3.1.1 血液学的検査

血液学的検査の測定値及びベースラインからの変化量については、SP0982 試験総括報告書（5.3.5.1.1）Table 12.1 に示した。PBO 群及び LCM 群共に血液学的検査項目の平均値は、試験期間を通しておおむね想定される範囲内であった。全体的に、血液学的検査項目の平均値又は中央値に、治験薬の投与に起因すると考えられる一貫した又は臨床的に重要な変化は認められなかった。

血液学的検査項目のベースラインからベースライン後の最大値のシフトテーブルの被験者の割合は PBO 群と LCM 群でおおむね同程度であった。血液学的検査項目のうち、ヘモグロビン、ヘマトクリット、血小板数、赤血球数、好塩基球数、好塩基球、好酸球数、リンパ球数及び好中球数では、PBO 群又は LCM 群のいずれもベースラインからベースライン後の最大値に悪化が認められた被験者の割合は 5%以下と低かった。いずれかの投与群において 5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最大値が基準範囲より高値になった血液学的検査項目は、白血球数（PBO 群 8.3%及び LCM 群 5.8%、以下同順）、好酸球（15.7%及び 10.7%）、リンパ球（15.7%及び 10.7%）、単球数（10.7%及び 7.4%）、単球（13.2%及び 12.4%）及び好中球（15.7%及び 16.5%）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 12.2］。

血液学的検査項目のベースラインからベースライン後の最小値のシフトテーブルの被験者の割合は PBO 群と LCM 群でおおむね同程度であった。血液学的検査項目のうち、血小板数、好塩基球数、好塩基球、好酸球数、好酸球、リンパ球数、単球数及び単球では、PBO 群又は LCM 群のいずれもベースラインからベースライン後の最小値に悪化が認められた被験者の割合は 5%以下と低かった。いずれかの投与群において 5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最小値が基準範囲より低値になった血液学的検査項目は、ヘモグロビン（PBO 群 5.8%及び LCM 群 4.1%、以下同順）、ヘマトクリット（10.7%及び 9.9%）、赤血球数（各 6.6%）、白血球数（13.2%及び 14.0%）、リンパ球（18.2%及び 16.5%）、好中球数（9.1%及び 8.3%）及び好中球（各 11.6%）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 12.3］。

治験薬投与開始後に血液学的検査の顕著な異常値に該当した被験者は少なく、PBO 群と LCM 群でおおむね同程度であった。治験薬投与開始後（治療期間のいずれかの来院時）に血液学的検査の顕著な異常値が報告された項目は、ヘモグロビン（PBO 群及び LCM 群各 1 例）、ヘマトクリット（PBO 群 1 例及び LCM 群 2 例）、血小板数（PBO 群 3 例）、赤血球数（PBO 群 2 例及び LCM 群 1 例）、白血球数（PBO 群 2 例及び LCM 群 1 例）、好酸球数（LCM 群 1 例）、好酸球（PBO 群 3 例及び LCM 群 4 例）、リンパ球数（PBO 群 5 例）、単球（PBO 群及び LCM 群各 1 例）及び好中球数（PBO 群 3 例及び LCM 群 4 例）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 12.4］。

治験薬投与開始後に米国国立がん研究所-共通毒性規準（NCI CTC）グレード 2 以上の血液学的検査値に該当した被験者は少なく、PBO 群と LCM 群でおおむね同程度であった。報告された NCI CTC グレード 2 以上の血液学的検査値のほとんどは、1 時点のみで認められた。治療期間のいずれかの来院時に NCI CTC グレード 2 以上の血液学的検査値が報告された項目は、ヘモグロビン（グレード 2：LCM 群 1 例、グレード 3：PBO 群 1 例）、血小板数（グレード 2：PBO 群 2 例）、白血球数（グレード 2：PBO 群 2 例及び LCM 群 1 例）、リンパ球数（グレード 2：PBO 群 2 例）及び好中球数（グレード 2：PBO 群及び LCM 群各 4 例）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 12.7］。

来院時別の NCI CTC グレード 2 以上の血液学的検査値の発現率に意味のある傾向は認められなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 12.6］。

血液学的検査値異常に関連する有害事象を投与群別に表 3-1 に示した。

表 3-1　血液学的検査値異常に関連する有害事象［SP0982 試験（SS）］

MedDRA v16.1 SOC PT	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All study participants N=242 n (%) [#]
血液およびリンパ系障害	1 (0.8) [1]	2 (1.7) [2]	3 (1.2) [3]
好酸球増加症	0	1 (0.8) [1]	1 (0.4) [1]
鉄欠乏性貧血	0	1 (0.8) [1]	1 (0.4) [1]
白血球減少症	1 (0.8) [1]	0	1 (0.4) [1]
臨床検査	11 (9.1) [21]	9 (7.4) [12]	20 (8.3) [33]
好酸球数増加	1 (0.8) [1]	1 (0.8) [1]	2 (0.8) [2]
リンパ球数減少	1 (0.8) [1]	0	1 (0.4) [1]
白血球数減少	1 (0.8) [1]	0	1 (0.4) [1]

AE=adverse event; LCM=lacosamide; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SOC=system organ class; SS=Safety Set; TEAE=treatment-emergent adverse event

Note: n=number of study participants reporting at least 1 TEAE within the SOC/PT.

Note: Percentages were based on the number of study participants in the SS.

Note: [#] is the number of individual occurrences of the TEAE.

Note: Treatment-emergent AEs shown in the table were selected based on the topic of concern and do not necessarily include all PTs within an SOC.

Data source: SP0982 CSR Table 11.2.1.1

血液学的検査の異常値に関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。PBO 群及び LCM 群の各 1 例に認められた好酸球数増加を除いて血液学的検査の異常値に関連する有害事象はいずれも 1 例のみの発現であった。

3.1.2　血液生化学検査

PBO 群及び LCM 群共に、血液生化学検査及び内分泌検査項目の平均値は、試験期間を通してほとんどが想定される範囲内であった。全体的に、血液生化学検査及び内分泌検査項目の平均値又は中央値に、治験薬の投与に起因すると考えられる一貫した又は臨床的に重要な変化は認められなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 13.1 及び Table 14.1］。

血液生化学検査項目のベースラインからベースライン後の最大値のシフトテーブルの被験者の割合は PBO 群と LCM 群でおおむね同程度であった。血液生化学検査項目のうち、カルシウム、クレアチニン、ビリルビン、グルコース、アルブミン、総蛋白、甲状腺刺激ホルモン、トリヨードサイロニン、遊離トリヨードサイロニン、サイロキシン及び遊離サイロキシンでは、PBO 群又は LCM 群のいずれもベースラインからベースライン後の最大値に悪化が認められた被験者の割合は 5%以下と低かった。いずれかの投与群において 5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最大値が基準範囲より高値になった血液生化学検査項目は、リン／リン酸塩（PBO 群 9.9%及び LCM 群 12.4%、以下同順）、ナトリウム（9.1%及び 7.4%）、カリウム

（8.3%及び 15.7%）、クロール（12.4%及び 11.6%）、重炭酸塩（5.1%及び 2.6%）、尿素窒素（各 5.8%）、AST（15.7%及び 4.1%）、ALT（14.9%及び 14.0%）、ALP（6.6%及び 0.8%）、GGT（5.8%及び 9.1%）及び尿酸（11.6%及び 5.8%）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 13.2］。

血液生化学検査項目のベースラインからベースライン後の最小値のシフトテーブルの被験者の割合は PBO 群と LCM 群でおおむね同程度であった。血液生化学検査項目のうち、ナトリウム、カリウム、クロール、ALT、ALP、GGT、グルコース、アルブミン、総蛋白、尿酸、甲状腺刺激ホルモン、トリヨードサイロニン、遊離トリヨードサイロニン、サイロキシン及び遊離サイロキシンでは、PBO 群及び LCM 群のいずれもベースラインからベースライン後の最小値に悪化が認められた被験者の割合は 5%以下と低かった。いずれかの投与群において 5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最小値が基準範囲より低値になった血液生化学検査項目は、カルシウム（PBO 群 9.9%及び LCM 群 9.1%、以下同順）、リン／リン酸塩（5.8%及び 6.6%）、重炭酸塩（9.4%及び 5.2%）、クレアチニン（6.6%及び 7.4%）、尿素窒素（8.3%及び 10.7%）、AST（各 5.8%）及びビリルビン（22.3%及び 28.9%）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 13.3］。

治験薬投与開始後に血液生化学検査の顕著な異常値に該当した被験者は少なく、PBO 群と LCM 群でおおむね同程度であった。治験薬投与開始後（治療期間のいずれかの来院時）に血液生化学検査の顕著な異常値が報告された項目は、リン／リン酸塩（PBO 群 1 例）、ナトリウム（PBO 群 1 例）、クロール（PBO 群 4 例及び LCM 群 5 例）、重炭酸塩（PBO 群 1 例）、尿酸窒素（LCM 群 1 例）、AST（PBO 群 1 例）、ALT（PBO 群 3 例及び LCM 群 2 例）、ビリルビン（PBO 群 1 例）、GGT（PBO 群及び LCM 群各 2 例）、グルコース（PBO 群 3 例）、尿酸（PBO 群 2 例及び LCM 群 1 例）及びサイロキシン（PBO 群及び LCM 群各 1 例）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 13.4］。

治験薬投与開始後に NCI CTC グレード 2 以上の血液生化学検査値に該当した被験者は少なく、PBO 群と LCM 群でおおむね同程度であった。報告された NCI CTC グレード 2 以上の血液生化学検査値のほとんどは、1 時点のみで認められた。治療期間のいずれかの来院時に NCI CTC グレード 2 以上の血液生化学検査値が報告された項目は、カルシウム（グレード 2：PBO 群及び LCM 群各 1 例）、リン／リン酸塩（グレード 2：PBO 群及び LCM 群各 6 例、グレード 3：PBO 群 1 例）、ナトリウム（グレード 2：PBO 群 1 例）、カリウム（グレード 2：PBO 群 1 例及び LCM 群 2 例）、AST（グレード 2：PBO 群 1 例、グレード 3：PBO 群及び LCM 群各 1 例）、ALT（グレード 2：PBO 群及び LCM 群各 2 例、グレード 3：PBO 群 1 例）、ビリルビン（グレード 2：PBO 群 2 例）、GGT（グレード 2：PBO 群及び LCM 群各 2 例、グレード 3：PBO 群 3 例及び LCM 群 1 例）、グルコース（グレード 2：PBO 群 5 例及び LCM 群 2 例、グレード 3：PBO 群 2 例）及び尿酸（グレード 4：PBO 群 1 例）であった［SP0982 試験総括報告書（5.3.5.1.1）Table 13.7］。

来院時別の NCI CTC グレード 2 以上の血液生化学検査値の発現率に意味のある傾向は認められなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 13.6］。

血液生化学検査値異常に関連する有害事象を投与群別に表 3-2 に示した。

表 3-2 血液生化学検査値異常に関連する有害事象［SP0982 試験（SS）］

MedDRA v16.1 SOC PT	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All study participants N=242 n (%) [#]
臨床検査	11 (9.1) [21]	9 (7.4) [12]	20 (8.3) [33]
アラニンアミノトランスフェラーゼ増加	4 (3.3) [4]	4 (3.3) [4]	8 (3.3) [8]
アスパラギン酸アミノトランスフェラーゼ増加	5 (4.1) [5]	2 (1.7) [2]	7 (2.9) [7]
γ－グルタミルトランスフェラーゼ増加	3 (2.5) [3]	1 (0.8) [1]	4 (1.7) [4]
肝機能検査異常	1 (0.8) [1]	1 (0.8) [1]	2 (0.8) [2]
トランスアミナーゼ上昇	0	1 (0.8) [1]	1 (0.4) [1]
血中ビリルビン増加	2 (1.7) [2]	0	2 (0.8) [2]
代謝および栄養障害	7 (5.8) [7]	3 (2.5) [3]	10 (4.1) [10]
高尿酸血症	0	1 (0.8) [1]	1 (0.4) [1]
高クロール血症	1 (0.8) [1]	0	1 (0.4) [1]
高カリウム血症	1 (0.8) [1]	0	1 (0.4) [1]
高脂血症	1 (0.8) [1]	0	1 (0.4) [1]
高ナトリウム血症	1 (0.8) [1]	0	1 (0.4) [1]

AE=adverse event; LCM=lacosamide; MedDRA=Medical Dictionary for Regulatory Activities; PT=Preferred term; SOC=system organ class; SS=Safety Set; TEAE=treatment-emergent adverse event

Note: n=number of study participants reporting at least 1 TEAE within the SOC/PT.

Note: Percentages were based on the number of study participants in the SS.

Note: [#] is the number of individual occurrences of the TEAE.

Note: Treatment-emergent AEs shown in the table were selected based on the topic of concern and do not necessarily include all PTs within an SOC.

