別に要約し，投与に起因する ADA（以下「TE-ADA」）陽性被験者の抗体価を各来院時ごとに要約した。リサンキズマブの曝露量及び安全性に及ぼす ADA の影響は，それぞれのグループで TE-ADA 陽性被験者と陰性被験者を比較して評価した。

安全性：

臨床検査値及びバイタルサインのベースライン及び投与後の値を投与グループ別に示した。臨床検査値及びバイタルサインに関しては，投与前の最終測定値を統計解析のためのベースライン値とした。

注射部位関連疼痛評価：

Substudy 1 では，投与後の 2 時点（注射終了直後及び注射終了 1 時間後）における各グループの疼痛評価データを要約した。連続変数（疼痛スコア）について要約統計量を算出し，カテゴリー変数については各カテゴリー内の被験者数及び割合を示した。疼痛スコアデータに対して反復測定解析を実施した。

OBDS の送達評価：

投与成功の可否を含む OBDS の送達評価項目の要約統計量をカテゴリーごとに示した。

結果：

薬物動態：

Substudy 1：

グループ 1 から 3 に関して，リサンキズマブ 90 mg PFS に対する 360 mg OBDS，並びに 360 mg OBDS に対する 180 mg OBDS のバイオアベイラビリティの点推定値及び 90%CI を示す。

Groups Test vs. Reference	Pharmacokinetic Parameter (units)	Central Value		Relative Bioavailability	
		Test	Reference	Point Estimate	90% Confidence Interval
Group 2: Risankizumab 360 mg OBDS × 1 SC Injection (2.4 mL of 150 mg/mL) vs. Group 1: Risankizumab 90 mg PFS × 4 SC Injections (4 mL of 90 mg/mL)	C_{max} (µg/mL)	43.1	34.1	1.263	1.184 – 1.347
	AUC_t (µg•day/mL)	1555	1461	1.065	1.000 – 1.134
	AUC_{inf} (µg•day/mL)	1700	1588	1.070	1.010 – 1.134
Group 3: Risankizumab 180 mg OBDS × 1 SC Injection (1.2 mL of 150 mg/mL) vs. Group 2: Risankizumab 360 mg OBDS × 1 SC Injection (2.4 mL of 150 mg/mL)	C_{max}/Dose (µg/mL/mg)	0.110	0.114	0.967	0.861 – 1.087
	AUC_t/Dose (µg•day/mL/mg)	4.257	4.225	1.008	0.894 – 1.137
	AUC_{inf}/Dose (µg•day/mL/mg)	5.057	4.596	1.100	0.994 – 1.218

Note: 28 subjects from Substudy 1 are excluded from analysis (11 subjects for OBDS-dosing failures or related issues; 8 subjects for incomplete PK profiles without terminal phase; 8 subjects for violating eligibility criterion #23 from the protocol by enrolling in both substudies; 1 subject for violating eligibility criterion #23 from the protocol by enrolling in two treatment groups of Substudy 1).

Substudy 2：

リサンキズマブ 300 mg 液剤バイアル（グループ 4）に対する 600 mg 液剤バイアル（グループ 5）のバイオアベイラビリティの点推定値及び 90%CI を示す。

Regimens Test vs. Reference	Pharmacokinetic Parameter	Central Value		Relative Bioavailability	
		Test	Reference	Point Estimate	90% Confidence Interval
600 mg liquid vial (Group 5) vs. 300 mg liquid vial (Group 4)	C_{max} (µg/mL)	735	736	0.998	0.952 – 1.046
	AUC_t (µg•day/mL)	11500	10700	1.079	1.001 – 1.164
	AUC_{inf} (µg•day/mL)	12400	11900	1.044	0.976 – 1.117

Note: Nine subjects from Substudy 2 are excluded from analysis (1 subject prematurely discontinued from the study at Day 2; 8 subjects for violating eligibility criterion #23 from the protocol by enrolling in both substudies).

免疫原性：

ベースライン時 ADA 及び TE-ADA の発現率は，すべての投与グループを通じてそれぞれ 2.0%から 6.9%及び 2.0%から 13%の範囲であった。TE-ADA の発現率は，360 mg OBDS 投与グループ（グループ 2，13%）の方が 90 mg/mL PFS 投与グループ（グループ 1，6%）に比べて高かったことを除き，両サブスタディのすべての投与グループでおおむね低かった。ADA 発現までの期間は，すべての投与グループを通じて 13 から 114 日であった。

本試験において，TE-ADA 陽性被験者のリサンキズマブの AUC_{inf} の範囲は，ADA 陰性被験者の AUC_{inf} の範囲に収まったことから，ADA の存在はリサンキズマブの曝露量に顕著な影響を及ぼさないことが示された。

全ての TE-ADA 陽性被験者で過敏症反応は認められなかった。注射部位反応（以下「ISR」）の大部分は，TE-ADA 陰性被験者に発現した。試験を通じて TE-ADA 陽性被験者 8 例に ISR が認められたが，その中で投与した時に ADA 陽性であった被験者はいなかった。本試験は単回投与試験であり，ADA が初めて発現するまでの期間が 13 から 114 日であったことを考慮すると，TE-ADA 陽性被験者 8 例で認められた ISR は，リサンキズマブに対する ADA が原因である可能性は低い。

安全性：

試験期間中，試験治療下で発現した有害事象（以下「TEAE」）により試験中止に至った例は認められなかった。試験期間中に死亡は報告されなかった。Substudy 1 において，AE の発現率は 360 mg OBDS 投与グループでは 49.6%であり，対照となる 90 mg/mL PFS 投与グループでの 30.7%に比べて高く，このことは ISR の発現率が 360 mg OBDS 投与グループで 34.9%であり，90 mg PFS 投与グループでの 8.7%に比べて高いことに起因すると考えられる。注射部位の AE の大部分は，硬結，紅斑及び腫脹に関連するものであり，注射部位あたりの薬剤の液量が多いことから，予想外の事象ではなかった。しかし，ISR 及びデバイス関連の AE はすべて Grade 1 で軽度であり，大部分（51/64 例，80%）は発現日中に回復した。更に，注射部位疼痛の AE は SC 投与グループ間で同程度であった。ISR 及びデバイスに関連した TEAE の発現率は，PFS と OBDS の間のドラッグデリバリーの機能的な差に一部起因すると考えられる。

OBDS は約 5 分間皮膚に付着させ，単回注射部位に多めの液量（用量 360 mg では 2.4 mL）注射するのに対し，PFS を介する 360 mg 投与では 4 回に分けて別々の部位に 1 mL ずつ注射する。圧迫感 / ヒリヒリ感といった患者報告アウトカムの頻度又は重症度については，PFS 投与グループと 360 mg OBDS 投与グループとの間に顕著な差は認められなかった。

ADA と ISR の関連性は認められなかった。ISR は治験薬投与と近接していたため，ISR が TE-ADA と関連している可能性は低かった。更に，ベースライン時（投与前）に ADA 陽性であった被験者において ISR は報告されなかった。

データ全体に基づくと，PFS 投与グループに比べて 360 mg OBDS 投与グループは ISR の発現率が高かったが，ISR の時間が限られていたこと及びその重症度から判断して，リサンキズマブと OBDS を組み合わせた製品の使用によるベネフィットーリスクバランスは良好に維持されていると考えられる。

2 つの IV 投与製剤（臨床試験で使用した製剤と市販予定製剤）を比較する Substudy 2 では，AE の発現頻度は両

グループ間で同程度であった。注射 / 注入部位反応及び過敏症反応について検討したが，新製剤の安全性上の懸念は示されなかった。

ADA と過敏症反応との関連は認められず，試験期間中に臨床的に意味のあるバイタルサイン又は臨床検査値異常は認められなかった。

結論：

Substudy 1 では，市販予定の 360 mg OBDS SC 投与製剤を第 III 相試験で用いた 90 mg/mL PFS 製剤と比較した。AUC の 90%CI は生物学的同等性基準の 0.8–1.25 の範囲内であった。C_{max} の 90% CI は 0.8–1.25 の上限を超え，範囲は 1.184–1.347 であり，点推定値は 1.263 であった。この C_{max} の差は臨床的に意味のあるものではないと考えられる。Substudy 2 で極めて高用量の 1800 mg を単回 IV 投与した健康被験者，及び最大 1200 mg までの幅広い用量範囲で 4 週間ごとに反復 IV 投与したクローン病患者において，リサンキズマブの忍容性は良好であった。これらの投与による C_{max} は，OBDS を用いて 360 mg を単回 SC 投与したときの C_{max} を大きく上回った（R&D/20/0587 及び R&D/20/1216）。リサンキズマブの用量又は曝露量に依存する安全性の問題は特定されていない。更に，有効性は主にリサンキズマブの AUC に関連する平均濃度によって決まることが示されており（R&D/20/1614），AUC は生物学的同等性の基準を満たしている。

したがって，C_{max} については生物学的同等性の上限を超えていたが，臨床試験データを総合的に見てリサンキズマブの治療域が広いことを考慮すると，市販予定の OBDS 製剤と第 III 相 SC 投与製剤の薬物動態の類似性は示されていると考えられる。また，180 mg OBDS 製剤と 360 mg OBDS 製剤の間で線形性が示された。

TE-ADA の発現率は，360 mg OBDS 投与グループの方が 90 mg/mL PFS 投与グループよりも数値的に高かったことを除き，すべての投与グループでおおむね低かった。免疫原性の影響に関する解析では，ADA 陽性被験者と陰性被験者の間でリサンキズマブの曝露量にごくわずかな差が認められたが，ADA は免疫関連の安全性事象（過敏症反応及び ISR）に影響を及ぼさなかったことから，360 mg OBDS で ADA の発現率がより高かったことは，臨床的に意味のある影響を及ぼす可能性は低いことが示された。

PFS 投与グループに比べて 360 mg OBDS 投与グループは ISR の発現率が高かったが，ISR の期間が限られていて重症度が軽度であったことから，リサンキズマブと OBDS を組み合わせた製品の使用によるベネフィットーリスクバランスは良好に維持されていると考えられる。

Substudy2 では，健康被験者にリサンキズマブ 1800 mg を単回 IV 投与したとき，リサンキズマブ 600 mg バイアルは 300 mg バイアルと生物学的に同等であることが示され，免疫原性及び安全性 / 忍容性プロファイルも類似していた。検討した用量の被験者における忍容性は良好であった。

結論として，本試験の結果から，IV 投与製剤及び SC 投与製剤のいずれにおいても第 III 相試験製剤と市販予定製剤との間の生物学的同等性及び / 又は類似性が示されるとともにリサンキズマブのベネフィットーリスクプロファイルは変わらなかった。

Subject [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
うつ病	X			

Treatment Group	Age at Study Start	Sex	Race
Risankizumab 90 mg PFS x 4 SC Injections	3[redacted]	MALE	WHITE

Medical History	Onset Year
WISDOM TEETH EXTRACTION X 4	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
NICOTINE GUM	NEVER			
NICOTINE PATCHES	NEVER			
OTHER SMOKING OR VAPING INSTRUMENT	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
RISANKIZUMAB	360 MG	SC		[redacted]20[redacted] / 1	[redacted]20[redacted] / 1	1

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
NOT REPORTED			

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BUPROPION	75 mg	QD	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 54
FLUOXETINE	20 mg	QD	Y-M: 20[redacted] / 55	Y-M: 20[redacted] / 128

Event #1: Serious Adverse Event

Event Description	DEPRESSION
Preferred term	うつ病
AE Onset Date / Rx Day	[redacted]:12:00 / 29 (28 DAY AFTER LAST TREATMENT)
Age at AE Onset	[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	128 (127 DAYS AFTER LAST TREATMENT)
Duration of AE	100 DAYS
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Relationship to Non-Study Treatment	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]:00:40
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-128

米国の治験責任医師からの報告。本被験者は3[redacted]歳男性であり，AbbVie のリサンキズマブの治験でリサンキズマブが投与され，うつ病の事象を発現した。関連する病歴は元飲酒者（1 日 2 杯未満），クローン病及び非喫煙者であった。

Event 1 の臨床経過：

投与 29 日後，被験者はうつ病を発現した。

投与 29 日後，被験者はうつ病のため精神科病棟に入院した。被験者によると，精神的に打ちのめされる感じがして，「神経が衰弱しつつある」とのことだった。最近友人を失い，前回の外来の帰り道に車で事故に遭ったとのことだった。また，被験者はガールフレンドと別れ，同棲していた家から出る予定とのことだった。被験者は自殺念慮を否定しており，単に精神的に打ちのめされているだけとのことだった。被験者は投薬治療を開始し，気分がよくなった。投与 35 日後，被験者は退院した。

被験者にはうつ病の既往歴はなかった。

被験者は Prozac 及び Wellbutrin の投薬治療を受けた。

Causality for RISANKIZUMAB (Open Label)

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1) Depression (10012378) (Depression (10012378)) [v.24.0] [10012378]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Open Label)

Event of DEPRESSION

- Investigator: not reported

- AbbVie: Event is more likely due to multiple concurrent stressors including loss of friend, car accident, breaking up with girlfriend and moving out of his home.

M16-533 試験

治験の標題：
A Study in Healthy Japanese and Caucasian Subjects to Assess the Pharmacokinetics, Safety and Tolerability After a Single Dose of Risankizumab

施設数 / 実施国名：
1 / 米国

治験責任医師：
[redacted], MD

公表文献 (参考資料) ：
なし

治験期間：	開発のフェーズ：I
最初の被験者の初回来院日：20[redacted] 年[redacted] 月[redacted] 日 最後の被験者の最終来院日：20[redacted] 年[redacted] 月[redacted] 日	

目的：
本試験の目的は，日本人及び白人の健康被験者にリサンキズマブを単回静脈内（以下「IV」）投与したときの薬物動態，安全性，忍容性及び免疫原性を評価することであった。

被験者数 (計画時と解析時) ：
計画例数：16，登録例数：17，完了例数：16，安全性評価例数：17，薬物動態評価例数：12

診断と主要な組入れ基準：
18 歳以上 45 歳以下の健康な日本人及び白人男性被験者

治験方法：
二重盲検，無作為化，プラセボ対照試験

Group	Treatment	
Japanese	1800 mg risankizumab IV, N = 6	Placebo, N = 3[a]
Caucasian	1800 mg risankizumab IV, N = 6	Placebo, N = 2

a. 1 名の被験者は予定された来院をしなかったため追跡不能となった。

薬物動態及び抗薬物抗体（以下「ADA」）解析のための血液試料を注入開始後約 3264 時間（137 日目）まで経時的に採取した。

被験薬，用量，投与液濃度，投与方法及びバッチ番号：

	Risankizumab	Placebo
Unit Strength	90 mg/mL	--
Dose	1800 mg	--
Mode of Administration	IV infusion	IV infusion
Material Master Identification	[redacted]	[redacted]
Bulk Product Lot Number	[redacted]	[redacted]

治療期間：
被験者はリサンキズマブ又はプラセボを約 3 時間かけて単回投与された。

評価基準：
薬物動態：
最高血漿中濃度（以下「C_{max}」），最高血漿中濃度到達時間（以下「T_{max}」），時間 0 から最終測定可能時間までの血漿中濃度 - 時間曲線下面積（以下「AUC_t」），及び時間 0 から無限大時間までの血漿中濃度 - 時間曲線下面積（以下「AUC_{inf}」）
免疫原性：
ADA 抗体価
安全性：
有害事象，バイタルサイン，心電図及び臨床検査

統計手法：
薬物動態：
C_{max}，AUC_t 及び AUC_{inf} の自然対数に対して分散分析（以下「ANOVA」）及び共分散分析（以下「ANCOVA」）を行い，民族は固定因子とした。ANOVA 及び ANCOVA モデルによる解析では，AUC 及び C_{max} の対数平均値の差の冪乗により日本人 / 白人の中心値の比を算出し，対数平均値の差の信頼区間の端点の冪乗により 90%信頼区間を求めた。体重を共変量とした解析としない解析を実施した。
安全性：
臨床検査値，バイタルサイン及び心電図（以下「ECG」）の変数のベースライン値及び投与後の値のベースラインからの変化量の要約を示した。
事前に規定した基準に従って，臨床的に重要と考えられる臨床検査値及びバイタルサインを特定した。ECG により QT 間隔及び心拍数で補正した QT 間隔（450 ms 超，480 ms 超及び 500 ms 超）並びにベースラインからの変化（30 ms 超及び 60 ms 超）を特定した。

結果 / 結論：
薬物動態の結果：
白人健康被験者に対する日本人健康被験者のリサンキズマブの C_{max} 及び AUC の比

		Exposure Ratios	
Regimens Test vs. Reference	Pharmacokinetic Parameter	Point Estimate	90% Confidence Interval
Japanese vs. Caucasian	C_{max}	1.137	0.984 – 1.315
	AUC_t	1.063	0.901 – 1.255
	AUC_{inf}	1.062	0.895 – 1.259

体重を共変量として検討したが，統計的に有意ではなかった。全体として，リサンキズマブの曝露量は白人被験者と日本人被験者で同程度であった。
免疫原性の結果：
すべての被験者はベースライン時に ADA 陰性であり，ADA を発現した 3 名の被験者の抗体価は低かった（抗体価 =2–16）。ADA 陽性被験者におけるリサンキズマブの曝露量は ADA 陰性被験者と同程度であったことから，リサンキズマブの曝露量は ADA の発現により影響を受けないことが示された。リサンキズマブを投与され ADA 陽性であった被験者では，過敏症，アナフィラキシー又は輸注反応は認められなかった。
安全性の結果：
日本人及び白人ともにリサンキズマブ 1800 mg 静脈内投与後の忍容性はおおむね良好であった。リサンキズマブを投与された被験者では，過敏症，アナフィラキシー又は輸注反応は認められなかった。重度又は重篤な有害事

象は報告されなかった。試験期間中，臨床的に重要なバイタルサイン，ECG 又は臨床検査値の結果は認められなかった。報告された有害事象に一定の傾向は認められず，本試験から新たな安全性の問題は特定されなかった。

結論：

リサンキズマブ 1800 mg を単回 IV 投与したときの日本人被験者におけるリサンキズマブの曝露量は白人被験者と同程度であった。本試験において 3 名に低抗体価の ADA が投与時に認められたが，リサンキズマブの曝露量に明らかな影響は認められなかった。本試験でのリサンキズマブ 1800 mgIV 投与の忍容性はおおむね良好であった。