Data source: SP0982 CSR Table 11.2.1.1

血液生化学検査の異常値に関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。最も多く認められた血液生化学検査の異常値に関連する有害事象は、アラニンアミノトランスフェラーゼ増加（8 例、3.3%）であり、次いでアスパラギン酸アミノトランスフェラーゼ増加（7 例、2.9%）及びγ-グルタミルトランスフェラーゼ増加（4 例、1.7%）であった。その他の血液生化学検査の異常値に関連する有害事象は、いずれも 2 例以下の発現であった。

3.2 EP0012 試験

臨床検査値の評価の詳細は、EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）8.13 項に記載し、以下に要約した。

3.2.1 血液学的検査

データカットオフ時点で、ほとんどの血液学的検査項目の平均値は、試験期間を通して基準範囲内であった。被験者数が少ない一部の来院時に基準範囲外の平均値又は中央値が認められたが、これらの変化は臨床的に重要ではないと判断された。全体的に、血液学的検査項目の平均値又は中央

値に、治験薬の投与に起因すると考えられる一貫した又は臨床的に重要な変化は認められなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.1］。

血液学的検査項目のうち、ヘモグロビン、血小板数、赤血球数、好塩基球数、好酸球数及びリンパ球数では、ベースラインからベースライン後の最大値に悪化が認められた被験者の割合は 5%以下と低かった。5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最大値が基準範囲より高値になった血液学的検査項目は、好中球（47 例、19.7%）、リンパ球（40 例、16.7%）、好酸球（37 例、15.5%）、単球（32 例、13.4%）、単球数（29 例、12.1%）、ヘマトクリット（28 例、11.7%）、好塩基球（23 例、9.6%）、白血球数（18 例、7.5%）及び好中球数（13 例、5.4%）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.2］。

血液学的検査項目のうち、血小板数、好塩基球数、好塩基球、好酸球数、好酸球、リンパ球数、単球数及び単球では、ベースラインからベースライン後の最小値に悪化が認められた被験者の割合は 5%以下と低かった。5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最小値が基準範囲より低値になった血液学的検査項目は、リンパ球（51 例、21.3%）、白血球数（35 例、14.6%）、ヘマトクリット（34 例、14.2%）、好中球（28 例、11.7%）、ヘモグロビン（19 例、7.9%）、赤血球数（19 例、7.9%）及び好中球数（16 例、6.7%）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.3］。

治験薬投与開始後（試験期間中のいずれかの来院時）に血液学的検査の顕著な異常値が報告された項目は、ヘモグロビン（2 歳以上 17 歳未満 1 例、17 歳以上 2 例）、ヘマトクリット（2 歳以上 17 歳未満 3 例、17 歳以上 2 例）、赤血球数（2 歳以上 1 例）、白血球数（成人 1 例）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.7］。

コホート別の治験薬投与開始後の血液学的検査の顕著な異常値に意味のある傾向は認められなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.6］。

治験薬投与開始後に NCI CTC グレード 2 以上の血液学的検査値に該当した被験者の割合は、いずれの検査項目でも 2.1%以下と低かった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.4］。治験薬投与開始後に NCI CTC グレード 2 以上の血液学的検査値に該当した被験者は 6 例（12 歳 1 例、17 歳 1 例、18～30 歳 4 例）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 11.5］。

全体的に、いずれの年齢グループでも血液学的検査の異常値に関連する有害事象の発現率は低かった。18 歳以上 65 歳未満では、血液学的検査の異常値に関連する有害事象として、白血球減少症及び貧血が各 3 例（1.6%）、好中球減少症、鉄欠乏性貧血及び白血球数増加が各 2 例（1.1%）、血小板減少症、白血球増加症及びリンパ球減少症が各 1 例（0.5%）に認められた。小児被験者では、血液学的検査の異常値に関連する有害事象として、鉄欠乏性貧血が 12 歳以上 18 歳未満の被験者 1 例（2.8%）に認められた［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 10.2］。

3.2.2 血液生化学検査

データカットオフ時点で、ほとんどの血液生化学検査項目の平均値は、試験期間を通して基準範囲内であった。被験者数が少ない一部の来院時に基準範囲外の平均値又は中央値が認められたが、これらの変化は臨床的に重要ではないと判断された。全体的に、血液生化学検査項目の平均値又は

中央値に、治験薬の投与に起因すると考えられる一貫した又は臨床的に重要な変化は認められなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.1］。

血液生化学検査項目のうち、カルシウム、クレアチニン、ビリルビン、グルコース、アルブミン、総蛋白及び絨毛性性腺刺激ホルモンβでは、ベースラインからベースライン後の最大値に悪化が認められた被験者の割合は 5%以下と低かった。5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最大値が基準範囲より高値になった血液生化学検査項目は、リン／リン酸塩（45 例、18.8%）、ALT（44 例、18.4%）、クロール（37 例、15.5%）、カリウム（32 例、13.4%）、GGT（28 例、11.7%）、AST（26 例、10.9%）、重炭酸塩（22 例、9.5%）、ナトリウム（22 例、9.2%）、尿酸（21 例、8.8%）、尿素窒素（18 例、7.5%）及び ALP（14 例、5.9%）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.2］。

血液生化学検査項目のうち、ナトリウム、カリウム、クロール、ALT、GGT、グルコース、アルブミン、尿酸及び絨毛性性腺刺激ホルモンβでは、ベースラインからベースライン後の最小値に悪化が認められた被験者の割合は 5%以下と低かった。5%超の被験者で、ベースライン値は基準範囲内であったがベースライン後の最小値が基準範囲より低値になった血液学的検査項目は、ビリルビン（71 例、29.7%）、クレアチニン（34 例、14.2%）、尿素窒素（33 例、13.8%）、重炭酸塩（27 例、11.6%）、ALP（21 例、8.8%）、総蛋白（20 例、8.4%）、カルシウム及び AST（各 17 例、7.1%）、並びにリン／リン酸塩（16 例、6.7%）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.3］。

治験薬投与開始後（試験期間中のいずれかの来院時）に血液生化学検査の顕著な異常値が報告された項目は、リン／リン酸塩（17 歳以上 2 例）、ナトリウム（1 ヵ月超 1 例）、カリウム（1 歳以上 1 例）、クロール（1 ヵ月超 14 例）、重炭酸塩（17 歳以上 4 例）、ALT（成人 3 例）、ビリルビン（1 ヵ月超 1 例）、GGT（17 歳以上 4 例）及びグルコース（17 歳以上 6 例）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.7］。

コホート別の治験薬投与開始後の血液生化学検査の顕著な異常値に意味のある傾向は認められなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.6］。

治験薬投与開始後に NCI CTC グレード 2 以上の血液生化学検査値に該当した被験者の割合は、いずれの検査項目でも 5.5%以下と低かった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.4］。治験薬投与開始後に NCI CTC グレード 2 の血液生化学検査値に該当した被験者は 33 例（10 歳及び 17 歳各 1 例、18～59 歳 31 例）、グレード 3 に該当した被験者は 10 例（12 歳 1 例、24～59 歳 9 例）、グレード 4 に該当した被験者は 2 例（38 歳及び 51 歳各 1 例）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.5］。グレード 2 に該当した被験者が多かった項目は、リン／リン酸塩（15 件、すべて成人）、グルコース（10 件、すべて成人）及び GGT（6 件、すべて成人）であった。グレード 3 に該当した被験者が多かった項目は、グルコース（5 件、すべて成人）及び GGT（3 件、すべて成人）であった。グレード 4 に該当した項目は、グルコース及び尿酸（各 1 件、いずれも成人）であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 12.5］。

全体的に、いずれの年齢グループでも血液生化学検査の異常値に関連する有害事象の発現率は低かった。4 歳以上 12 歳未満では、血液生化学検査の異常値に関連する有害事象として、血中アルカリホスファターゼ増加が 1 例（6.3%）に認められた。12 歳以上 18 歳未満では、アラニンアミノトランスフェラーゼ増加が 2 例（5.6%）に認められた。18 歳以上 65 歳未満では、γ-グルタミルト

ランスフェラーゼ増加が 6 例（3.2%）、アラニンアミノトランスフェラーゼ増加が 3 例（1.6%）、並びにアスパラギン酸アミノトランスフェラーゼ増加、血中クレアチンホスホキナーゼ増加、血中ブドウ糖増加及び血中尿酸増加が各 1 例（0.5%）に認められた［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 10.2］。

3.3 SP0961 試験

臨床検査値の評価の詳細は、SP0961 試験総括報告書（5.3.5.2.2）8.12 項に記載し、以下に要約した。

3.3.1 血液学的検査

全体的に、血液学的検査項目の中央値は基準範囲内であり［SP0961 試験総括報告書（5.3.5.2.2）Listing 7.1.1］、ベースラインからの変化量は臨床的に重要な意味を持つものではなかった。

治療期間に血液学的検査の顕著な異常値が 3 例報告された［SP0961 試験総括報告書（5.3.5.2.2）Table 11.6.1］。2 例（被験者番号[redacted] 及び[redacted]）は白血球数低値（3.0 g/L 以下）で、1 例（被験者番号[redacted]）は好酸球数高値（1.0 g/L 以上）及び好酸球高値（10%以上）に該当した。好中球数低値（1.5 g/L 未満）及び白血球数高値（16.0 g/L 以上）に該当した被験者はいなかった。

血液学的検査の異常値に関連する有害事象は、白血球増加症及び好中球増加症（各 1 例、2.0%）のみであった［SP0961 試験総括報告書（5.3.5.2.2）Table 9.2.1］。

3.3.2 血液生化学検査

全体的に、血液生化学検査項目の中央値は基準範囲内であり［SP0961 試験総括報告書（5.3.5.2.2）Listing 7.2.1］、ベースラインからの変化量は臨床的に重要な意味を持つものではなかった。

治療期間に血液生化学検査の顕著な異常値が 4 例報告された［SP0961 試験総括報告書（5.3.5.2.2）Table 11.8.1］。2 例（被験者番号[redacted] 及び[redacted]）はグルコース低値（2.78 mmol/L 未満）、1 例（被験者番号[redacted]）は GGT 高値（基準範囲上限値の 3 倍以上）及び 1 例（被験者番号[redacted]）はクロール高値（112 mmol/L 以上）に該当した。

血液生化学検査の異常値に関連する有害事象は、アラニン・アミノトランスフェラーゼ増加及び低カリウム血症（各 1 例、2.0%）であった［SP0961 試験総括報告書（5.3.5.2.2）Table 9.2.1］。

3.4 SP0962 試験

臨床検査値の評価の詳細は、SP0962 試験総括報告書（5.3.5.2.3）8.3.1.1 項に記載し、以下に要約した。

3.4.1 血液学的検査

全体的に、血液学的検査項目の測定値は基準範囲内であり［SP0962 試験総括報告書（5.3.5.2.3）Listing 6.1.1］、ベースラインからの変化量は臨床的に重要な意味を持つものではなかった。

治療期間中に血液学的検査の顕著な異常値は報告されなかった［SP0962 試験総括報告書（5.3.5.2.3）Table 11.5.1 及び Table 11.5.2］。

血液学的検査の異常値に関連する有害事象は、好酸球数異常（1 例、2.6%）のみであった［SP0962 試験総括報告書（5.3.5.2.3）Table 10.2.1］。

3.4.2 血液生化学検査

全体的に、血液生化学検査項目の測定値は基準範囲内であり［SP0962 試験総括報告書（5.3.5.2.3）Listing 6.2.1］、ベースラインからの変化量は臨床的に重要な意味を持つものではなかった。

最も多く報告された血液生化学検査の顕著な異常値は、GGT 高値（基準範囲上限値の 3 倍以上）で 5 例（13.5%）が該当した。次いでクロール高値（112 mmol/L 以上）で 2 例（5.6%）が該当した。その他の血液生化学検査の顕著な異常値に該当した被験者の割合は 5%以下であった［SP0962 試験総括報告書（5.3.5.2.3）Table 11.6.1］。

1 回以上の顕著な GGT 高値が報告された 5 例のうち、4 例は高値が認められたのは 1 回のみであったが、1 例は第 3 回来院及び最終の規定来院に顕著な高値が認められた［SP0962 試験総括報告書（5.3.5.2.3）Table 11.6.2 及び Listing 6.6.1］。顕著なクロール高値が認められた 2 例は、いずれも高値が認められたのは 1 回のみであった。顕著な ALT 高値（基準範囲上限値の 10 倍以上）及び AST 高値（基準範囲上限値の 3 倍以上）が 1 例（被験者番号[redacted]）に認められたが、いずれも最終の規定来院に 1 回のみであった。本被験者は、LCM の最終投与 14 日後に A 型肝炎抗体陽性の判定を受けたが、治験薬との因果関係は否定された［SP0962 試験総括報告書（5.3.5.2.3）Listing 5.4.1］。

血液生化学検査の異常値に関連する有害事象は、アラニン・アミノトランスフェラーゼ増加、アスパラギン酸アミノトランスフェラーゼ増加及びγ-グルタミルトランスフェラーゼ増加（各 2 例、5.1%）、並びに血中アルカリホスファターゼ増加及び血中カルシウム減少（各 1 例、2.6%）であった［SP0962 試験総括報告書（5.3.5.2.3）Table 10.2.1］。

3.5 臨床検査値のまとめ

臨床検査の安全性評価では、併合データ（Pool SGTC-1 及び Pool SGTC-2）の解析は行わず、各試験（第 III 相試験である SP0982 試験及び EP0012 試験、第 II 相試験である SP0961 試験及び SP0962 試験）の結果を示した。

SP0982 試験では、PBO 群及び LCM 群共に血液学的検査項目の平均値は、試験期間を通しておおむね想定される範囲内であった。全体的に、血液学的検査項目の平均値又は中央値に、治験薬の投与に起因すると考えられる一貫した又は臨床的に重要な変化は認められなかった。一部の例外を除いて、PBO 群及び LCM 群のいずれも血液学的検査項目及び血液生化学検査項目のベースラインからベースライン後の最大値又は最小値に悪化が認められた被験者の割合は 5%以下と低かった。