M15-993 試験

治験の標題： A Phase 2, Multicenter, Randomized, Double-Blind, Multiple Dose, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy, Pharmacokinetics, and Safety of BI 655066 (Risankizumab), an IL-23 p19 Antagonist Monoclonal Antibody, in Patients With Moderately to Severely Active Crohn's Disease Who Are Naïve to or Were Previously Treated With Anti-TNF Therapy	
施設数 / 実施国名： 36 施設 / 9 ヵ国（ベルギー，カナダ，ドイツ，韓国，オランダ，ポーランド，スペイン，イギリス，米国）	
治験責任医師： [redacted], MD，他	
公表文献 (参考資料) ： 6 報	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：II
治験の種類： proof of concept，多施設共同，ランダム化，二重盲検，プラセボ対照，並行群間，第 II 相，用量範囲探索	
目的： 主要目的 投与 12 週時のクローン病活動度指数（以下「CDAI」）に基づく臨床的寛解（以下「臨床的 CDAI 寛解」）の導入におけるリサンキズマブの有効性を評価する。 副次目的 ・内視鏡的改善，CDAI に基づく臨床的改善（以下「臨床的 CDAI 改善」），内視鏡的粘膜治癒及び完全寛解の導入におけるリサンキズマブの有効性を評価する。 ・リサンキズマブの安全性を評価する。 ・クローン病治療におけるリサンキズマブの薬物動態及び薬力学を探索する。	
被験者数 (計画時と解析時) ： 計画時：被験者約 120 例を 3 群に 1:1:1 の比でランダム化することとした。 解析時：被験者 121 例がランダム化され，治験薬の投与を受け，intent-to-treat（以下「ITT」）解析対象集団に含められた。	
診断と主要な組入れ基準： 年齢が 18 歳以上 75 歳以下で，Visit 1 の 3 ヵ月以上前に内視鏡又は画像検査によりクローン病と確定診断された男女の患者。患者は，Visit 1.1 で以下に定義される中等症から重症のクローン病を有することとされた：CDAI が 220 以上 450 以下，かつ，回腸又は結腸の 1 ヵ所以上の部位に粘膜潰瘍を有しており，Crohn's Disease Endoscopic Index of Severity（以下「CDEIS」）が 7 以上（病変が回腸に限局している患者の場合は 4 以上）。ランダム化前に大腸内視鏡で評価し，中央独立判定の評価者により確定された。抗腫瘍壊死因子（以下「TNF」）製剤（インフリキシマブ，アダリムマブ又はセルトリズマブ　ペゴル）に未治療又はクローン病の適応用量で 1 種類以上に既治療の患者を適格とした。	
治験方法： M15-993　試験は，中等症から重症の活動性クローン病を有する被験者を対象にした，リサンキズマブの proof of concept，多施設共同，ランダム化，二重盲検，プラセボ対照，並行群間，第 II 相，用量範囲探索試験であった。本試験は，最大 4 週間のスクリーニング期間，12 週間の二重盲検静脈内（以下「IV」）投与ピリオド（第 1	

ピリオド），14 週間の非盲検 IV 投与 / 休薬ピリオド（第 2 ピリオド），26 週間の皮下（以下「SC」）投与ピリオド（第 3 ピリオド），及び 15 週間の追跡調査ピリオドで構成された。

被験薬，用量，投与方法及びバッチ番号：

Study Drug Unit Strength	Dosage Form; Dose	Bulk Lot Number
Risankizumab 100 mg risankizumab in a vial with 10 mL solution (concentration 10 mg/mL)	IV infusion (3 infusions separated by 4 weeks); 200 mg or 600 mg	[redacted]
Risankizumab 90 mg risankizumab in a pre-filled syringe with 1 mL solution (concentration 90 mg/mL)	SC (4 injections separated by 8 weeks); 180 mg	[redacted]

IV = 静脈内，SC = 皮下

治療期間：

3 ピリオド全体で約 67 週間及び 15 週間の追跡調査ピリオド

対照薬，用量，投与方法及びバッチ番号：

Study Drug Unit Strength	Dosage Form; Dose	Bulk Lot Number
Placebo (matching) 0 mg/mL	IV infusion (3 infusions separated by 4 weeks); NA	[redacted]

IV = 静脈内，NA = 該当なし

評価基準：

有効性：

主要評価項目は，投与 12 週時の臨床的 CDAI 寛解（CDAI スコアが 150 未満）とした。副次評価項目は，投与 12 週時の臨床的 CDAI 改善（CDAI スコアが 150 未満又は CDAI スコアがベースラインから 100 以上の減少），投与 12 週時の CDEIS に基づく内視鏡的寛解（以下「内視鏡的 CDEIS　　寛解」）（CDEIS スコアが 4 以下［当初病変が回腸に限局していた被験者の場合，CDEIS スコアが 2 以下］），投与 12 週時の CDEIS に基づく内視鏡的改善（以下「内視鏡的 CDEIS 改善」）（CDEIS スコアがベースラインから 50%以上の減少），投与 12 週時の内視鏡的粘膜治癒（粘膜潰瘍の不在）及び投与 12 週時の完全寛解（臨床的 CDAI 寛解及び内視鏡的 CDEIS 寛解）とした。複数の探索的評価項目についても評価した。

薬物動態：

血漿中リサンキズマブ濃度のトラフ値及び免疫原性を評価するための抗薬物抗体の相対抗体価を予定来院時にバリデートされた解析方法で測定した。

安全性：

安全性は，早期中止，免疫抑制及び注射部位反応に関連した有害事象を中心に解析した。臨床検査値は，免疫抑制に関連した血液学的検査値を中心に解析した。

統計手法：

有効性：

投与 12 週時の臨床的 CDAI 寛解を達成した被験者の割合について，リサンキズマブ 200 mg 及び 600 mg IV 併合群とプラセボ群の群間差は，ランダム化時の抗 TNF 製剤使用の有無（未治療，既治療）の層別因子で層別化し，Greenland & Robins が提唱する重み付けを用いた Cochran-Mantel-Haenszel（以下「CMH」）法によるリスク差の推定量により推定・検定した。3 群（リサンキズマブ 200 mg IV 群，600 mg IV 群，プラセボ群）間の対比

較について，主解析と同様に解析した。多重性の調整は行わず，名目 *P* 値を提示した。投与 12 週時の 2 値変数で表されるすべての副次評価項目についてリサンキズマブ 200 mg 及び 600 mg IV 併合群とプラセボ群の群間差は，主要評価項目と同様に，ランダム化時の層別因子で層別化し，CMH 法により推定・検定した。対比較について，主要評価項目と同様に解析した。

薬物動態及び免疫原性：
血漿中リサンキズマブ濃度のトラフ値の記述統計量を要約した。また，抗薬物抗体及び中和抗体に対して陽性又は陰性であった被験者の割合の記述統計量を要約した。

安全性：
ベースライン時及びベースライン後の時点のいずれにおいても臨床検査パラメータ及びバイタルサインの測定値を有する被験者について，要約統計量（ベースライン時及び治験実施計画書に規定された各来院時の平均値，並びにベースラインからの変化量の平均値，標準偏差及び中央値）を提示した。カテゴリーデータは頻度及び割合を要約した。

有効性の結果

投与 12 週時の結果から，選択的インターロイキン（以下「IL」）-23p19 阻害薬であるリサンキズマブはプラセボに対して，臨床的 CDAI 寛解及び改善，内視鏡的 CDEIS 寛解，改善及び粘膜治癒，完全寛解，バイオマーカー（C 反応性蛋白及び便中カルプロテクチン）及び生活の質に関する評価項目（炎症性腸疾患質問票［以下「IBDQ」］）の達成において優越性を示した。また，用量に比例して改善が認められ，臨床的及び内視鏡的評価項目を共に達成した被験者の割合は，リサンキズマブ 600 mg IV 群で 200 mg IV 群及びプラセボ群と比較して高かった。この結果，リサンキズマブ 600 mg IV 投与による導入療法は，低用量と比較して優れていることが示された。リサンキズマブ IV 投与のより高用量な導入療法を更に評価することが支持される。

第 2 ピリオドへの組入れの際，完全寛解を達成しなかったすべての被験者は，非盲検下でリサンキズマブ 600 mg IV 投与 4 週ごと（以下「Q4W」）を 3 回受けた。第 1 ピリオドで完全寛解を達成しなかった被験者に対する第 2 ピリオドでのリサンキズマブ 600 mg による再導入療法により，投与 26 週時の臨床的 CDAI 寛解を達成した被験者の割合は，投与 12 週時と比較して高かった。プラセボからリサンキズマブ 600 mg へ切り替えた被験者の臨床的 CDAI 寛解を達成した割合は 54.5%であり，第 1 ピリオドで盲検下でのリサンキズマブ 600 mg IV 投与により認められた有効性を確認する結果となった。第 1 ピリオドでリサンキズマブ 200 mg 又は 600 mg の投与を受け，リサンキズマブ 600 mg を継続投与された被験者の臨床的 CDAI 寛解を達成した割合は 52.9%であり，高用量での導入療法を継続することによりベネフィットを受ける被験者もいることが示された。第 2 ピリオドで休薬群に組み入れられた 6 例の被験者は，いずれも投与 26 週時に臨床的 CDAI 寛解を維持しており，リサンキズマブの薬力学的プロファイルより持続性が示唆された。

第 3 ピリオドでのリサンキズマブ SC 投与は臨床的 CDAI 寛解の維持に有効であった。投与 52 週時の内視鏡的評価項目（内視鏡的 CDEIS 寛解，改善及び粘膜治癒）を達成した被験者の割合は，第 1 ピリオドでリサンキズマブ 600 mg IV 投与を受けた被験者で最も高く，疾患活動度の内

視鏡的消失を達成するためには，導入療法時により高用量での曝露が必要であることが示唆された。

薬物動態及び免疫原性の結果

第 1 ピリオドの投与 0 週時，投与 4 週時及び投与 8 週時にリサンキズマブ 200 mg 又は 600 mg IV 投与による導入療法を受けたクローン病の被験者において，血漿中リサンキズマブ濃度のトラフ値はおおむね用量に比例して増加した。リサンキズマブ 600 mg IV 投与を受けた被験者において，第 2 ピリオドでは第 1 ピリオドと同様のリサンキズマブ濃度のトラフ値が認められた。リサンキズマブ 180 mg SC 投与 8 週ごと（以下「Q8W」）を投与 26 週時から開始したとき，投与 42 週時までにほぼ定常状態に到達した。

投与後に抗薬物抗体陽性の反応が認められた割合は，リサンキズマブの投与を 1 回以上受けた被験者の 8%（9/108 例）であった。リサンキズマブの投与を受けた被験者で抗薬物抗体陽性の試料が最初に認められるまでの時間の範囲は投与後 12 週間から 18 週間であった。抗薬物抗体陽性の反応のほとんどは一過性であった。試験期間中に抗薬物抗体陽性が認められた被験者のいずれにおいても，中和抗体は陽性ではなかった。抗薬物抗体陽性被験者の数は限定的であったが，抗薬物抗体による血漿中リサンキズマブ濃度に対する影響は認められなかった。

安全性の結果

本試験において，第 1 ピリオド及びリサンキズマブが投与されたすべての試験ピリオドでの有害事象，重篤な有害事象及び特に注目すべき有害事象の評価，並びに，臨床検査，身体検査及びバイタルサインの評価の結果，リサンキズマブはおおむね安全で忍容性は良好であることが示された。重大で，未知の安全性に関する問題は認められなかった。

第 1 ピリオドでは，有害事象を発現した被験者の割合は，リサンキズマブ 200 mg 及び 600 mg IV 併合群で 79.3%（65/82 例），プラセボ群 82.1%（32/39 例）であり，両群でほぼ同様であった。全試験期間を通じて，リサンキズマブの投与を受けた被験者での曝露期間で調整した有害事象の発現件数は，第 1 ピリオドと比較して著しい上昇は認められなかった。

試験期間中に悪性腫瘍及び死亡に至った有害事象は認められなかった。ほとんどの有害事象は重篤な有害事象の定義に該当するものではなく，治験薬の投与中止に至った有害事象はごく少数であった。第 1 ピリオドでは，重篤な有害事象又は治験薬の投与中止に至った有害事象を発現した被験者の割合は，リサンキズマブ 200 mg 及び 600 mg IV 併合群と比較してプラセボ群で高かった。

発現割合が高かった特に注目すべき事象は感染症であり，感染症のうち特に鼻咽頭炎の有害事象の発現割合が高かった。感染症の多くは第 1 ピリオドに発現した。日和見感染，結核及び真菌感染は，リサンキズマブの投与を受けた被験者の少数に報告された。

うつ病，自殺念慮又は自殺行為を発現した被験者の割合は，第 1 ピリオドではリサンキズマブ群とプラセボ群で同様であり，全体として発現例数は少なかった。

臨床検査値及びバイタルサインに臨床的に意義のある変化は認められなかった。

結論

全体として，本 proof of concept，第 II 相試験の結果，中等症から重症の活動性クローン病の被験者において，選択的 IL-23p19 阻害薬であるリサンキズマブはプラセボに対して，臨床的，内視鏡的，バイオマーカー及び生活の質に関する評価項目の改善において優越性を示した。更に，試験の結果，リサンキズマブ SC 投与の維持療法としての有効性が示された。血漿中リサンキズマブ濃度のトラフ値はおおむね用量に比例して増加し，抗薬物抗体による血漿中リサンキズマブ濃度に対する影響は認められなかった。リサンキズマブはおおむね安全で忍容性は良好であり，安全性に関する新たなシグナルは特定されなかった。

本試験の曝露状況の概要及び本試験で発現した有害事象を以下のとおり示す。

項目	二重盲検 IV 投与ピリオド（第 1 ピリオド）	リサンキズマブが投与された全試験期間
曝露状況の概要	表 1，表 2	-
有害事象の概要	表 3	表 4
すべての有害事象	表 5	表 6
治験薬と関連ありの有害事象	表 7	表 8
Grade 3 以上の有害事象	表 9	表 10
重篤な有害事象	表 11	表 12
中止に至った有害事象	表 13	表 14

IV = 静脈内

表 1. Duration of Exposure to Study Drug by Period 1 Treatment Assignment: Continuous (Days) (Safety Population)

Treatment	N	Mean	SD	Median	Min	Max
Placebo	39	319.51	128.532	285.00	106.00	463.00
Risankizumab 200 mg IV	41	335.39	128.974	344.00	106.00	487.00
Risankizumab 600 mg IV	41	348.20	105.931	288.00	134.00	470.00
Risankizumab 200 + 600 mg IV	82	341.79	117.463	343.50	106.00	487.00
Total	121	334.61	121.054	288.00	106.00	487.00

Note: Duration of exposure is defined for each subject as number of days since first dose of study drug through the last study drug dose date + 105 days.

相互参照：M15-993 試験 CSR Table 21

表 2. Duration of Exposure to Study Drug by Period 1 Treatment Assignment: Categorical (Days) (Safety Population)

Duration Interval (Days)	Placebo N = 39	Risankizumab 200 mg IV N = 41	Risankizumab 600 mg IV N = 41	Risankizumab Total 200 + 600 mg IV N = 82	All Subjects N = 121
			n (%)		
1 – 28 days	0	0	0	0	0
29 – 56 days	0	0	0	0	0
57 – 84 days	0	0	0	0	0
85 – 126 days	6 (15.4)	4 (9.8)	0	4 (4.9)	10 (8.3)
127 – 154 days	0	2 (4.9)	1 (2.4)	3 (3.7)	3 (2.5)
155 – 182 days	0	0	1 (2.4)	1 (1.2)	1 (0.8)
183 – 238 days	2 (5.1)	2 (4.9)	1 (2.4)	3 (3.7)	5 (4.1)
239 – 294 days	14 (35.9)	11 (26.8)	18 (43.9)	29 (35.4)	43 (35.5)
295 – 350 days	1 (2.6)	3 (7.3)	0	3 (3.7)	4 (3.3)
> 350 days	16 (41.0)	19 (46.3)	20 (48.8)	39 (47.6)	55 (45.5)

Note: Duration of exposure is defined for each subject as number of days since first dose of study drug through the last study drug dose date + 105 days.

相互参照：M15-993 試験 CSR Table 22

表3

[redacted]20[redacted] 23:32 <[redacted] >
RISANKIZUMAB (CROHN'S)
STUDY M15-993
R&D/17/0073 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.1.1.1

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
(Safety Population)

	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
Subjects with:				
Any adverse event (AE)	32 (82.1)	34 (82.9)	31 (75.6)	65 (79.3)
Any AE at least possibly drug related$	7 (17.9)	11 (26.8)	6 (14.6)	17 (20.7)
Any AE with toxicity grade 3 or 4	9 (23.1)	7 (17.1)	3 (7.3)	10 (12.2)
Any serious AE	13 (33.3)	10 (24.4)	4 (9.8)	14 (17.1)
Any AE leading to discontinuation of study drug	6 (15.4)	5 (12.2)	2 (4.9)	7 (8.5)
Any AE leading to death	0	0	0	0
Any drug induced liver injury (DILI)	1 (2.6)	2 (4.9)	0	2 (2.4)
Any infections	13 (33.3)	14 (34.1)	14 (34.1)	28 (34.1)
Any serious infections	4 (10.3)	1 (2.4)	2 (4.9)	3 (3.7)
Any opportunistic infections	0	1 (2.4)	2 (4.9)	3 (3.7)
Any tuberculosis	0	0	1 (2.4)	1 (1.2)
Any fungal infections	0	2 (4.9)	2 (4.9)	4 (4.9)
Any malignancies	0	0	0	0
Any systemic hypersensitivity/anaphylactic reactions	12 (30.8)	8 (19.5)	5 (12.2)	13 (15.9)
Any depression, suicidal ideation and behavior (SIB)	1 (2.6)	1 (2.4)	1 (2.4)	2 (2.4)
Any hepatic disorder	1 (2.6)	2 (4.9)	0	2 (2.4)
Any cardiac arrhythmias	0	0	0	0
Deaths#	0	0	0	0

Note: Treatment-Emergent adverse events during double-blind intravenous therapy period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.
$ As assessed by investigator.
# Includes non treatment-emergent deaths.