治験薬投与開始後の顕著な異常値、又は NCI CTC グレード 2 以上の血液学的検査値若しくは血液生化学検査値に該当する被験者は少なく、PBO 群と LCM 群でおおむね同程度であった。来院時別の NCI CTC グレード 2 以上の血液学的検査値又は血液生化学検査値の発現率に意味のある傾向は認められなかった。血液学的検査の異常値に関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。PBO 群及び LCM 群の各 1 例に認められた好酸球数増加を除いて血液学的検査の異常値に関連する有害事象はいずれも 1 例のみの発現であった。血液生化学検査の異常値に関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。最も多く認められた血液生化学検査の異常値に関連する有害事象は、アラニンアミノトランスフェラーゼ増加（8 例、3.3%）であり、次いでアスパラギン酸アミノトランスフェラーゼ増加（7 例、2.9%）及びγ-グルタミルトランスフェラーゼ増加（4 例、1.7%）であった。その他の血液生化学検査の異常値に関連する有害事象は、いずれも 2 例以下の発現であった。

EP0012 試験では、データカットオフ時点で、ほとんどの血液学的検査項目及び血液生化学検査項目の平均値は基準範囲内であった。一部の例外を除いて血液学的検査項目及び血液生化学検査項目のベースラインからベースライン後の最大値又は最小値に悪化が認められた被験者の割合は 5%以下と低かった。治験薬投与開始後に血液学的検査の顕著な異常値が 10 例に、血液生化学検査の顕著な異常値が 36 例に報告された。コホート別の治験薬投与開始後の血液学的検査及び血液生化学検査の顕著な異常値に意味のある傾向は認められなかった。全体的に、治験薬投与開始後に NCI CTC グレード 2 以上の血液学的検査値又は血液生化学検査値に該当する被験者の割合はいずれの検査項目でも 2.1%以下又は 5.5%以下と低かった。全体的に、血液学的検査又は血液生化学検査の異常値に関連する有害事象の発現率は低かった。

SP0961 試験では、全体的に、血液学的検査項目及び血液生化学検査項目の中央値は基準範囲内であり、ベースラインからの変化量は臨床的に重要な意味を持つものではなかった。治療期間に血液学的検査の顕著な異常値が 3 例、血液生化学検査の顕著な異常値が 4 例報告された。血液学的検査の異常値に関連する有害事象は、白血球増加症及び好中球増加症（各 1 例、2.0%）であった。血液生化学検査の異常値に関連する有害事象は、アラニン・アミノトランスフェラーゼ増加及び低カリウム血症（各 1 例、2.0%）であった。

SP0962 試験では、全体的に、血液学的検査項目及び血液生化学検査項目の測定値は基準範囲内であり、ベースラインからの変化量は臨床的に重要な意味を持つものではなかった。治療期間に血液学的検査の顕著な異常値が報告された被験者はいなかった。最も多く報告された血液生化学検査の顕著な異常値は、GGT 高値（基準範囲上限値の 3 倍以上）が 5 例（13.5%）であり、次いでクロール高値（112 mmol/L 以上）が 2 例（5.6%）であった。その他の血液生化学検査の顕著な異常値に該当した被験者の割合は 5%以下であった。血液学的検査の異常値に関連する有害事象は、好酸球数異常（1 例、2.6%）のみであった。血液生化学検査の異常値に関連する有害事象は、アラニン・アミノトランスフェラーゼ増加、アスパラギン酸アミノトランスフェラーゼ増加及びγ-グルタミルトランスフェラーゼ増加（各 2 例、5.1%）、血中アルカリホスファターゼ増加及び血中カルシウム減少（各 1 例、2.6%）であった。

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

4.1 バイタルサイン及び身体的所見

Pool SGTC-1 及び Pool SGTC-2 については、バイタルサイン及び安全性に関連する他の観察項目の解析を行わなかった。各試験の総括報告書のデータを基に、バイタルサイン及び安全性に関連する他の観察項目の結果を要約した。

4.1.1 SP0982 試験

全被験者の収縮期血圧、拡張期血圧、脈拍数、体重、身長、BMI の平均値及び中央値は、ベースライン及びベースライン後のすべての測定時において想定される範囲内であった。いずれのバイタルサインの検査項目も、LCM の投与後に一貫した又は臨床的に重要なベースラインからの変化は認められなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 16.1］。

バイタルサインに関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。最も多く認められたバイタルサインに関連する有害事象は、高血圧（4 例、1.7%）であり、次いで発熱及び体重減少（各 2 例、0.8%）であった。その他のバイタルサインに関連する有害事象はいずれも 1 例のみの発現であった［SP0982 試験総括報告書（5.3.5.1.1）Table 10-14］。

全体的に、神経学的検査の結果は、ほとんどの被験者でベースラインから最終来院時まで変化がなく安定していた。LCM 群の 1 例（0.8%）に小脳機能検査項目（歩行又は粗大運動）で、正常から異常への臨床的に重要な変化が認められた。ベースラインから最終来院時までに認められた正常から異常への変化に意味のある傾向は認められなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 18.1］。

臨床的に重要な身体所見は有害事象として報告された（2.1.2.1 項）。

4.1.2 EP0012 試験

全被験者の収縮期血圧、拡張期血圧、脈拍数、体重、身長、BMI の平均値及び中央値は、ベースライン及びベースライン後のすべての測定時において想定される範囲内であった。被験者数が少ない（1 例以下）一部の来院時に基準範囲外の平均値が認められたが、いずれのバイタルサインの検査項目も、LCM の投与後に一貫した又は臨床的に重要なベースラインからの変化は認められなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 15.1］。

4.1.3 SP0961 試験

バイタルサイン（脈拍数、収縮期血圧、拡張期血圧）、体重、身体所見及び神経学的検査の評価で、臨床的に重要な所見は認められなかった［SP0961 試験総括報告書（5.3.5.2.2）Table 12.1.1 及び Table 14.1.1］。

全体的に、神経学的検査の結果は、ほとんどの被験者でベースラインから最終来院時まで変化がなく安定していた。ベースラインで正常であったが最終来院時に臨床的に重要な異常が認められた被験者はいなかった［SP0961 試験総括報告書（5.3.5.2.2）8.14.2 項］。

4.1.4 SP0962 試験

ベースラインから第 5 回来院までのバイタルサイン又は体重の変化量の中央値に臨床的に重要な傾向は認められなかった［SP0962 試験総括報告書（5.3.5.2.3）Table 12.1.1］。

いずれの来院時もバイタルサインが異常値の基準に該当した被験者はいなかった［SP0962 試験総括報告書（5.3.5.2.3）Table 12.2.1 及び Table 12.2.2］。バイタルサインに関連する有害事象は認められなかった。体重に関連する有害事象として体重増加（4 例、10.3%）のみ認められた［SP0962 試験総括報告書（5.3.5.2.3）Table 10.2.1］。

4.2 安全性に関連する他の観察項目

4.2.1 SP0982 試験

4.2.1.1 12 誘導心電図

12 誘導心電図では、全被験者及び小児／成人被験者のいずれの結果も、PR 間隔の変化量（平均値）を除いてベースラインから最終来院時までの変化量（平均値及び中央値）は小さかった。PR 間隔の変化量（平均値）は PBO 群が−0.79 msec 及び LCM 群が 9.96 msec であった。これは既知の LCM の安全性プロファイルと一致した。12 誘導心電図のベースラインから最終来院時までの変化量（平均値及び中央値）は臨床的に重要な意味を持つものではなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 17.2］。

12 誘導心電図の異常所見に関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。多く認められた 12 誘導心電図の異常所見に関連する有害事象は、洞性徐脈及び右脚ブロック（各 2 例、0.8%）であった。その他の 12 誘導心電図の異常所見に関連する有害事象はいずれも 1 例のみの発現であった［SP0982 試験総括報告書（5.3.5.1.1）Table 10-16］。

4.2.1.2 自殺の評価

PBO 群では 1 例で維持期間中（57 日目）にコロンビア自殺評価スケール（C-SSRS）の回答が陽性（質問 4 又は質問 5 に「はい」と回答）であった。本被験者は「計画性のない自殺念慮」に該当した。本被験者には試験期間中、その他に C-SSRS で陽性の回答はなかった。本被験者は、有害事象としてうつ病（正確な発現時期は不明）が認められた。うつ病は、非重篤な有害事象で、重症度は高度、治験薬との因果関係は否定された。うつ病は試験期間中に消失せず、治験薬の投与中止に至った［SP0982 試験総括報告書（5.3.5.1.1）Listing 7.2 及び Listing 9.7］。

LCM 群では治療期間中に C-SSRS の回答が陽性の被験者はいなかった［SP0982 試験総括報告書（5.3.5.1.1）Listing 9.7］。治療期間中に LCM 群の 2 例に自殺念慮の有害事象が認められた。

4.2.2 EP0012 試験

4.2.2.1 12 誘導心電図

データカットオフ時点で、すべての測定時において、すべての 12 誘導心電図の測定値、QT、QTcB 及び QTcF のベースラインからの変化量（平均値及び中央値）は小さかった。12 誘導心電図の評価項目ではベースラインからの変化は小さく、臨床的に重要な意味を持つものではなかった。

ベースライン後のすべての測定時において、LCM の投与後に QT、QTcB 及び QTcF が延長する徴候は認められなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Listing 9.3］。

全被験者及び年齢グループ別のいずれもすべての測定時において、すべての 12 誘導心電図の評価項目でベースラインからの変化量（平均値及び中央値）は小さかった。いずれの 12 誘導心電図の評価項目でも LCM の投与後に臨床的に重要なベースラインからの変化は認められなかった。

治験薬投与開始後の顕著な異常値が、第 1 回来院に 1/38 例（2.6%）、第 8 回来院に 60/173 例（34.7%）、第 11 回来院に 41/109 例（37.6%）、最終来院に 78/238 例（32.8%）に認められた［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 16.3］。

4.2.2.2 自殺の評価

データカットオフ時点で、ベースラインの C-SSRS の回答が陽性（質問 4 又は質問 5 に「はい」と回答）であった被験者は 3 例であった。2 例に自殺関連の有害事象が認められたが、C-SSRS では自殺企図の報告はなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Listing 9.7］。

4.2.3 SP0961 試験

その他の安全性評価項目の詳細は、SP0961 試験総括報告書（5.3.5.2.2）8.12.4 項及び 8.12.5 項に記載した。

4.2.3.1 12 誘導心電図

ベースラインの 12 誘導心電図の所見は、多くの被験者が正常であった。12 誘導心電図で臨床的に重要と判断された異常所見及び有害事象と判断された異常所見は認められなかった。治療期間中に臨床的に重要な 12 誘導心電図の異常所見が認められた被験者はいなかった。

4.2.4 SP0962 試験

4.2.4.1 12 誘導心電図

治験薬投与開始後の 12 誘導心電図で臨床的に重要な所見は認められなかった［SP0962 試験総括報告書（5.3.5.2.3）Table 13.1.1］。

4.2.4.2 自殺の評価

試験期間中に C-SSRS で自殺念慮が 2 例報告された［SP0962 試験総括報告書（5.3.5.2.3）Listing 10.1.1］。いずれの被験者も「前回の来院以降」用 C-SSRS の回答が陽性（質問 4 又は質問 5 に「はい」と回答）で示される実際の自殺念慮は認められず、中止基準による治験中止には該当しなかった。

4.3 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のまとめ

バイタルサイン、身体所見及び安全性に関連する他の観察項目では、併合データ（Pool SGTC-1 及び Pool SGTC-2）の解析は行わず、各試験（第 III 相試験である SP0982 試験及び EP0012 試験、第 II 相試験である SP0961 試験及び SP0962 試験）の結果を示した。

いずれの試験でも、LCM の投与による収縮期血圧、拡張期血圧、脈拍数、体重、身長、BMI への影響は少なかった。例外として、SP0982 試験では高血圧（4 例、1.7%）、発熱及び体重減少（各 2 例、0.8%）が、SP0962 試験では体重増加（4 例、10.3%）が認められた。

いずれの試験でも、神経学的検査及び身体所見に意味のある傾向は認められなかった。

SP0982 試験では、12 誘導心電図のベースラインから最終来院時までの変化量（平均値及び中央値）は臨床的に重要な意味を持つものではなかった。12 誘導心電図の異常所見に関連する有害事象の発現率は低く、PBO 群と LCM 群でおおむね同程度であった。多く認められた 12 誘導心電図の異常所見に関連する有害事象は洞性徐脈及び右脚ブロック（各 2 例、0.8%）であった。その他の 12 誘導心電図の異常所見に関連する有害事象はいずれも 1 例のみの発現であった。

EP0012 試験では、12 誘導心電図のベースラインからの変化量（平均値及び中央値）は臨床的に重要な意味を持つものではなかった。ベースライン後のすべての測定時において、LCM の投与後に QT、QTcB 及び QTcF が延長する徴候は認められず、いずれの 12 誘導心電図の評価項目も LCM の投与後に臨床的に重要なベースラインからの変化量（平均値及び中央値）は認められなかった。治験薬投与開始後の顕著な 12 誘導心電図の異常値が報告されたが、いずれの来院時も被験者の割合は同程度であった。