Program Source Code: [redacted]

表4

[redacted]20[redacted] 23:32 <[redacted] >
RISANKIZUMAB (CROHN'S)
STUDY M15-993
R&D/17/0073 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.1.1.4

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
(Subjects Who Received at Least One Dose of Risankizumab)

	Risankizumab (N=115) n (%)
Subjects with:	
Any adverse event (AE)	101 (87.8)
Any AE at least possibly drug related$	40 (34.8)
Any AE with toxicity grade 3 or 4	21 (18.3)
Any serious AE	31 (27.0)
Any AE leading to discontinuation of study drug	10 (8.7)
Any AE leading to death	0
Any drug induced liver injury (DILI)	7 (6.1)
Any infections	62 (53.9)
Any serious infections	5 (4.3)
Any opportunistic infections	3 (2.6)
Any tuberculosis	1 (0.9)
Any fungal infections	5 (4.3)
Any malignancies	0
Any systemic hypersensitivity/anaphylactic reactions	35 (30.4)
Any depression, suicidal ideation and behavior (SIB)	3 (2.6)
Any hepatic disorder	7 (6.1)
Any cardiac arrhythmias	1 (0.9)
Deaths#	0

Note: Treatment-Emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.
$ As assessed by investigator.
# Includes non treatment-emergent deaths.

Program Source Code: [redacted]

表5

[redacted]20[redacted] 23:32 <[redacted] >
RISANKIZUMAB (CROHN'S)
STUDY M15-993
R&D/17/0073 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 11

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
Any adverse event	32 (82.1)	34 (82.9)	31 (75.6)	65 (79.3)
血液およびリンパ系障害				
貧血	4 (10.3)	0	3 (7.3)	3 (3.7)
内出血発生の増加傾向	0	1 (2.4)	0	1 (1.2)
鉄欠乏性貧血	1 (2.6)	0	0	0
リンパ節症	1 (2.6)	0	0	0
好中球減少症	1 (2.6)	0	0	0
正色素性正球性貧血	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	6 (15.4)	2 (4.9)	3 (7.3)	5 (6.1)
心臓障害				
右脚ブロック	1 (2.6)	0	0	0
動悸	0	0	1 (2.4)	1 (1.2)
洞性徐脈	0	1 (2.4)	0	1 (1.2)
頻脈	1 (2.6)	0	0	0
Subjects with one or more events	2 (5.1)	1 (2.4)	1 (2.4)	2 (2.4)
耳および迷路障害				
耳痛	1 (2.6)	1 (2.4)	1 (2.4)	2 (2.4)
耳鳴	0	1 (2.4)	0	1 (1.2)
回転性めまい	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	1 (2.6)	2 (4.9)	1 (2.4)	3 (3.7)
内分泌障害				
クッシング様症状	0	2 (4.9)	0	2 (2.4)
Subjects with one or more events	0	2 (4.9)	0	2 (2.4)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
眼障害				
複視	0	1 (2.4)	0	1 (1.2)
上強膜炎	1 (2.6)	1 (2.4)	0	1 (1.2)
眼瞼浮腫	1 (2.6)	0	0	0
流涙増加	0	1 (2.4)	0	1 (1.2)
眼充血	1 (2.6)	0	0	0
ぶどう膜炎	0	0	1 (2.4)	1 (1.2)
Subjects with one or more events	2 (5.1)	3 (7.3)	1 (2.4)	4 (4.9)
胃腸障害				
腹部不快感	1 (2.6)	0	0	0
腹部腫瘤	0	1 (2.4)	0	1 (1.2)
腹痛	5 (12.8)	6 (14.6)	4 (9.8)	10 (12.2)
下腹部痛	0	1 (2.4)	2 (4.9)	3 (3.7)
上腹部痛	0	2 (4.9)	1 (2.4)	3 (3.7)
腹部圧痛	0	1 (2.4)	0	1 (1.2)
裂肛	1 (2.6)	0	0	0
痔瘻	2 (5.1)	0	0	0
アフタ性潰瘍	2 (5.1)	0	0	0
口腔灼熱感症候群	0	0	1 (2.4)	1 (1.2)
慢性胃炎	1 (2.6)	1 (2.4)	0	1 (1.2)
クローン病	6 (15.4)	2 (4.9)	1 (2.4)	3 (3.7)
下痢	2 (5.1)	2 (4.9)	3 (7.3)	5 (6.1)
口内乾燥	1 (2.6)	0	0	0
鼓腸	0	0	1 (2.4)	1 (1.2)
胃炎	0	1 (2.4)	0	1 (1.2)
血便排泄	2 (5.1)	0	2 (4.9)	2 (2.4)
痔核	0	1 (2.4)	1 (2.4)	2 (2.4)
回腸狭窄	0	0	1 (2.4)	1 (1.2)
腸閉塞	1 (2.6)	0	0	0
腸管穿孔	1 (2.6)	1 (2.4)	0	1 (1.2)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
胃腸障害 (Cont.)				
口唇乾燥	0	0	1 (2.4)	1 (1.2)
悪心	4 (10.3)	9 (22.0)	4 (9.8)	13 (15.9)
嚥下痛	0	0	1 (2.4)	1 (1.2)
食道炎	0	1 (2.4)	0	1 (1.2)
肛門周囲痛	1 (2.6)	0	1 (2.4)	1 (1.2)
流涎過多	0	0	1 (2.4)	1 (1.2)
小腸閉塞	0	1 (2.4)	0	1 (1.2)
舌潰瘍	0	1 (2.4)	0	1 (1.2)
嘔吐	4 (10.3)	4 (9.8)	2 (4.9)	6 (7.3)
Subjects with one or more events	21 (53.8)	18 (43.9)	17 (41.5)	35 (42.7)
一般・全身障害および投与部位の状態				
無力症	3 (7.7)	4 (9.8)	2 (4.9)	6 (7.3)
胸部不快感	1 (2.6)	0	1 (2.4)	1 (1.2)
悪寒	1 (2.6)	0	0	0
疾患進行	0	0	1 (2.4)	1 (1.2)
疲労	3 (7.7)	0	2 (4.9)	2 (2.4)
全身健康状態低下	0	1 (2.4)	0	1 (1.2)
炎症	0	0	1 (2.4)	1 (1.2)
インフルエンザ様疾患	2 (5.1)	1 (2.4)	2 (4.9)	3 (3.7)
倦怠感	0	0	1 (2.4)	1 (1.2)
粘膜変色	0	1 (2.4)	0	1 (1.2)
末梢性浮腫	0	2 (4.9)	0	2 (2.4)
疼痛	0	1 (2.4)	0	1 (1.2)
末梢腫脹	2 (5.1)	0	0	0
発熱	3 (7.7)	3 (7.3)	3 (7.3)	6 (7.3)
Subjects with one or more events	11 (28.2)	11 (26.8)	11 (26.8)	22 (26.8)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
肝胆道系障害				
胆石症	1 (2.6)	0	0	0
Subjects with one or more events	1 (2.6)	0	0	0
免疫系障害				
化学物質アレルギー	1 (2.6)	0	0	0
アナフィラキシー反応	1 (2.6)	0	0	0
過敏症	1 (2.6)	0	1 (2.4)	1 (1.2)
季節性アレルギー	1 (2.6)	0	0	0
Subjects with one or more events	4 (10.3)	0	1 (2.4)	1 (1.2)
感染症および寄生虫症				
腹部膿瘍	1 (2.6)	0	0	0
肛門膿瘍	1 (2.6)	0	2 (4.9)	2 (2.4)
無症候性細菌尿	0	1 (2.4)	0	1 (1.2)
細菌尿	0	1 (2.4)	0	1 (1.2)
膀胱炎	1 (2.6)	0	0	0
硬結性紅斑	0	0	1 (2.4)	1 (1.2)
胃腸炎	1 (2.6)	1 (2.4)	1 (2.4)	2 (2.4)
ヘリコバクター性胃炎	0	1 (2.4)	0	1 (1.2)
単純ヘルペス	1 (2.6)	0	0	0
咬傷感染	0	1 (2.4)	0	1 (1.2)
インフルエンザ	0	1 (2.4)	1 (2.4)	2 (2.4)
鼻咽頭炎	3 (7.7)	2 (4.9)	2 (4.9)	4 (4.9)
口腔カンジダ症	0	1 (2.4)	2 (4.9)	3 (3.7)
口腔ヘルペス	0	1 (2.4)	0	1 (1.2)
骨髄炎	0	0	1 (2.4)	1 (1.2)
咽頭炎	0	0	1 (2.4)	1 (1.2)
肺炎	1 (2.6)	1 (2.4)	0	1 (1.2)
膿尿	1 (2.6)	1 (2.4)	0	1 (1.2)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
感染症および寄生虫症 (Cont.)				
膿疱性皮疹	1 (2.6)	0	0	0
直腸膿瘍	1 (2.6)	0	0	0
副鼻腔炎	0	1 (2.4)	1 (2.4)	2 (2.4)
扁桃炎	0	1 (2.4)	0	1 (1.2)
歯膿瘍	0	0	2 (4.9)	2 (2.4)
尿路感染	0	2 (4.9)	2 (4.9)	4 (4.9)
腟膿瘍	1 (2.6)	0	0	0
ウイルス感染	0	1 (2.4)	0	1 (1.2)
外陰部腟カンジダ症	0	1 (2.4)	0	1 (1.2)
外陰腟真菌感染	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	12 (30.8)	13 (31.7)	14 (34.1)	27 (32.9)
傷害、中毒および処置合併症				
挫傷	1 (2.6)	0	0	0
瘢痕ヘルニア	0	0	1 (2.4)	1 (1.2)
注入に伴う反応	2 (5.1)	1 (2.4)	0	1 (1.2)
半月板損傷	0	0	1 (2.4)	1 (1.2)
肉離れ	0	0	1 (2.4)	1 (1.2)
橈骨神経損傷	0	0	1 (2.4)	1 (1.2)
腱断裂	1 (2.6)	0	0	0
Subjects with one or more events	3 (7.7)	1 (2.4)	4 (9.8)	5 (6.1)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
臨床検査				
血中マグネシウム減少	0	0	1 (2.4)	1 (1.2)
γ－グルタミルトランスフェラーゼ増加	1 (2.6)	1 (2.4)	0	1 (1.2)
肝酵素上昇	0	1 (2.4)	0	1 (1.2)
リンパ節触知	0	0	1 (2.4)	1 (1.2)
体重減少	1 (2.6)	0	0	0
尿中白血球	0	0	1 (2.4)	1 (1.2)
Subjects with one or more events	2 (5.1)	2 (4.9)	3 (7.3)	5 (6.1)
代謝および栄養障害				
食欲減退	2 (5.1)	0	1 (2.4)	1 (1.2)
体液貯留	0	1 (2.4)	0	1 (1.2)
高血糖	0	1 (2.4)	0	1 (1.2)
低カリウム血症	3 (7.7)	0	2 (4.9)	2 (2.4)
低ナトリウム血症	0	1 (2.4)	0	1 (1.2)
低リン酸血症	0	0	1 (2.4)	1 (1.2)
鉄欠乏	1 (2.6)	1 (2.4)	0	1 (1.2)
栄養障害	2 (5.1)	1 (2.4)	0	1 (1.2)
代謝性アシドーシス	0	1 (2.4)	0	1 (1.2)
ビタミンD欠乏	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	8 (20.5)	5 (12.2)	3 (7.3)	8 (9.8)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
筋骨格系および結合組織障害				
関節痛	4 (10.3)	6 (14.6)	8 (19.5)	14 (17.1)
背部痛	2 (5.1)	1 (2.4)	3 (7.3)	4 (4.9)
側腹部痛	0	0	1 (2.4)	1 (1.2)
胤径部痛	0	1 (2.4)	0	1 (1.2)
関節腫脹	0	0	1 (2.4)	1 (1.2)
筋痙縮	0	1 (2.4)	0	1 (1.2)
筋肉痛	1 (2.6)	1 (2.4)	1 (2.4)	2 (2.4)
頚部痛	0	0	1 (2.4)	1 (1.2)
骨減少症	0	0	1 (2.4)	1 (1.2)
四肢痛	2 (5.1)	2 (4.9)	1 (2.4)	3 (3.7)
末梢関節炎	1 (2.6)	0	0	0
多発性関節炎	1 (2.6)	0	0	0
滑膜炎	0	0	1 (2.4)	1 (1.2)
腱障害	1 (2.6)	0	0	0
腱炎	1 (2.6)	0	0	0
Subjects with one or more events	10 (25.6)	11 (26.8)	13 (31.7)	24 (29.3)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
神経系障害				
反射消失	0	1 (2.4)	0	1 (1.2)
浮動性めまい	1 (2.6)	1 (2.4)	3 (7.3)	4 (4.9)
異常感覚	0	0	1 (2.4)	1 (1.2)
味覚異常	0	1 (2.4)	1 (2.4)	2 (2.4)
頭痛	5 (12.8)	6 (14.6)	5 (12.2)	11 (13.4)
感覚鈍麻	0	1 (2.4)	1 (2.4)	2 (2.4)
嗜眠	3 (7.7)	0	0	0
片頭痛	1 (2.6)	1 (2.4)	0	1 (1.2)
末梢性ニューロパチー	0	0	1 (2.4)	1 (1.2)
錯感覚	0	0	2 (4.9)	2 (2.4)
失神寸前の状態	0	0	1 (2.4)	1 (1.2)
下肢静止不能症候群	0	0	1 (2.4)	1 (1.2)
振戦	1 (2.6)	0	0	0
Subjects with one or more events	9 (23.1)	11 (26.8)	9 (22.0)	20 (24.4)
精神障害				
不安	0	1 (2.4)	0	1 (1.2)
抑うつ気分	1 (2.6)	0	0	0
うつ病	0	1 (2.4)	1 (2.4)	2 (2.4)
不眠症	0	1 (2.4)	3 (7.3)	4 (4.9)
易刺激性	0	0	1 (2.4)	1 (1.2)
悪夢	0	0	1 (2.4)	1 (1.2)
パニック発作	0	0	1 (2.4)	1 (1.2)
睡眠障害	2 (5.1)	1 (2.4)	0	1 (1.2)
Subjects with one or more events	3 (7.7)	4 (9.8)	6 (14.6)	10 (12.2)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
腎および尿路障害				
急性腎障害	0	1 (2.4)	0	1 (1.2)
失禁	1 (2.6)	0	0	0
頻尿	1 (2.6)	0	0	0
腎仙痛	0	1 (2.4)	0	1 (1.2)
腎不全	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	1 (2.6)	3 (7.3)	0	3 (3.7)
生殖系および乳房障害				
女性生殖器瘻	1 (2.6)	0	0	0
生殖器嚢胞	0	1 (2.4)	0	1 (1.2)
卵巣嚢胞	0	1 (2.4)	0	1 (1.2)
骨盤痛	0	0	1 (2.4)	1 (1.2)
腟分泌物	0	1 (2.4)	0	1 (1.2)
外陰腟乾燥	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	1 (2.6)	2 (4.9)	1 (2.4)	3 (3.7)
呼吸器、胸郭および縦隔障害				
咳嗽	4 (10.3)	1 (2.4)	0	1 (1.2)
労作性呼吸困難	0	1 (2.4)	0	1 (1.2)
鼻出血	0	1 (2.4)	0	1 (1.2)
口腔咽頭痛	1 (2.6)	2 (4.9)	1 (2.4)	3 (3.7)
胸水	1 (2.6)	0	0	0
気胸	1 (2.6)	0	0	0
Subjects with one or more events	6 (15.4)	5 (12.2)	1 (2.4)	6 (7.3)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
皮膚および皮下組織障害				
ざ瘡	0	1 (2.4)	0	1 (1.2)
脱毛症	2 (5.1)	0	1 (2.4)	1 (1.2)
ざ瘡様皮膚炎	0	1 (2.4)	0	1 (1.2)
乾癬様皮膚炎	0	0	1 (2.4)	1 (1.2)
皮膚乾燥	0	0	1 (2.4)	1 (1.2)
湿疹	1 (2.6)	2 (4.9)	0	2 (2.4)
結節性紅斑	1 (2.6)	0	0	0
多汗症	0	1 (2.4)	1 (2.4)	2 (2.4)
斑	0	0	1 (2.4)	1 (1.2)
痒疹	0	1 (2.4)	0	1 (1.2)
そう痒症	0	0	1 (2.4)	1 (1.2)
乾癬	1 (2.6)	0	1 (2.4)	1 (1.2)
膿疱性乾癬	0	0	1 (2.4)	1 (1.2)
発疹	0	2 (4.9)	1 (2.4)	3 (3.7)
丘疹性皮疹	0	1 (2.4)	0	1 (1.2)
皮膚剥脱	0	1 (2.4)	0	1 (1.2)
皮膚病変	0	1 (2.4)	0	1 (1.2)
乾皮症	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	5 (12.8)	10 (24.4)	8 (19.5)	18 (22.0)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.1