SP0961 試験及び SP0962 試験では、12 誘導心電図の所見に安全性上の懸念事項は認められなかった。

SP0961 試験以外のすべての試験で自殺の評価が行われた。SP0982 試験では、治療期間中に PBO 群の 1 例が C-SSRS の回答が陽性（質問 4 又は質問 5 に「はい」と回答）であった。LCM 群では C-SSRS の回答が陽性の被験者はいなかった。治療期間中に LCM 群の 2 例に自殺念慮の有害事象が認められた。EP0012 試験では、1 例に自殺念慮の有害事象が認められた。SP0962 試験では、C-SSRS で自殺念慮が 2 例報告された。いずれの被験者も「前回の来院以降」用 C-SSRS の回答が陽性（質問 4 又は質問 5 に「はい」と回答）で示される実際の自殺念慮は認められず、中止基準による治験中止には該当しなかった。

5. 特別な患者集団及び状況下における安全性

5.1 内因性要因

5.1.1 小児被験者における安全性

強直間代発作を有する小児被験者への LCM の影響については、SP0982 試験総括報告書（5.3.5.1.1）10.2.1 項、10.2.2 項、10.2.2.1 項、10.2.6 項、10.4 項、10.5 項、10.9.3.1 項、10.9.3.2 項、10.10.1.1 項、10.10.2.1 項、10.11.1.2 項、10.11.1.3 項、10.11.4 項及び 10.11.6 項に記載した。SP0982 試験では、有害事象、重篤な有害事象、治験薬の投与中止に至った有害事象、治験薬との因果関係が否定できない有害事象、高度の有害事象の発現率は、いずれの年齢グループも PBO 群と LCM 群で同程度又は PBO 群と比較して LCM 群で高かった。試験期間中の有害事象の発現率は、4 歳以上 12 歳未満（17 例）、12 歳以上 18 歳未満（32 例）及び 18 歳以上 65 歳未満（191

例）で、それぞれ 52.9%、87.5%及び 71.7%であった（以下同順）。重篤な有害事象の発現率はそれぞれ 0%、6.3%及び 5.2%であった。治験薬の投与中止に至った有害事象の発現率はそれぞれ 0%、3.1%及び 7.3%であった。治験薬との因果関係が否定できない有害事象の発現率はそれぞれ 5.9%、43.8%及び 42.9%であった。高度の有害事象の発現率はそれぞれ 0%、6.3%及び 3.1%であった。なお、65 歳以上の被験者は 2 例で、PBO 群及び LCM 群各 1 例であった。65 歳以上では被験者数が少なかったため、他の年齢グループとの有害事象の比較は行わなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 11.1.2］。

EP0012 試験での強直間代発作を有する小児被験者における LCM の長期安全性については 5.1.1.1 項に示した。

5.1.1.1 EP0012 試験–SP0982 試験のベースライン時の年齢グループ別の有害事象

有害事象の概要を年齢グループ別に表 5-1 に示した。

表 5-1 有害事象の概要［EP0012 試験（SS）］

	Baseline age in SP0982 (years)				All study participants
Category	≥4 to <12 N=16 n (%) [#]	≥12 to <18 N=36 n (%) [#]	≥18 to <65 N=186 n (%) [#]	≥65 N=1 n (%) [#]	N=239 n (%) [#]
Any TEAEs	10 (62.5) [56]	31 (86.1) [148]	155 (83.3) [890]	1 (100) [3]	197 (82.4) [1097]
Serious TEAEs	2 (12.5) [5]	8 (22.2) [12]	28 (15.1) [48]	0	38 (15.9) [65]
Study participant discontinuations due to TEAEs	0	2 (5.6) [2]	7 (3.8) [15]	1 (100) [1]	10 (4.2) [18]
Drug-related TEAEs	3 (18.8) [6]	11 (30.6) [24]	68 (36.6) [164]	1 (100) [2]	83 (34.7) [196]
Severe TEAEs	1 (6.3) [1]	3 (8.3) [7]	21 (11.3) [38]	1 (100) [1]	26 (10.9) [47]
All Deaths	0	0	0	0	0
Deaths (TEAEs leading to Death)	0	0	0	0	0

AE=adverse event; SS=Safety Set; TEAE=treatment-emergent adverse event

Note: n=number of study participants reporting at least one TEAE in that category.

Note: Percentages were based on the number of study participants in the SS.

Note: [#] was the number of individual occurrences of the TEAE in that category.

Note: An AE with missing intensity was treated as severe; an AE with missing drug relationship was treated as related.

Data source: EP0012 2nd interim CSR Table 10.1

有害事象の発現率は SP0982 試験のベースラインの年齢グループ別に比較した。年齢グループ別の有害事象の発現率は、12 歳以上 18 歳未満（86.1%）と 18 歳以上 65 歳未満（83.3%）で同程度であり、4 歳以上 12 歳未満（62.5%）でわずかに低かった。

重篤な有害事象の発現率はいずれの年齢グループでもおおむね同程度であり、4 歳以上 12 歳未満で 2 例（12.5%）、12 歳以上 18 歳未満で 8 例（22.2%）及び 18 歳以上 65 歳未満で 28 例（15.1%）に認められた。

治験薬の投与中止に至った有害事象の発現率はいずれの年齢グループでも低く、12 歳以上 18 歳未満で 2 例（5.6%）及び 18 歳以上 65 歳未満で 7 例（3.8%）に認められた。4 歳以上 12 歳未満では治験薬の投与中止に至った有害事象は認められなかった。

治験薬との因果関係が否定できない有害事象の年齢グループ別の発現率は、12 歳以上 18 歳未満［11 例（30.6%）］と 18 歳以上 65 歳未満［68 例（36.6%）］で同程度であり、4 歳以上 12 歳未満［3 例（18.8%）］でわずかに低かった。

高度の有害事象の発現率はいずれの年齢グループでも低く、4 歳以上 12 歳未満で 1 例（6.3%）、12 歳以上 18 歳未満で 3 例（8.3%）及び 18 歳以上 65 歳未満で 21 例（11.3%）に認められた。

EP0012 試験での年齢グループ別の有害事象は、EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 10.2 に示し、以下に要約した。

最も多く認められた有害事象（SOC）は神経系障害（121 例、50.6%）であり、次いで感染症および寄生虫症（104 例、43.5%）、傷害、中毒および処置合併症（66 例、27.6%）及び胃腸障害（53 例、22.2%）であった。精神障害（29 例、12.1%）の発現率は低かった。最も多く認められた有害事象（PT）は、鼻咽頭炎（47 例、19.7%）であり、次いで頭痛（44 例、18.4%）、浮動性めまい（35 例、14.6%）、傾眠（25 例、10.5%）、大発作痙攣、インフルエンザ、悪心及び嘔吐（各 17 例、7.1%）、挫傷及び回転性めまい（各 16 例、6.7%）、上気道感染及び下痢（各 14 例、5.9%）、並びに背部痛（13 例、5.4%）であった。精神障害の SOC で認められた PT の発現率は低かった（全被験者で 3%未満）。

回転性めまい（16 例、6.7%）及び複視（8 例、3.3%）は高頻度で中枢神経系と関連している有害事象であり、本治験の対象集団で予想される有害事象であった。挫傷等の損傷（16 例、6.7%）は痙攣発作に関連している可能性が考えられる。自殺念慮及び自殺企図（各 1 例、0.4%）の発現率は低かった。

4 歳以上 12 歳未満では、最も多く認められた有害事象（SOC）は感染症および寄生虫症（6 例、37.5%）、次いで神経系障害（4 例、25.0%）であった。最も多く認められた有害事象（PT）は鼻咽頭炎（5 例、31.3%）であり、次いで傾眠（3 例、18.8%）であった。

12 歳以上 18 歳未満では、最も多く認められた有害事象（SOC）は感染症および寄生虫症（19 例、52.8%）であり、次いで神経系障害（18 例、50.0%）、胃腸障害（12 例、33.3%）及び傷害、中毒および処置合併症（9 例、25.0%）であった。最も多く認められた有害事象（PT）は鼻咽頭炎（10 例、27.8%）であり、次いで嘔吐（6 例、16.7%）、挫傷、浮動性めまい及び頭痛（各 5 例、13.9%）、並びに傾眠及び悪心（各 4 例、11.1%）であった。

18 歳以上 65 歳未満では、最も多く認められた有害事象（SOC）は神経系障害（98 例、52.7%）であり、次いで感染症および寄生虫症（79 例、42.5%）、傷害、中毒および処置合併症（54 例、29.0%）及び胃腸障害（39 例、21.0%）であった。最も多く認められた有害事象（PT）は頭痛（37 例、19.9%）であり、次いで鼻咽頭炎（32 例、17.2%）及び浮動性めまい（29 例、15.6%）であった。

65 歳以上では、1 例（100%）に神経系障害の SOC で 3 件の有害事象（平衡障害 2 件及び健忘 1 件）が認められた。

5.1.1.2 EP0012 試験–タナー分類による評価

データカットオフ時点で、治療の最初の 2 年間におけるタナー分類の評価項目のベースラインから最終来院時までの変化量は、女性（30 例）及び男性（21 例）共に小さかった。いずれの変化量もベースラインから最終来院時にかけて高くなっており、対象となる年齢グループから予想される結果であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 17.1］。治療の 2 年超～5 年間におけるタナー分類の評価項目のベースラインから最終来院時までの変化量は、女性（12 例）及び男性（7 例）共に小さかった。いずれの変化量もベースラインから最終来院時にかけて高くなっており、対象となる年齢グループから予想される結果であった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 17.2］。治療の最初の 2 年間又は 2 年超～5 年間にタナー分類の評価の変化量が低くなった被験者はいなかった［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 17.1 及び Table 17.2］。

5.1.2 日本人集団における安全性

強直間代発作を有する日本人集団における LCM の安全性を評価するため、SP0982 試験の安全性データは本邦の治験実施医療機関で登録された被験者について個別に解析した。SP0982 試験の日本人集団の安全性データを以下に要約した。

5.1.2.1 SP0982 試験の日本人集団の被験者の内訳

SP0982 試験では日本人被験者 30 例が無作為化され、19 例が PBO 群、11 例が LCM 群に割り付けられた。このうち、29 例（96.7%）が本治験を完了した［完了例：PBO 群 18 例（94.7%）、LCM 群 11 例（100%）］。PBO 群の 1 例が本治験を中止した。中止理由はその他（過度の強直間代発作による早期中止）であった。

5.1.2.2 SP0982 試験の日本人集団の人口統計学的特性及びベースラインの疾患特性

日本人集団の年齢の平均値（標準偏差）は PBO 群で 25.21 歳（10.84 歳）、LCM 群で 19.55 歳（3.42 歳）であった。4 歳以上 12 歳未満では LCM 群に割り付けられた日本人被験者はいなかった。日本人集団の 30 例中 13 例（43.3%）が男性であった。体重、身長及び BMI の平均値が全集団と比較して日本人集団でわずかに低かったことを除いて、人口統計学的特性は全集団と日本人集団でおおむね同様であった。

日本人集団の Combined ベースライン期間の 28 日あたりの強直間代発作回数の中央値は、PBO 群が 1.51 回（範囲：0.8～19.4）、LCM 群が 1.23 回（範囲：0.8～6.8 回）であった。発症年齢の中央値は PBO 群が 12.11 歳、LCM 群が 12.81 歳であり、罹病期間の中央値は PBO 群が 13.20 年、LCM 群が 6.20 年であった。

日本人集団の 30 例すべてが全般発作の既往があり、PBO 群及び LCM 群共に最も多かった発作型は強直間代発作［PBO 群 19 例（100%）及び LCM 群 11 例（100%）］であった。部分発作又は分類不能のてんかん発作の発作型を有する日本人被験者はいなかった。

5.1.2.3 SP0982 試験の日本人集団の曝露状況

日本人集団では PBO 群 19 例及び LCM 群 11 例が治験薬を投与された。治療期間の曝露期間の中央値は、PBO 群が 45.0 日（範囲：30.0～171.0 日）、LCM 群が 169.0 日（範囲：60.0～170.0 日）であった。

PBO 群及び LCM 群共に、ほとんどの日本人被験者が最頻投与量（維持期間に被験者が最も長い期間投与された 1 日投与量）である 400 mg/日を投与された［PBO 群 7/8 例（87.5%）及び LCM 群 7/10 例（70.0%）］。

5.1.2.4 SP0982 試験の日本人集団の有害事象の概要

日本人集団で報告された有害事象のプロファイルは、全集団と同様であった。日本人集団では治療期間に有害事象が 24 例（80.0%）に認められ、PBO 群 13 例（68.4%）及び LCM 群 11 例（100%）であった。日本人集団で最も多く認められた有害事象は傾眠（9 例、30.0%）であり、次いで挫傷及び鼻咽頭炎（各 4 例、13.3%）、腹痛、便秘及び背部痛（各 3 例、10.0%）であった。PBO 群で最も多く認められた有害事象は傾眠（4 例、21.1%）であり、次いで挫傷（3 例、15.8%）、洞性徐脈、便秘、背部痛及び体位性めまい（各 2 例、10.5%）であった。LCM 群で最も多く認められた有害事象は傾眠（5 例、45.5%）であり、次いで鼻咽頭炎（3 例、27.3%）、腹痛及び悪心（各 2 例、18.2%）であった。年齢グループ別の有害事象の発現率は、4 歳以上 12 歳未満（0 例）及び 65 歳以上（0 例）で 0%、12 歳以上 18 歳未満（6 例）及び 18 歳以上 65 歳未満（18 例）で 85.7%であった。