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
血管障害				
深部静脈血栓症	1 (2.6)	0	0	0
血腫	0	0	1 (2.4)	1 (1.2)
ほてり	1 (2.6)	0	0	0
高血圧	0	1 (2.4)	0	1 (1.2)
低血圧	0	1 (2.4)	1 (2.4)	2 (2.4)
起立性低血圧	0	1 (2.4)	0	1 (1.2)
末梢冷感	1 (2.6)	0	0	0
血栓性静脈炎	0	0	1 (2.4)	1 (1.2)
Subjects with one or more events	3 (7.7)	3 (7.3)	2 (4.9)	5 (6.1)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

表6

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RISANKIZUMAB (CROHN'S)
STUDY M15-993
R&D/17/0073 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 14

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
Any adverse event	101 (87.8)
血液およびリンパ系障害	
貧血	6 (5.2)
内出血発生の増加傾向	1 (0.9)
鉄欠乏性貧血	1 (0.9)
リンパ節痛	1 (0.9)
正色素性正球性貧血	1 (0.9)
脾腫	1 (0.9)
Subjects with one or more events	11 (9.6)
心臓障害	
期外収縮	1 (0.9)
動悸	4 (3.5)
洞性徐脈	1 (0.9)
Subjects with one or more events	5 (4.3)
耳および迷路障害	
耳痛	4 (3.5)
乗物酔い	2 (1.7)
突発性難聴	1 (0.9)
耳鳴	3 (2.6)
回転性めまい	2 (1.7)
Subjects with one or more events	10 (8.7)
内分泌障害	
クッシング様症状	2 (1.7)
Subjects with one or more events	2 (1.7)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
眼障害	
一過性失明	1 (0.9)
複視	1 (0.9)
上強膜炎	1 (0.9)
眼刺激	1 (0.9)
流涙増加	1 (0.9)
ぶどう膜炎	1 (0.9)
霧視	2 (1.7)
視力低下	1 (0.9)
Subjects with one or more events	8 (7.0)
胃腸障害	
腹部膨満	3 (2.6)
腹部腫瘤	1 (0.9)
腹痛	21 (18.3)
下腹部痛	4 (3.5)
上腹部痛	8 (7.0)
腹部圧痛	2 (1.7)
裂肛	1 (0.9)
肛門そう痒症	1 (0.9)
口腔灼熱感症候群	1 (0.9)
慢性胃炎	1 (0.9)
便秘	4 (3.5)
クローン病	11 (9.6)
便意切迫	1 (0.9)
下痢	9 (7.8)
排便障害	1 (0.9)
鼓腸	2 (1.7)
食中毒	1 (0.9)
胃炎	2 (1.7)
胃腸出血	1 (0.9)
胃腸音異常	1 (0.9)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
胃腸障害 (Cont.)	
胃腸毒性	1 (0.9)
歯肉痛	1 (0.9)
血便排泄	4 (3.5)
痔核	2 (1.7)
胃酸過多	1 (0.9)
回腸狭窄	2 (1.7)
腸閉塞	3 (2.6)
腸管穿孔	2 (1.7)
口唇乾燥	1 (0.9)
悪心	18 (15.7)
嚥下痛	1 (0.9)
食道炎	2 (1.7)
肛門周囲痛	3 (2.6)
直腸分泌物	1 (0.9)
直腸しぶり	1 (0.9)
流涎過多	1 (0.9)
小腸閉塞	3 (2.6)
舌潰瘍	1 (0.9)
歯の磨耗	1 (0.9)
歯痛	3 (2.6)
嘔吐	11 (9.6)
Subjects with one or more events	63 (54.8)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
一般・全身障害および投与部位の状態	
無力症	9 (7.8)
胸部不快感	1 (0.9)
胸痛	2 (1.7)
悪寒	1 (0.9)
状態悪化	1 (0.9)
不快感	1 (0.9)
疾患進行	1 (0.9)
疲労	8 (7.0)
全身健康状態低下	1 (0.9)
全身性浮腫	1 (0.9)
炎症	1 (0.9)
インフルエンザ様疾患	3 (2.6)
注射部位紅斑	2 (1.7)
注射部位疼痛	1 (0.9)
倦怠感	7 (6.1)
粘膜変色	1 (0.9)
末梢性浮腫	4 (3.5)
疼痛	1 (0.9)
発熱	15 (13.0)
恥骨上痛	1 (0.9)
Subjects with one or more events	43 (37.4)
肝胆道系障害	
自己免疫性肝炎	1 (0.9)
胆石症	1 (0.9)
肝線維症	1 (0.9)
脂肪肝	2 (1.7)
Subjects with one or more events	2 (1.7)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
免疫系障害	
節足動物刺傷アレルギー	1 (0.9)
過敏症	1 (0.9)
Subjects with one or more events	2 (1.7)
感染症および寄生虫症	
肛門膿瘍	4 (3.5)
虫垂炎	1 (0.9)
無症候性細菌尿	2 (1.7)
細菌尿	1 (0.9)
気管支炎	2 (1.7)
膀胱炎	1 (0.9)
硬結性紅斑	1 (0.9)
皮膚真菌感染	1 (0.9)
胃腸炎	5 (4.3)
消化管感染	1 (0.9)
歯肉炎	1 (0.9)
ヘリコバクター性胃炎	1 (0.9)
単純ヘルペス	1 (0.9)
切開部位膿瘍	1 (0.9)
咬傷感染	1 (0.9)
インフルエンザ	5 (4.3)
下気道感染	1 (0.9)
乳腺炎	1 (0.9)
鼻咽頭炎	18 (15.7)
口腔カンジダ症	3 (2.6)
口腔ヘルペス	2 (1.7)
骨髄炎	1 (0.9)
中耳炎	2 (1.7)
咽頭炎	2 (1.7)
レンサ球菌性咽頭炎	1 (0.9)
肺炎	1 (0.9)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
感染症および寄生虫症 (Cont.)	
膿尿	1 (0.9)
膿疱性皮疹	1 (0.9)
気道感染	2 (1.7)
鼻炎	1 (0.9)
副鼻腔炎	7 (6.1)
扁桃炎	1 (0.9)
歯膿瘍	3 (2.6)
歯感染	2 (1.7)
上気道感染	4 (3.5)
尿路感染	5 (4.3)
腟感染	1 (0.9)
ウイルス感染	1 (0.9)
外陰部腟カンジダ症	1 (0.9)
外陰腟真菌感染	1 (0.9)
Subjects with one or more events	61 (53.0)
傷害、中毒および処置合併症	
眼挫傷	1 (0.9)
転倒	2 (1.7)
骨折	1 (0.9)
手骨折	2 (1.7)
瘢痕ヘルニア	1 (0.9)
注入に伴う反応	4 (3.5)
半月板損傷	1 (0.9)
肉離れ	1 (0.9)
橈骨神経損傷	1 (0.9)
肋骨骨折	1 (0.9)
Subjects with one or more events	14 (12.2)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
臨床検査	
アラニンアミノトランスフェラーゼ増加	2 (1.7)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.7)
血中クレアチンホスホキナーゼ増加	1 (0.9)
血中マグネシウム減少	1 (0.9)
腎クレアチニン・クリアランス減少	1 (0.9)
便中カルプロテクチン増加	2 (1.7)
γ－グルタミルトランスフェラーゼ増加	2 (1.7)
肝酵素上昇	1 (0.9)
国際標準比増加	1 (0.9)
リパーゼ増加	1 (0.9)
肝機能検査異常	1 (0.9)
低比重リポ蛋白減少	1 (0.9)
リンパ節触知	1 (0.9)
血清フェリチン減少	1 (0.9)
トランスフェリン増加	1 (0.9)
ビタミンD減少	1 (0.9)
体重減少	3 (2.6)
体重増加	2 (1.7)
尿中白血球	1 (0.9)
Subjects with one or more events	20 (17.4)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
代謝および栄養障害	
食欲減退	3 (2.6)
脱水	1 (0.9)
糖尿病	1 (0.9)
体液貯留	1 (0.9)
高血糖	2 (1.7)
低カリウム血症	3 (2.6)
低ナトリウム血症	1 (0.9)
低リン酸血症	2 (1.7)
鉄欠乏	1 (0.9)
栄養障害	2 (1.7)
代謝性アシドーシス	1 (0.9)
ビタミンD欠乏	2 (1.7)
Subjects with one or more events	15 (13.0)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
筋骨格系および結合組織障害	
関節痛	25 (21.7)
関節炎	2 (1.7)
背部痛	9 (7.8)
外骨腫	1 (0.9)
側腹部痛	2 (1.7)
単径部痛	2 (1.7)
椎間板突出	1 (0.9)
関節腫脹	1 (0.9)
筋痙縮	1 (0.9)
筋骨格系胸痛	1 (0.9)
筋骨格硬直	2 (1.7)
筋肉痛	4 (3.5)
頚部痛	2 (1.7)
変形性関節症	1 (0.9)
骨減少症	2 (1.7)
四肢痛	4 (3.5)
脊椎痛	1 (0.9)
滑膜炎	2 (1.7)
腱鞘炎	1 (0.9)
弾発指	1 (0.9)
Subjects with one or more events	46 (40.0)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	
皮膚乳頭腫	1 (0.9)
Subjects with one or more events	1 (0.9)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
神経系障害	
反射消失	1 (0.9)
脳脊髄液漏	1 (0.9)
浮動性めまい	9 (7.8)
異常感覚	1 (0.9)
味覚異常	2 (1.7)
頭痛	23 (20.0)
不全片麻痺	1 (0.9)
感覚鈍麻	2 (1.7)
嗜眠	2 (1.7)
片頭痛	3 (2.6)
前兆を伴う片頭痛	1 (0.9)
末梢性ニューロパチー	1 (0.9)
錯感覚	2 (1.7)
失神寸前の状態	1 (0.9)
下肢静止不能症候群	1 (0.9)
坐骨神経痛	2 (1.7)
失神	1 (0.9)
Subjects with one or more events	35 (30.4)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
精神障害	
不安	1 (0.9)
うつ病	2 (1.7)
不眠症	6 (5.2)
易刺激性	1 (0.9)
気分変化	1 (0.9)
神経過敏	1 (0.9)
悪夢	1 (0.9)
パニック発作	1 (0.9)
精神的機能代償不全	1 (0.9)
睡眠障害	1 (0.9)
自殺企図	1 (0.9)
Subjects with one or more events	14 (12.2)
腎および尿路障害	
急性腎障害	1 (0.9)
慢性糸球体腎炎	1 (0.9)
血尿	1 (0.9)
腎結石症	1 (0.9)
頻尿	1 (0.9)
腎仙痛	1 (0.9)
腎不全	1 (0.9)
腎臓痛	1 (0.9)
Subjects with one or more events	7 (6.1)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
生殖系および乳房障害	
生殖器嚢胞	1 (0.9)
月経過多	1 (0.9)
卵巣嚢胞	1 (0.9)
骨盤痛	1 (0.9)
腟分泌物	1 (0.9)
外陰腟乾燥	1 (0.9)
Subjects with one or more events	3 (2.6)
呼吸器、胸郭および縦隔障害	
気管支反応性亢進	1 (0.9)
咳嗽	7 (6.1)
呼吸困難	1 (0.9)
労作性呼吸困難	1 (0.9)
鼻出血	1 (0.9)
過換気	1 (0.9)
鼻閉	2 (1.7)
口腔咽頭痛	8 (7.0)
呼吸時疼痛	1 (0.9)
Subjects with one or more events	19 (16.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
皮膚および皮下組織障害	
ざ瘡	4 (3.5)
脱毛症	4 (3.5)
水疱	1 (0.9)
肝斑	1 (0.9)
皮膚炎	1 (0.9)
ざ瘡様皮膚炎	2 (1.7)
乾癬様皮膚炎	1 (0.9)
皮膚乾燥	3 (2.6)
湿疹	4 (3.5)
紅斑	1 (0.9)
結節性紅斑	1 (0.9)
多汗症	3 (2.6)
斑	1 (0.9)
点状出血	1 (0.9)
痒疹	1 (0.9)
そう痒症	5 (4.3)
乾癬	1 (0.9)
膿疱性乾癬	1 (0.9)
発疹	5 (4.3)
丘疹性皮疹	3 (2.6)
そう痒性皮疹	1 (0.9)
脂漏性皮膚炎	1 (0.9)
皮膚剥脱	2 (1.7)
皮膚病変	2 (1.7)
蕁麻疹	1 (0.9)
乾皮症	1 (0.9)
Subjects with one or more events	39 (33.9)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.2.1.4

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
外科および内科処置	
人工流産	1 (0.9)
Subjects with one or more events	1 (0.9)
血管障害	
循環虚脱	1 (0.9)
血腫	1 (0.9)
ほてり	3 (2.6)
高血圧	1 (0.9)
低血圧	4 (3.5)
起立性低血圧	2 (1.7)
蒼白	1 (0.9)
血栓性静脈炎	1 (0.9)
Subjects with one or more events	11 (9.6)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Number and Percentage of Subjects with Reasonable Possibility of Being Related to Study Drug
Treatment-Emergent Adverse Events during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
Any adverse event	7 (17.9)	11 (26.8)	6 (14.6)	17 (20.7)
眼障害				
複視	0	1 (2.4)	0	1 (1.2)
眼瞼浮腫	1 (2.6)	0	0	0
流涙増加	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	1 (2.6)	2 (4.9)	0	2 (2.4)
胃腸障害				
クローン病	2 (5.1)	0	0	0
悪心	0	2 (4.9)	0	2 (2.4)
Subjects with one or more events	2 (5.1)	2 (4.9)	0	2 (2.4)
一般・全身障害および投与部位の状態				
無力症	0	1 (2.4)	0	1 (1.2)
胸部不快感	1 (2.6)	0	0	0
インフルエンザ様疾患	0	1 (2.4)	0	1 (1.2)
末梢腫脹	1 (2.6)	0	0	0
Subjects with one or more events	2 (5.1)	2 (4.9)	0	2 (2.4)
感染症および寄生虫症				
骨髄炎	0	0	1 (2.4)	1 (1.2)
膿疱性皮疹	1 (2.6)	0	0	0
尿路感染	0	0	1 (2.4)	1 (1.2)
Subjects with one or more events	1 (2.6)	0	2 (4.9)	2 (2.4)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Number and Percentage of Subjects with Reasonable Possibility of Being Related to Study Drug
Treatment-Emergent Adverse Events during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
傷害、中毒および処置合併症				
注入に伴う反応	2 (5.1)	1 (2.4)	0	1 (1.2)
Subjects with one or more events	2 (5.1)	1 (2.4)	0	1 (1.2)
筋骨格系および結合組織障害				
関節痛	0	0	2 (4.9)	2 (2.4)
筋肉痛	1 (2.6)	1 (2.4)	0	1 (1.2)
頚部痛	0	0	1 (2.4)	1 (1.2)
Subjects with one or more events	1 (2.6)	1 (2.4)	2 (4.9)	3 (3.7)
神経系障害				
浮動性めまい	0	0	1 (2.4)	1 (1.2)
味覚異常	0	1 (2.4)	0	1 (1.2)
頭痛	1 (2.6)	2 (4.9)	1 (2.4)	3 (3.7)
嗜眠	1 (2.6)	0	0	0
片頭痛	1 (2.6)	0	0	0
Subjects with one or more events	3 (7.7)	3 (7.3)	1 (2.4)	4 (4.9)
呼吸器、胸郭および縦隔障害				
咳嗽	1 (2.6)	0	0	0
口腔咽頭痛	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	1 (2.6)	1 (2.4)	0	1 (1.2)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Number and Percentage of Subjects with Reasonable Possibility of Being Related to Study Drug
Treatment-Emergent Adverse Events during Double-Blind Intravenous Therapy Period
by Primary MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class MedDRA 19.1 Preferred Term	Placebo (N=39) n (%)	Risankizumab 200 mg IV (N=41) n (%)	Risankizumab 600 mg IV (N=41) n (%)	Risankizumab 200 + 600mg IV (N=82) n (%)
皮膚および皮下組織障害				
皮膚乾燥	0	0	1 (2.4)	1 (1.2)
多汗症	0	1 (2.4)	0	1 (1.2)
乾癬	0	0	1 (2.4)	1 (1.2)
膿疱性乾癬	0	0	1 (2.4)	1 (1.2)
発疹	0	1 (2.4)	1 (2.4)	2 (2.4)
皮膚剥脱	0	1 (2.4)	0	1 (1.2)
乾皮症	0	1 (2.4)	0	1 (1.2)
Subjects with one or more events	0	4 (9.8)	4 (9.8)	8 (9.8)
血管障害				
ほてり	1 (2.6)	0	0	0
Subjects with one or more events	1 (2.6)	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events during double-blind intravenous period are defined as events that begin or worsen during this period, and within 105 days after the last dose of the study drug if subject discontinued treatment in this period.

Program Source Code: [redacted]

表8

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RISANKIZUMAB (CROHN'S)
STUDY M15-993
R&D/17/0073 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 4

TABLE 14.3__1.6.4

Number and Percentage of Subjects with Reasonable Possibility of Being Related to Study Drug
Treatment-Emergent Adverse Events during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
Any adverse event	40 (34.8)
耳および迷路障害	
乗物酔い	1 (0.9)
Subjects with one or more events	1 (0.9)
眼障害	
複視	1 (0.9)
流涙増加	1 (0.9)
Subjects with one or more events	2 (1.7)
胃腸障害	
クローン病	2 (1.7)
鼓腸	1 (0.9)
悪心	2 (1.7)
Subjects with one or more events	5 (4.3)
一般・全身障害および投与部位の状態	
無力症	1 (0.9)
疲労	1 (0.9)
インフルエンザ様疾患	1 (0.9)
注射部位紅斑	2 (1.7)
注射部位疼痛	1 (0.9)
発熱	1 (0.9)
Subjects with one or more events	5 (4.3)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.6.4

Number and Percentage of Subjects with Reasonable Possibility of Being Related to Study Drug
Treatment-Emergent Adverse Events during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
感染症および寄生虫症	
肛門膿瘍	1 (0.9)
歯肉炎	1 (0.9)
切開部位膿瘍	1 (0.9)
口腔ヘルペス	1 (0.9)
骨髄炎	1 (0.9)
中耳炎	1 (0.9)
歯感染	1 (0.9)
尿路感染	1 (0.9)
Subjects with one or more events	8 (7.0)
傷害、中毒および処置合併症	
注入に伴う反応	2 (1.7)
Subjects with one or more events	2 (1.7)
臨床検査	
アラニンアミノトランスフェラーゼ増加	2 (1.7)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.7)
γ－グルタミルトランスフェラーゼ増加	1 (0.9)
肝機能検査異常	1 (0.9)
Subjects with one or more events	3 (2.6)
筋骨格系および結合組織障害	
関節痛	3 (2.6)
筋肉痛	1 (0.9)
頚部痛	1 (0.9)
変形性関節症	1 (0.9)
Subjects with one or more events	5 (4.3)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]

TABLE 14.3__1.6.4

Number and Percentage of Subjects with Reasonable Possibility of Being Related to Study Drug
Treatment-Emergent Adverse Events during the Administration of Risankizumab
by Primary MedDRA System Organ Class and Preferred Term
(Subjects Who Received at Least One Dose of Risankizumab)

System Organ Class MedDRA 19.1 Preferred Term	Risankizumab (N=115) n (%)
神経系障害	
浮動性めまい	3 (2.6)
味覚異常	1 (0.9)
頭痛	7 (6.1)
Subjects with one or more events	9 (7.8)
精神障害	
神経過敏	1 (0.9)
Subjects with one or more events	1 (0.9)
呼吸器、胸郭および縦隔障害	
口腔咽頭痛	2 (1.7)
Subjects with one or more events	2 (1.7)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total. Treatment-emergent adverse events are defined as events that begin or worsen either on or after the first dose of the study medication, and within 105 days after the last dose of the study drug.

Program Source Code: [redacted]