日本人集団では治験薬との因果関係が否定できない有害事象は、PBO 群で 6 例（31.6%）、LCM 群で 7 例（63.6%）に認められた。PBO 群で最も多く認められた因果関係が否定できない有害事象は傾眠（4 例、21.1%）であり、次いで便秘（2 例、10.5%）であった。LCM 群で最も多く認められた因果関係が否定できない有害事象は傾眠（5 例、45.5%）であった。いずれの投与群もその他の事象は 1 例のみの発現であった。

日本人集団で治験薬との因果関係が否定できない有害事象として報告された傾眠の発現率は、PBO 群（21.1%）と比較して LCM 群（45.5%）で高かった。小児／成人被験者別の日本人集団の治験薬との因果関係が否定できない有害事象の発現率は、小児被験者では PBO 群 16.7%及び LCM 群 100%、成人被験者では PBO 群 38.5%及び LCM 群 50.0%であった。

経口液（シロップ）を投与された日本人の小児被験者の有害事象の発現率は、PBO 群で 50.0%（1/2 例）、LCM 群の 4 mg/kg/日以上 8 mg/kg/日未満のグループで 100%（1/1 例）であった。LCM 群の 0 mg/kg/日又は投与量不明、0 mg/kg/日超 4 mg/kg/日未満、8 mg/kg/日以上のグループでは有害事象は認められなかった［SP0982 試験総括報告書（5.3.5.1.1）Table 11.11.1］。

日本人集団では、重篤な有害事象、治験薬の投与中止に至った有害事象、高度の有害事象は認められなかった。

5.1.2.5 SP0982 試験の日本人集団の臨床検査値の評価

日本人集団の血液学的検査の結果と全集団の結果に顕著な差は認められず、PBO 群及び LCM 群共に血液学的検査の異常値に関連する有害事象は認められなかった。

日本人集団の血液生化学検査及び内分泌検査の結果と全集団の結果に顕著な差は認められなかった。日本人集団では、PBO 群の 1 例（5.3%）にアスパラギン酸アミノトランスフェラーゼ増加が、LCM 群の 1 例（9.1%）に高尿酸血症が認められた。いずれの被験者も 18 歳以上 65 歳未満の年齢グループであった。

日本人集団の尿検査の結果と全集団の結果に顕著な差は認められず、尿検査の異常値に関連する有害事象は認められなかった。

5.1.2.6 SP0982 試験の日本人集団のバイタルサイン及び安全性に関連する他の観察項目の評価

全被験者及び年齢グループ別のいずれも日本人集団の収縮期血圧、拡張期血圧、脈拍数、体重、身長、BMI の平均値及び中央値は、ベースライン及びベースライン後のすべての測定時において想定される範囲内であった。いずれのバイタルサインの検査項目も、LCM の投与後に一貫した又は臨床的に重要なベースラインからの変化は認められなかった。日本人集団では、バイタルサインに関連する有害事象として、18 歳以上 65 歳未満の年齢グループで 1 例（3.3%）に発熱が認められた。

全被験者及び小児／成人被験者別でも、日本人集団の 12 誘導心電図のベースラインから最終来院時までの変化量（平均値及び中央値）は小さかった。12 誘導心電図のベースラインから最終来院時までの変化量（平均値及び中央値）は臨床的に重要な意味を持つものではなかった。12 誘導心電図の異常所見に関連する有害事象は PBO 群の 2 例（10.5%）に認められた洞性徐脈のみであった。いずれの被験者も 18 歳以上 65 歳未満の年齢グループであった。

Combined ベースライン期間と比較して治療期間中に新たな発作型が認められた日本人被験者はいなかった。LCM 群の 1 例（20.0%）で Prospective ベースライン期間と比較して治療期間のミオクロニー発作発現日数が 25%以下増加した日本人被験者がいた。本被験者は小児であった。日本人集団で Prospective ベースライン期間と比較して増量期間、治療期間の最初の 12 週間及び 24 週間に欠神発作発現日数が 50%増悪した被験者の割合は、いずれも PBO 群 33.3%（1/3 例）及び LCM 群 0%（0/3 例）であった。

欠神発作発現日数が 50%増悪した PBO 群の日本人被験者は小児であった。増量期間、治療期間の最初の 12 週間及び 24 週間にミオクロニー発作発現日数が 50%増悪した日本人被験者は PBO 群及び LCM 群共にいなかった。治療期間に欠神発作又はミオクロニー発作の有害事象が認められた日本人被験者は PBO 群及び LCM 群共にいなかった。

日本人集団では、治療期間（3 ヵ月ごとの LCM 曝露期間）にてんかんに関連する有害事象は認められなかった。

神経学的検査の結果は、すべての日本人被験者でベースラインから最終来院時まで変化がなく安定していた。いずれの評価時点でも C-SSRS の回答が陽性（質問 4 又は質問 5 に「はい」と回答）であった日本人被験者はいなかった。

5.1.2.7 SP0982 試験の強直間代発作を有する日本人集団の安全性のまとめ

LCM の安全性プロファイルは日本人集団と全集団で同様であった。日本人集団で認められた有害事象の発現率は全集団と同程度であり、いずれも重症度は軽度であった。重篤な有害事象、治験薬の投与中止に至った有害事象、死亡に至った有害事象は認められなかった。治療期間中に新たな発作型が認められた日本人被験者はおらず、Prospective ベースライン期間と比較して治療期間の欠神発作又はミオクロニー発作発現日数が増加した日本人被験者は少なかった（LCM 群の 1 例でミオクロニー発作発現日数が増加）。血液学的検査、血液生化学検査、内分泌検査、尿検査、バイタルサイン、12 誘導心電図及び安全性に関連する他の観察項目の結果は全集団の結果と一致しており、日本人集団で安全性上の新たな懸念事項は認められなかった。

5.2 外因性要因

外因性要因について、強直間代発作における LCM の安全性は解析しなかった。

5.3 薬物相互作用

薬物相互作用に関しては、添付文書 16.7 項に記載した。

本承認申請では、すべての臨床試験で併用薬（抗てんかん薬を含む）の使用が可能であったが、治験薬との因果関係が否定できない薬物相互作用を示唆する有害事象の報告はなかった。強直間代発作を有する被験者において、現行の添付文書情報の他に安全性上の懸念事項は認められなかった。

5.4 妊娠及び授乳時の使用

5.4.1 妊娠

妊娠に関しては、添付文書 9.5 項に記載した。

EP0012 試験［EP0012 試験第 2 回中間解析報告書（5.3.5.2.4）Table 10.2］及び SP0961 試験［SP0961 試験総括報告書（5.3.5.2.2）Listing 7.7.1］では、妊娠の報告はなかった。

SP0982 試験では、1 例が移行期間の最終来院時の尿の妊娠検査が陽性であった。本被験者は、重篤な有害事象として人工流産が報告されており、安全性追跡調査期間の来院時に行ったその後の尿の妊娠検査では陰性であった［SP0982 試験総括報告書（5.3.5.1.1）Listing 7.2 及び Listing 8.4］。

SP0962 試験では、2 例で妊娠が報告された［SP0962 試験総括報告書（5.3.5.2.3）Listing 6.7.1］。

- 被験者番号[redacted] は、31 歳の黒人女性であり、早期中止来院時に尿の妊娠検査及び血清の妊娠検査のいずれも陽性であった。本被験者は、治験薬投与 309 日後に妊娠のため本治験を中止した。妊娠に関連する有害事象は認められなかった。本被験者は健康児を出産した
- 被験者番号[redacted] は、32 歳の白人女性であり、第 3 回来院時に尿の妊娠検査が陽性であった。本被験者は、治験薬投与 67 日後に治験実施計画書からの逸脱のため本治験を中止した。治験薬の最終投与 30 日以上後に有害事象として子癇前症及び早産が認められた。いずれも非重篤な有害事象で、重症度は軽度であり、治験薬との因果関係は否定された。これら

の有害事象により被験者は入院したが、治験責任医師は入院は妊娠及び分娩のための処置であると判断した。分娩後に有害事象は認められず、出産後 3 日で母子は退院した

強直間代発作を有する被験者において、現行の添付文書情報の他に安全性上の懸念事項は認められなかった。

5.4.2 授乳

授乳に関しては、添付文書 9.6 項に記載した。

本承認申請では、授乳に関連する追加の情報はなかった。

5.5 自殺関連

自殺念慮及び自殺行為は、複数の適応症において抗てんかん薬を投与された患者に報告されている。抗てんかん薬の無作為化 PBO 対照試験のメタアナリシスにおいても、自殺念慮及び自殺行為はわずかにリスクが上昇している。自殺に関しては、添付文書 8.4 項及び 15.1 項に記載した。

本承認申請に用いた臨床試験における自殺に関する評価は 4.2 項に示した。強直間代発作を有する被験者において、現行の添付文書情報の他に安全性上の懸念事項は認められなかった。

5.6 過量投与

過量投与に関しては、添付文書 13 項に記載した。

本承認申請に示した曝露データから、LCM の過量投与は認められず、過量投与に関連する有害事象も認められなかった。強直間代発作を有する被験者において、現行の添付文書情報の他に安全性上の懸念事項は認められなかった。

5.7 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

自動車運転及び機械操作に対する影響に関しては、添付文書 8.2 項に記載しており、「本剤投与中の患者には自動車の運転等、危険を伴う機械の操作に従事させないよう注意すること」としている。本承認申請の情報に基づく添付文書の変更は必要なく、強直間代発作を有する被験者において、現行の添付文書情報の他に安全性上の懸念事項は認められなかった。

6. 市販後データ

製造販売後調査結果報告書は M 5.3.6.3 項に添付し、以下に要約した。

2008 年 8 月 29 日から 2019 年 2 月 28 日までに報告された UCB Global Safety database から、製造販売後に LCM が投与された強直間代発作の可能性がある患者に関して 578 例の安全性症例報告を特定した。578 例のうち、281 例は強直間代発作に関連する安全性症例報告で、297 例は強直間代発作ではない安全性症例報告と判断された。

死亡（てんかんにおける突然死を含む）した症例、重要な有害事象（心臓障害、失神及び意識消失、自殺、肝毒性、多臓器過敏症反応及び重度皮膚有害反応、並びに浮動性めまい及び運動失調に

関連する有害事象）及びその他の重要な有害事象（好中球減少症、アナフィラキシー、横紋筋融解症、腎不全及び腎機能障害、並びに傷害、中毒および処置合併症の SOC の有害事象）を発現した症例を包括的にレビューした。その結果、強直間代発作を有するてんかん患者に LCM の投与による特有の安全性上の懸念事項は認められなかった。

LCM を投与された強直間代発作を有する症例のうち、妊娠及び授乳症例、高齢者症例及び小児症例をレビューした。その結果、添付文書に記載された LCM の既知の安全性プロファイルと比較して懸念事項は認められなかった。

薬物乱用、薬効欠如、LCM の静脈内投与及び経口投与、並びに発作の悪化又は新規発症に関連する症例をレビューした。その結果、強直間代発作を有するてんかん患者に LCM の投与による特有の安全性上の懸念事項は認められなかった。

製造販売後調査結果報告書に記載のとおり、強直間代発作を有するてんかん患者への LCM の投与について、関連する文献をレビューした。その結果、他の抗てんかん薬の投与と混同したものの、特有の安全性上の懸念事項は認められなかった。強直間代発作の治療薬として LCM の忍容性は良好であった。文献全般で、強直間代発作を有する被験者に対して LCM の投与は発作回数を減少させることが示されたが、特発性全般てんかん患者に対する LCM の効果を確立するための臨床試験データの必要性が報告された。

以上より、製造販売後に強直間代発作を有するてんかん患者に LCM が投与された症例を解析した結果、新たな安全性上の懸念事項は認められなかった。安全性プロファイルは、添付文書に記載された LCM の既知の安全性プロファイルと一致した。

7. 付録

付録 1. LCM 曝露期間別の有害事象 103

付録 1. LCM 曝露期間別の有害事象

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
Number evaluated	255		255		218		201		164	
Any TEAE	219	(85.9)	180	(70.6)	75	(34.4)	74	(36.8)	42	(25.6)
血液およびリンパ系障害	8	(3.1)	3	(1.2)	2	(0.9)	1	(0.5)	0	
貧血	2	(0.8)	0		0		1	(0.5)	0	
鉄欠乏性貧血	2	(0.8)	1	(0.4)	0		0		0	
白血球減少症	2	(0.8)	1	(0.4)	0		0		0	
好中球減少症	2	(0.8)	1	(0.4)	0		0		0	
好酸球増加症	1	(0.4)	1	(0.4)	0		0		0	
リンパ球減少症	1	(0.4)	0		1	(0.5)	0		0	
血小板減少症	1	(0.4)	0		1	(0.5)	0		0	
心臓障害	12	(4.7)	7	(2.7)	3	(1.4)	2	(1.0)	0	
右脚ブロック	3	(1.2)	1	(0.4)	1	(0.5)	1	(0.5)	0	
第一度房室ブロック	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
動悸	2	(0.8)	1	(0.4)	0		1	(0.5)	0	
洞性頻脈	2	(0.8)	1	(0.4)	1	(0.5)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
Number evaluated	255		147		128		114		97	
Any TEAE	219	(85.9)	31	(21.1)	29	(22.7)	25	(21.9)	14	(14.4)
血液およびリンパ系障害	8	(3.1)	1	(0.7)	0		1	(0.9)	1	(1.0)
貧血	2	(0.8)	0		0		1	(0.9)	0	
鉄欠乏性貧血	2	(0.8)	0		0		0		1	(1.0)
白血球減少症	2	(0.8)	1	(0.7)	0		0		0	
好中球減少症	2	(0.8)	1	(0.7)	0		0		0	
好酸球増加症	1	(0.4)	0		0		0		0	
リンパ球減少症	1	(0.4)	0		0		0		0	
血小板減少症	1	(0.4)	0		0		0		0	
心臓障害	12	(4.7)	0		0		0		0	
右脚ブロック	3	(1.2)	0		0		0		0	
第一度房室ブロック	2	(0.8)	0		0		0		0	
動悸	2	(0.8)	0		0		0		0	
洞性頻脈	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
Number evaluated	255	81	64	46	37
Any TEAE	219 (85.9)	15 (18.5)	9 (14.1)	11 (23.9)	3 (8.1)
血液およびリンパ系障害	8 (3.1)	0	0	0	0
貧血	2 (0.8)	0	0	0	0
鉄欠乏性貧血	2 (0.8)	0	0	0	0
白血球減少症	2 (0.8)	0	0	0	0
好中球減少症	2 (0.8)	0	0	0	0
好酸球増加症	1 (0.4)	0	0	0	0
リンパ球減少症	1 (0.4)	0	0	0	0
血小板減少症	1 (0.4)	0	0	0	0
心臓障害	12 (4.7)	0	0	0	0
右脚ブロック	3 (1.2)	0	0	0	0
第一度房室ブロック	2 (0.8)	0	0	0	0
動悸	2 (0.8)	0	0	0	0
洞性頻脈	2 (0.8)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)		>39 - <=42 n (%)	
Number evaluated	255		12		3	
Any TEAE	219	(85.9)	1	(8.3)	1	(33.3)
血液およびリンパ系障害	8	(3.1)	0		0	
貧血	2	(0.8)	0		0	
鉄欠乏性貧血	2	(0.8)	0		0	
白血球減少症	2	(0.8)	0		0	
好中球減少症	2	(0.8)	0		0	
好酸球増加症	1	(0.4)	0		0	
リンパ球減少症	1	(0.4)	0		0	
血小板減少症	1	(0.4)	0		0	
心臓障害	12	(4.7)	0		0	
右脚ブロック	3	(1.2)	0		0	
第一度房室ブロック	2	(0.8)	0		0	
動悸	2	(0.8)	0		0	
洞性頻脈	2	(0.8)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
心臓障害										
不整脈	1	(0.4)	1	(0.4)	0		0		0	
徐脈	1	(0.4)	1	(0.4)	0		0		0	
洞性徐脈	1	(0.4)	1	(0.4)	0		0		0	
耳および迷路障害	25	(9.8)	16	(6.3)	1	(0.5)	5	(2.5)	2	(1.2)
回転性めまい	23	(9.0)	14	(5.5)	1	(0.5)	4	(2.0)	2	(1.2)
耳痛	1	(0.4)	0		0		1	(0.5)	0	
乗物酔い	1	(0.4)	1	(0.4)	0		0		0	
耳鳴	1	(0.4)	1	(0.4)	0		0		0	
眼障害	23	(9.0)	16	(6.3)	3	(1.4)	1	(0.5)	2	(1.2)
複視	9	(3.5)	5	(2.0)	1	(0.5)	1	(0.5)	1	(0.6)
霧視	7	(2.7)	7	(2.7)	0		0		0	
視力障害	4	(1.6)	1	(0.4)	1	(0.5)	0		1	(0.6)
眼乾燥	1	(0.4)	0		0		0		0	
眼瞼湿疹	1	(0.4)	0		0		0		0	
眼刺激	1	(0.4)	1	(0.4)	0		0		0	
流涙増加	1	(0.4)	1	(0.4)	0		0		0	
変視症	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
心臓障害										
不整脈	1	(0.4)	0		0		0		0	
徐脈	1	(0.4)	0		0		0		0	
洞性徐脈	1	(0.4)	0		0		0		0	
耳および迷路障害	25	(9.8)	0		0		2	(1.8)	0	
回転性めまい	23	(9.0)	0		0		2	(1.8)	0	
耳痛	1	(0.4)	0		0		0		0	
乗物酔い	1	(0.4)	0		0		0		0	
耳鳴	1	(0.4)	0		0		0		0	
眼障害	23	(9.0)	1	(0.7)	1	(0.8)	1	(0.9)	0	
複視	9	(3.5)	1	(0.7)	0		0		0	
霧視	7	(2.7)	0		0		0		0	
視力障害	4	(1.6)	0		1	(0.8)	0		0	
眼乾燥	1	(0.4)	0		0		0		0	
眼瞼湿疹	1	(0.4)	0		0		0		0	
眼刺激	1	(0.4)	0		0		0		0	
流涙増加	1	(0.4)	0		0		0		0	
変視症	1	(0.4)	0		0		1	(0.9)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
			n	(%)	n	(%)	n	(%)	n	(%)
心臓障害										
不整脈	1	(0.4)	0		0		0		0	
徐脈	1	(0.4)	0		0		0		0	
洞性徐脈	1	(0.4)	0		0		0		0	
耳および迷路障害	25	(9.8)	0		0		0		0	
回転性めまい	23	(9.0)	0		0		0		0	
耳痛	1	(0.4)	0		0		0		0	
乗物酔い	1	(0.4)	0		0		0		0	
耳鳴	1	(0.4)	0		0		0		0	
眼障害	23	(9.0)	1	(1.2)	0		1	(2.2)	0	
複視	9	(3.5)	0		0		0		0	
霧視	7	(2.7)	0		0		0		0	
視力障害	4	(1.6)	0		0		0		0	
眼乾燥	1	(0.4)	1	(1.2)	0		0		0	
眼瞼湿疹	1	(0.4)	0		0		1	(2.2)	0	
眼刺激	1	(0.4)	0		0		0		0	
流涙増加	1	(0.4)	0		0		0		0	
変視症	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
心臓障害				
不整脈	1	(0.4)	0	0
徐脈	1	(0.4)	0	0
洞性徐脈	1	(0.4)	0	0
耳および迷路障害	25	(9.8)	0	0
回転性めまい	23	(9.0)	0	0
耳痛	1	(0.4)	0	0
乗物酔い	1	(0.4)	0	0
耳鳴	1	(0.4)	0	0
眼障害	23	(9.0)	0	0
複視	9	(3.5)	0	0
霧視	7	(2.7)	0	0
視力障害	4	(1.6)	0	0
眼乾燥	1	(0.4)	0	0
眼瞼湿疹	1	(0.4)	0	0
眼刺激	1	(0.4)	0	0
流涙増加	1	(0.4)	0	0
変視症	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
眼障害										
視神経乳頭浮腫	1	(0.4)	0		1	(0.5)	0		0	
光視症	1	(0.4)	1	(0.4)	0		0		0	
斜視	1	(0.4)	0		0		0		0	
視力低下	1	(0.4)	0		1	(0.5)	0		0	
胃腸障害	66	(25.9)	39	(15.3)	7	(3.2)	9	(4.5)	5	(3.0)
悪心	24	(9.4)	16	(6.3)	0		5	(2.5)	1	(0.6)
嘔吐	18	(7.1)	9	(3.5)	3	(1.4)	3	(1.5)	1	(0.6)
下痢	14	(5.5)	4	(1.6)	0		1	(0.5)	2	(1.2)
腹痛	7	(2.7)	3	(1.2)	1	(0.5)	0		0	
上腹部痛	4	(1.6)	2	(0.8)	0		0		0	
便秘	4	(1.6)	3	(1.2)	1	(0.5)	0		0	
齲歯	4	(1.6)	2	(0.8)	1	(0.5)	0		0	
口内乾燥	4	(1.6)	4	(1.6)	0		0		0	
胃炎	4	(1.6)	2	(0.8)	1	(0.5)	0		1	(0.6)
腹部不快感	3	(1.2)	1	(0.4)	0		2	(1.0)	0	
下腹部痛	3	(1.2)	2	(0.8)	0		0		0	
口の感覚鈍麻	2	(0.8)	1	(0.4)	0		0		0	
口の錯感覚	2	(0.8)	2	(0.8)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
眼障害										
視神経乳頭浮腫	1	(0.4)	0		0		0		0	
光視症	1	(0.4)	0		0		0		0	
斜視	1	(0.4)	0		0		1	(0.9)	0	
視力低下	1	(0.4)	0		0		0		0	
胃腸障害	66	(25.9)	4	(2.7)	6	(4.7)	1	(0.9)	3	(3.1)
悪心	24	(9.4)	1	(0.7)	0		0		0	
嘔吐	18	(7.1)	0		0		1	(0.9)	0	
下痢	14	(5.5)	2	(1.4)	1	(0.8)	0		2	(2.1)
腹痛	7	(2.7)	0		0		0		1	(1.0)
上腹部痛	4	(1.6)	0		0		1	(0.9)	1	(1.0)
便秘	4	(1.6)	0		0		0		0	
齲歯	4	(1.6)	0		1	(0.8)	0		0	
口内乾燥	4	(1.6)	0		0		0		0	
胃炎	4	(1.6)	0		0		0		0	
腹部不快感	3	(1.2)	0		0		0		0	
下腹部痛	3	(1.2)	0		1	(0.8)	0		0	
口の感覚鈍麻	2	(0.8)	0		1	(0.8)	0		0	
口の錯感覚	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
眼障害										
視神経乳頭浮腫	1	(0.4)	0		0		0		0	
光視症	1	(0.4)	0		0		0		0	
斜視	1	(0.4)	0		0		0		0	
視力低下	1	(0.4)	0		0		0		0	
胃腸障害	66	(25.9)	8	(9.9)	0		0		0	
悪心	24	(9.4)	1	(1.2)	0		0		0	
嘔吐	18	(7.1)	1	(1.2)	0		0		0	
下痢	14	(5.5)	2	(2.5)	0		0		0	
腹痛	7	(2.7)	2	(2.5)	0		0		0	
上腹部痛	4	(1.6)	0		0		0		0	
便秘	4	(1.6)	0		0		0		0	
齲歯	4	(1.6)	0		0		0		0	
口内乾燥	4	(1.6)	0		0		0		0	
胃炎	4	(1.6)	0		0		0		0	
腹部不快感	3	(1.2)	0		0		0		0	
下腹部痛	3	(1.2)	0		0		0		0	
口の感覚鈍麻	2	(0.8)	0		0		0		0	
口の錯感覚	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
眼障害				
視神経乳頭浮腫	1	(0.4)	0	0
光視症	1	(0.4)	0	0
斜視	1	(0.4)	0	0
視力低下	1	(0.4)	0	0
胃腸障害	66	(25.9)	0	0
悪心	24	(9.4)	0	0
嘔吐	18	(7.1)	0	0
下痢	14	(5.5)	0	0
腹痛	7	(2.7)	0	0
上腹部痛	4	(1.6)	0	0
便秘	4	(1.6)	0	0
齲歯	4	(1.6)	0	0
口内乾燥	4	(1.6)	0	0
胃炎	4	(1.6)	0	0
腹部不快感	3	(1.2)	0	0
下腹部痛	3	(1.2)	0	0
口の感覚鈍麻	2	(0.8)	0	0
口の錯感覚	2	(0.8)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
胃腸障害					
口内炎	2 (0.8)	0	0	0	0
口唇炎	1 (0.4)	0	0	0	0
セリアック病	1 (0.4)	0	0	0	0
鼓腸	1 (0.4)	1 (0.4)	0	0	0
胃食道逆流性疾患	1 (0.4)	0	1 (0.5)	0	0
痔核	1 (0.4)	0	0	0	0
歯周病	1 (0.4)	0	0	0	0
レッチング	1 (0.4)	1 (0.4)	0	0	0
小腸穿孔	1 (0.4)	0	0	0	0
舌障害	1 (0.4)	1 (0.4)	0	0	0
埋伏歯	1 (0.4)	0	0	0	0
歯の脱落	1 (0.4)	0	0	0	0
歯痛	1 (0.4)	0	0	0	0
一般・全身障害および投与部位の状態	49 (19.2)	26 (10.2)	5 (2.3)	3 (1.5)	7 (4.3)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
胃腸障害										
口内炎	2	(0.8)	1	(0.7)	1	(0.8)	0		0	
口唇炎	1	(0.4)	0		0		0		0	
セリアック病	1	(0.4)	0		0		0		0	
鼓腸	1	(0.4)	0		0		0		0	
胃食道逆流性疾患	1	(0.4)	0		0		0		0	
痔核	1	(0.4)	0		1	(0.8)	0		0	
歯周病	1	(0.4)	0		1	(0.8)	0		0	
レッチング	1	(0.4)	0		0		0		0	
小腸穿孔	1	(0.4)	0		0		0		0	
舌障害	1	(0.4)	0		0		0		0	
埋伏歯	1	(0.4)	0		1	(0.8)	0		0	
歯の脱落	1	(0.4)	0		0		0		0	
歯痛	1	(0.4)	0		0		0		0	
一般・全身障害および投与部位の状態	49	(19.2)	6	(4.1)	3	(2.3)	1	(0.9)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
胃腸障害										
口内炎	2	(0.8)	0		0		0		0	
口唇炎	1	(0.4)	1	(1.2)	0		0		0	
セリアック病	1	(0.4)	1	(1.2)	0		0		0	
鼓腸	1	(0.4)	0		0		0		0	
胃食道逆流性疾患	1	(0.4)	0		0		0		0	
痔核	1	(0.4)	0		0		0		0	
歯周病	1	(0.4)	0		0		0		0	
レッチング	1	(0.4)	0		0		0		0	
小腸穿孔	1	(0.4)	1	(1.2)	0		0		0	
舌障害	1	(0.4)	0		0		0		0	
埋伏歯	1	(0.4)	0		0		0		0	
歯の脱落	1	(0.4)	1	(1.2)	0		0		0	
歯痛	1	(0.4)	1	(1.2)	0		0		0	
一般・全身障害および投与部位の状態	49	(19.2)	0		1	(1.6)	3	(6.5)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
胃腸障害				
口内炎	2	(0.8)	0	0
口唇炎	1	(0.4)	0	0
セリアック病	1	(0.4)	0	0
鼓腸	1	(0.4)	0	0
胃食道逆流性疾患	1	(0.4)	0	0
痔核	1	(0.4)	0	0
歯周病	1	(0.4)	0	0
レッチング	1	(0.4)	0	0
小腸穿孔	1	(0.4)	0	0
舌障害	1	(0.4)	0	0
埋伏歯	1	(0.4)	0	0
歯の脱落	1	(0.4)	0	0
歯痛	1	(0.4)	0	0
一般・全身障害および投与部位の状態	49	(19.2)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	16	(6.3)	10	(3.9)	1	(0.5)	1	(0.5)	0	
発熱	10	(3.9)	3	(1.2)	3	(1.4)	0		1	(0.6)
易刺激性	6	(2.4)	4	(1.6)	0		1	(0.5)	1	(0.6)
無力症	3	(1.2)	2	(0.8)	0		0		1	(0.6)
悪寒	3	(1.2)	2	(0.8)	0		0		0	
非心臓性胸痛	3	(1.2)	0		0		0		1	(0.6)
評価不能の事象	3	(1.2)	2	(0.8)	0		1	(0.5)	0	
局所腫脹	2	(0.8)	0		0		0		0	
倦怠感	2	(0.8)	2	(0.8)	0		0		0	
胸痛	1	(0.4)	0		0		0		1	(0.6)
活力増進	1	(0.4)	1	(0.4)	0		0		0	
酩酊感	1	(0.4)	1	(0.4)	0		0		0	
熱感	1	(0.4)	1	(0.4)	0		0		0	
歩行障害	1	(0.4)	1	(0.4)	0		0		0	
低体温	1	(0.4)	0		0		0		1	(0.6)
炎症	1	(0.4)	0		0		0		0	
インフルエンザ様疾患	1	(0.4)	1	(0.4)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
			n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	16	(6.3)	2	(1.4)	2	(1.6)	0		0	
発熱	10	(3.9)	1	(0.7)	0		0		0	
易刺激性	6	(2.4)	0		0		0		0	
無力症	3	(1.2)	0		0		0		0	
悪寒	3	(1.2)	1	(0.7)	0		0		0	
非心臓性胸痛	3	(1.2)	0		0		1	(0.9)	0	
評価不能の事象	3	(1.2)	0		0		0		0	
局所腫脹	2	(0.8)	1	(0.7)	0		0		0	
倦怠感	2	(0.8)	0		0		0		0	
胸痛	1	(0.4)	0		0		0		0	
活力増進	1	(0.4)	0		0		0		0	
酩酊感	1	(0.4)	0		0		0		0	
熱感	1	(0.4)	0		0		0		0	
歩行障害	1	(0.4)	0		0		0		0	
低体温	1	(0.4)	0		0		0		0	
炎症	1	(0.4)	0		1	(0.8)	0		0	
インフルエンザ様疾患	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
一般・全身障害および投与部位の状態										
疲労	16	(6.3)	0		0		0		0	
発熱	10	(3.9)	0		0		2	(4.3)	0	
易刺激性	6	(2.4)	0		0		0		0	
無力症	3	(1.2)	0		0		0		0	
悪寒	3	(1.2)	0		0		0		0	
非心臓性胸痛	3	(1.2)	0		1	(1.6)	0		0	
評価不能の事象	3	(1.2)	0		0		0		0	
局所腫脹	2	(0.8)	0		0		1	(2.2)	0	
倦怠感	2	(0.8)	0		0		0		0	
胸痛	1	(0.4)	0		0		0		0	
活力増進	1	(0.4)	0		0		0		0	
酩酊感	1	(0.4)	0		0		0		0	
熱感	1	(0.4)	0		0		0		0	
歩行障害	1	(0.4)	0		0		0		0	
低体温	1	(0.4)	0		0		0		0	
炎症	1	(0.4)	0		0		0		0	
インフルエンザ様疾患	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
一般・全身障害および投与部位の状態				
疲労	16	(6.3)	0	0
発熱	10	(3.9)	0	0
易刺激性	6	(2.4)	0	0
無力症	3	(1.2)	0	0
悪寒	3	(1.2)	0	0
非心臓性胸痛	3	(1.2)	0	0
評価不能の事象	3	(1.2)	0	0
局所腫脹	2	(0.8)	0	0
倦怠感	2	(0.8)	0	0
胸痛	1	(0.4)	0	0
活力増進	1	(0.4)	0	0
酩酊感	1	(0.4)	0	0
熱感	1	(0.4)	0	0
歩行障害	1	(0.4)	0	0
低体温	1	(0.4)	0	0
炎症	1	(0.4)	0	0
インフルエンザ様疾患	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
粘膜びらん	1	(0.4)	0		0		0		1	(0.6)
末梢性浮腫	1	(0.4)	0		1	(0.5)	0		0	
疼痛	1	(0.4)	0		0		0		0	
口渇	1	(0.4)	1	(0.4)	0		0		0	
肝胆道系障害	2	(0.8)	1	(0.4)	0		0		0	
脂肪肝	2	(0.8)	1	(0.4)	0		0		0	
免疫系障害	4	(1.6)	1	(0.4)	1	(0.5)	0		0	
季節性アレルギー	2	(0.8)	0		1	(0.5)	0		0	
薬物過敏症	1	(0.4)	0		0		0		0	
過敏症	1	(0.4)	1	(0.4)	0		0		0	
感染症および寄生虫症	105	(41.2)	47	(18.4)	22	(10.1)	21	(10.4)	20	(12.2)
鼻咽頭炎	43	(16.9)	15	(5.9)	8	(3.7)	8	(4.0)	7	(4.3)
上気道感染	17	(6.7)	8	(3.1)	1	(0.5)	4	(2.0)	2	(1.2)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
粘膜びらん	1	(0.4)	0		0		0		0	
末梢性浮腫	1	(0.4)	0		0		0		0	
疼痛	1	(0.4)	1	(0.7)	0		0		0	
口渇	1	(0.4)	0		0		0		0	
肝胆道系障害	2	(0.8)	0		1	(0.8)	0		0	
脂肪肝	2	(0.8)	0		1	(0.8)	0		0	
免疫系障害	4	(1.6)	0		0		0		0	
季節性アレルギー	2	(0.8)	0		0		0		0	
薬物過敏症	1	(0.4)	0		0		0		0	
過敏症	1	(0.4)	0		0		0		0	
感染症および寄生虫症	105	(41.2)	8	(5.4)	4	(3.1)	7	(6.1)	1	(1.0)
鼻咽頭炎	43	(16.9)	1	(0.7)	1	(0.8)	0		0	
上気道感染	17	(6.7)	2	(1.4)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
粘膜びらん	1	(0.4)	0		0		0		0	
末梢性浮腫	1	(0.4)	0		0		0		0	
疼痛	1	(0.4)	0		0		0		0	
口渇	1	(0.4)	0		0		0		0	
肝胆道系障害	2	(0.8)	0		0		0		0	
脂肪肝	2	(0.8)	0		0		0		0	
免疫系障害	4	(1.6)	2	(2.5)	0		0		0	
季節性アレルギー	2	(0.8)	1	(1.2)	0		0		0	
薬物過敏症	1	(0.4)	1	(1.2)	0		0		0	
過敏症	1	(0.4)	0		0		0		0	
感染症および寄生虫症	105	(41.2)	2	(2.5)	2	(3.1)	3	(6.5)	0	
鼻咽頭炎	43	(16.9)	0		1	(1.6)	1	(2.2)	0	
上気道感染	17	(6.7)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	All Subjects		n	(%)	n	(%)
一般・全身障害および投与部位の状態						
粘膜びらん	1	(0.4)	0		0	
末梢性浮腫	1	(0.4)	0		0	
疼痛	1	(0.4)	0		0	
口渇	1	(0.4)	0		0	
肝胆道系障害	2	(0.8)	0		0	
脂肪肝	2	(0.8)	0		0	
免疫系障害	4	(1.6)	0		0	
季節性アレルギー	2	(0.8)	0		0	
薬物過敏症	1	(0.4)	0		0	
過敏症	1	(0.4)	0		0	
感染症および寄生虫症	105	(41.2)	0		1	(33.3)
鼻咽頭炎	43	(16.9)	0		1	(33.3)
上気道感染	17	(6.7)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
感染症および寄生虫症										
インフルエンザ	11	(4.3)	3	(1.2)	2	(0.9)	1	(0.5)	4	(2.4)
尿路感染	8	(3.1)	2	(0.8)	1	(0.5)	1	(0.5)	0	
胃腸炎	7	(2.7)	2	(0.8)	2	(0.9)	1	(0.5)	2	(1.2)
咽頭炎	5	(2.0)	1	(0.4)	0		1	(0.5)	1	(0.6)
ウイルス性気道感染	4	(1.6)	2	(0.8)	2	(0.9)	0		0	
鼻炎	4	(1.6)	2	(0.8)	0		0		0	
気管支炎	3	(1.2)	0		1	(0.5)	1	(0.5)	0	
肺炎	3	(1.2)	0		1	(0.5)	0		0	
急性扁桃炎	2	(0.8)	0		0		2	(1.0)	0	
蜂巣炎	2	(0.8)	0		1	(0.5)	0		0	
膀胱炎	2	(0.8)	0		1	(0.5)	0		1	(0.6)
耳感染	2	(0.8)	1	(0.4)	0		0		0	
ライム病	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
咽頭扁桃炎	2	(0.8)	2	(0.8)	0		0		0	
気道感染	2	(0.8)	0		0		0		1	(0.6)
皮下組織膿瘍	2	(0.8)	0		1	(0.5)	0		1	(0.6)
四肢膿瘍	1	(0.4)	0		0		0		1	(0.6)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
感染症および寄生虫症										
インフルエンザ	11	(4.3)	0		1	(0.8)	0		0	
尿路感染	8	(3.1)	2	(1.4)	0		1	(0.9)	0	
胃腸炎	7	(2.7)	0		0		0		0	
咽頭炎	5	(2.0)	0		1	(0.8)	1	(0.9)	0	
ウイルス性気道感染	4	(1.6)	0		0		0		0	
鼻炎	4	(1.6)	0		0		2	(1.8)	0	
気管支炎	3	(1.2)	1	(0.7)	0		0		0	
肺炎	3	(1.2)	0		0		1	(0.9)	0	
急性扁桃炎	2	(0.8)	0		0		0		0	
蜂巣炎	2	(0.8)	0		0		0		0	
膀胱炎	2	(0.8)	0		0		0		0	
耳感染	2	(0.8)	0		0		1	(0.9)	0	
ライム病	2	(0.8)	0		0		0		0	
咽頭扁桃炎	2	(0.8)	0		0		0		0	
気道感染	2	(0.8)	1	(0.7)	0		0		0	
皮下組織膿瘍	2	(0.8)	0		0		0		0	
四肢膿瘍	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
感染症および寄生虫症										
インフルエンザ	11	(4.3)	0		0		0		0	
尿路感染	8	(3.1)	0		0		1	(2.2)	0	
胃腸炎	7	(2.7)	0		0		0		0	
咽頭炎	5	(2.0)	0		0		0		0	
ウイルス性気道感染	4	(1.6)	0		0		0		0	
鼻炎	4	(1.6)	0		0		0		0	
気管支炎	3	(1.2)	0		0		0		0	
肺炎	3	(1.2)	0		0		1	(2.2)	0	
急性扁桃炎	2	(0.8)	0		0		0		0	
蜂巣炎	2	(0.8)	0		0		1	(2.2)	0	
膀胱炎	2	(0.8)	0		0		0		0	
耳感染	2	(0.8)	0		0		0		0	
ライム病	2	(0.8)	0		0		0		0	
咽頭扁桃炎	2	(0.8)	0		0		0		0	
気道感染	2	(0.8)	0		0		0		0	
皮下組織膿瘍	2	(0.8)	0		0		0		0	
四肢膿瘍	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
感染症および寄生虫症				
インフルエンザ	11	(4.3)	0	0
尿路感染	8	(3.1)	0	0
胃腸炎	7	(2.7)	0	0
咽頭炎	5	(2.0)	0	0
ウイルス性気道感染	4	(1.6)	0	0
鼻炎	4	(1.6)	0	0
気管支炎	3	(1.2)	0	0
肺炎	3	(1.2)	0	0
急性扁桃炎	2	(0.8)	0	0
蜂巣炎	2	(0.8)	0	0
膀胱炎	2	(0.8)	0	0
耳感染	2	(0.8)	0	0
ライム病	2	(0.8)	0	0
咽頭扁桃炎	2	(0.8)	0	0
気道感染	2	(0.8)	0	0
皮下組織膿瘍	2	(0.8)	0	0
四肢膿瘍	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
		n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症					
カンジダ感染	1 (0.4)	1 (0.4)	0	0	0
大腸菌性尿路感染	1 (0.4)	1 (0.4)	0	0	0
眼瞼毛包炎	1 (0.4)	1 (0.4)	0	0	0
ウイルス性胃炎	1 (0.4)	0	0	0	0
ウイルス性胃腸炎	1 (0.4)	0	1 (0.5)	0	0
消化管感染	1 (0.4)	0	0	0	0
歯肉炎	1 (0.4)	0	0	1 (0.5)	0
鼠径部膿瘍	1 (0.4)	0	0	0	1 (0.6)
帯状疱疹	1 (0.4)	1 (0.4)	0	0	0
麦粒腫	1 (0.4)	0	0	0	0
膿痂疹	1 (0.4)	1 (0.4)	0	0	0
腎感染	1 (0.4)	1 (0.4)	0	0	0
喉頭炎	1 (0.4)	1 (0.4)	0	0	0
大葉性肺炎	1 (0.4)	0	0	0	0
口腔カンジダ症	1 (0.4)	0	0	1 (0.5)	0
外耳炎	1 (0.4)	0	0	0	0
中耳炎	1 (0.4)	0	0	0	1 (0.6)
乳頭腫ウイルス感染	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
感染症および寄生虫症										
カンジダ感染	1	(0.4)	0		0		0		0	
大腸菌性尿路感染	1	(0.4)	0		0		0		0	
眼瞼毛包炎	1	(0.4)	0		0		0		0	
ウイルス性胃炎	1	(0.4)	0		0		1	(0.9)	0	
ウイルス性胃腸炎	1	(0.4)	0		0		0		0	
消化管感染	1	(0.4)	0		0		0		0	
歯肉炎	1	(0.4)	0		0		0		0	
鼠径部膿瘍	1	(0.4)	0		0		0		0	
帯状疱疹	1	(0.4)	0		0		0		0	
麦粒腫	1	(0.4)	0		0		0		1	(1.0)
膿痂疹	1	(0.4)	0		0		0		0	
腎感染	1	(0.4)	0		0		0		0	
喉頭炎	1	(0.4)	0		0		0		0	
大葉性肺炎	1	(0.4)	0		1	(0.8)	0		0	
口腔カンジダ症	1	(0.4)	0		0		0		0	
外耳炎	1	(0.4)	0		0		0		0	
中耳炎	1	(0.4)	0		0		0		0	
乳頭腫ウイルス感染	1	(0.4)	0		0		1	(0.9)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
			n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
カンジダ感染	1	(0.4)	0		0		0		0	
大腸菌性尿路感染	1	(0.4)	0		0		0		0	
眼瞼毛包炎	1	(0.4)	0		0		0		0	
ウイルス性胃炎	1	(0.4)	0		0		0		0	
ウイルス性胃腸炎	1	(0.4)	0		0		0		0	
消化管感染	1	(0.4)	1	(1.2)	0		0		0	
歯肉炎	1	(0.4)	0		0		0		0	
鼠径部膿瘍	1	(0.4)	0		0		0		0	
帯状疱疹	1	(0.4)	0		0		0		0	
麦粒腫	1	(0.4)	0		0		0		0	
膿痂疹	1	(0.4)	0		0		0		0	
腎感染	1	(0.4)	0		0		0		0	
喉頭炎	1	(0.4)	0		0		0		0	
大葉性肺炎	1	(0.4)	0		0		0		0	
口腔カンジダ症	1	(0.4)	0		0		0		0	
外耳炎	1	(0.4)	0		1	(1.6)	0		0	
中耳炎	1	(0.4)	0		0		0		0	
乳頭腫ウイルス感染	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
感染症および寄生虫症				
カンジダ感染	1	(0.4)	0	0
大腸菌性尿路感染	1	(0.4)	0	0
眼瞼毛包炎	1	(0.4)	0	0
ウイルス性胃炎	1	(0.4)	0	0
ウイルス性胃腸炎	1	(0.4)	0	0
消化管感染	1	(0.4)	0	0
歯肉炎	1	(0.4)	0	0
鼡径部膿瘍	1	(0.4)	0	0
帯状疱疹	1	(0.4)	0	0
麦粒腫	1	(0.4)	0	0
膿痂疹	1	(0.4)	0	0
腎感染	1	(0.4)	0	0
喉頭炎	1	(0.4)	0	0
大葉性肺炎	1	(0.4)	0	0
口腔カンジダ症	1	(0.4)	0	0
外耳炎	1	(0.4)	0	0
中耳炎	1	(0.4)	0	0
乳頭腫ウイルス感染	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症					
爪囲炎	1 (0.4)	1 (0.4)	0	0	0
歯冠周囲炎	1 (0.4)	0	0	0	1 (0.6)
歯周炎	1 (0.4)	0	0	0	1 (0.6)
毛巣嚢胞	1 (0.4)	1 (0.4)	0	0	0
副鼻腔炎	1 (0.4)	1 (0.4)	0	0	0
皮膚細菌感染	1 (0.4)	0	0	0	0
細菌性扁桃炎	1 (0.4)	1 (0.4)	0	0	0
歯膿瘍	1 (0.4)	0	0	1 (0.5)	0
歯感染	1 (0.4)	0	0	0	1 (0.6)
腟感染	1 (0.4)	1 (0.4)	0	0	0
ウイルス感染	1 (0.4)	0	0	1 (0.5)	0
ウイルス性上気道感染	1 (0.4)	0	1 (0.5)	0	0
外陰腟真菌感染	1 (0.4)	0	0	0	0
外陰部腟炎	1 (0.4)	1 (0.4)	0	0	0
創傷感染	1 (0.4)	1 (0.4)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
		n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症					
爪囲炎	1 (0.4)	0	0	0	0
歯冠周囲炎	1 (0.4)	0	0	0	0
歯周炎	1 (0.4)	0	0	0	0
毛巣嚢胞	1 (0.4)	0	0	0	0
副鼻腔炎	1 (0.4)	0	0	0	0
皮膚細菌感染	1 (0.4)	0	0	0	0
細菌性扁桃炎	1 (0.4)	0	0	0	0
歯膿瘍	1 (0.4)	0	0	0	0
歯感染	1 (0.4)	0	0	0	0
腟感染	1 (0.4)	0	0	0	0
ウイルス感染	1 (0.4)	0	0	0	0
ウイルス性上気道感染	1 (0.4)	0	0	0	0
外陰腟真菌感染	1 (0.4)	1 (0.7)	0	0	0
外陰部腟炎	1 (0.4)	0	0	0	0
創傷感染	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
感染症および寄生虫症							
爪囲炎	1	(0.4)	0		0	0	0
歯冠周囲炎	1	(0.4)	0		0	0	0
歯周炎	1	(0.4)	0		0	0	0
毛巣嚢胞	1	(0.4)	0		0	0	0
副鼻腔炎	1	(0.4)	0		0	0	0
皮膚細菌感染	1	(0.4)	1	(1.2)	0	0	0
細菌性扁桃炎	1	(0.4)	0		0	0	0
歯膿瘍	1	(0.4)	0		0	0	0
歯感染	1	(0.4)	0		0	0	0
腟感染	1	(0.4)	0		0	0	0
ウイルス感染	1	(0.4)	0		0	0	0
ウイルス性上気道感染	1	(0.4)	0		0	0	0
外陰腟真菌感染	1	(0.4)	0		0	0	0
外陰部腟炎	1	(0.4)	0		0	0	0
創傷感染	1	(0.4)	0		0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
感染症および寄生虫症				
爪囲炎	1	(0.4)	0	0
歯冠周囲炎	1	(0.4)	0	0
歯周炎	1	(0.4)	0	0
毛巣嚢胞	1	(0.4)	0	0
副鼻腔炎	1	(0.4)	0	0
皮膚細菌感染	1	(0.4)	0	0
細菌性扁桃炎	1	(0.4)	0	0
歯膿瘍	1	(0.4)	0	0
歯感染	1	(0.4)	0	0
腟感染	1	(0.4)	0	0
ウイルス感染	1	(0.4)	0	0
ウイルス性上気道感染	1	(0.4)	0	0
外陰腟真菌感染	1	(0.4)	0	0
外陰部腟炎	1	(0.4)	0	0
創傷感染	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症	61	(23.9)	18	(7.1)	14	(6.4)	13	(6.5)	5	(3.0)
挫傷	17	(6.7)	5	(2.0)	5	(2.3)	3	(1.5)	1	(0.6)
頭部損傷	10	(3.9)	4	(1.6)	0		3	(1.5)	1	(0.6)
裂傷	7	(2.7)	0		2	(0.9)	1	(0.5)	0	
転倒	6	(2.4)	2	(0.8)	2	(0.9)	1	(0.5)	0	
靭帯捻挫	6	(2.4)	3	(1.2)	0		2	(1.0)	0	
歯牙破折	5	(2.0)	1	(0.4)	0		2	(1.0)	0	
擦過傷	3	(1.2)	0		0		0		1	(0.6)
顔面骨骨折	3	(1.2)	1	(0.4)	0		0		0	
手骨折	3	(1.2)	1	(0.4)	0		0		1	(0.6)
関節損傷	3	(1.2)	1	(0.4)	0		0		0	
節足動物咬傷	2	(0.8)	0		1	(0.5)	0		0	
上腕骨骨折	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
皮下血腫	2	(0.8)	1	(0.4)	0		0		1	(0.6)
熱傷	2	(0.8)	1	(0.4)	0		1	(0.5)	0	
動物咬傷	1	(0.4)	0		0		0		0	
背部損傷	1	(0.4)	1	(0.4)	0		0		0	
第２度熱傷	1	(0.4)	0		0		0		1	(0.6)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症	61	(23.9)	5	(3.4)	4	(3.1)	7	(6.1)	2	(2.1)
挫傷	17	(6.7)	1	(0.7)	0		1	(0.9)	0	
頭部損傷	10	(3.9)	1	(0.7)	1	(0.8)	0		0	
裂傷	7	(2.7)	0		0		1	(0.9)	2	(2.1)
転倒	6	(2.4)	1	(0.7)	0		0		0	
靱帯捻挫	6	(2.4)	0		0		0		0	
歯牙破折	5	(2.0)	0		1	(0.8)	1	(0.9)	0	
擦過傷	3	(1.2)	2	(1.4)	0		0		0	
顔面骨骨折	3	(1.2)	0		0		1	(0.9)	0	
手骨折	3	(1.2)	0		0		0		0	
関節損傷	3	(1.2)	0		1	(0.8)	0		0	
節足動物咬傷	2	(0.8)	0		0		0		0	
上腕骨骨折	2	(0.8)	0		0		0		0	
皮下血腫	2	(0.8)	0		0		0		0	
熱傷	2	(0.8)	0		0		0		0	
動物咬傷	1	(0.4)	1	(0.7)	0		0		0	
背部損傷	1	(0.4)	0		0		0		0	
第２度熱傷	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)
傷害、中毒および処置合併症	61	(23.9)	3	(3.7)	3	(4.7)	2	(4.3)	0
挫傷	17	(6.7)	0		1	(1.6)	0		0
頭部損傷	10	(3.9)	0		0		0		0
裂傷	7	(2.7)	0		1	(1.6)	0		0
転倒	6	(2.4)	0		0		0		0
靭帯捻挫	6	(2.4)	1	(1.2)	0		0		0
歯牙破折	5	(2.0)	0		0		0		0
擦過傷	3	(1.2)	0		0		0		0
顔面骨骨折	3	(1.2)	0		1	(1.6)	0		0
手骨折	3	(1.2)	1	(1.2)	0		0		0
関節損傷	3	(1.2)	0		0		1	(2.2)	0
節足動物咬傷	2	(0.8)	0		0		1	(2.2)	0
上腕骨骨折	2	(0.8)	0		0		0		0
皮下血腫	2	(0.8)	0		0		0		0
熱傷	2	(0.8)	0		0		0		0
動物咬傷	1	(0.4)	0		0		0		0
背部損傷	1	(0.4)	0		0		0		0
第２度熱傷	1	(0.4)	0		0		0		0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset

Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
傷害、中毒および処置合併症	61	(23.9)	0	0
挫傷	17	(6.7)	0	0
頭部損傷	10	(3.9)	0	0
裂傷	7	(2.7)	0	0
転倒	6	(2.4)	0	0
靭帯捻挫	6	(2.4)	0	0
歯牙破折	5	(2.0)	0	0
擦過傷	3	(1.2)	0	0
顔面骨骨折	3	(1.2)	0	0
手骨折	3	(1.2)	0	0
関節損傷	3	(1.2)	0	0
節足動物咬傷	2	(0.8)	0	0
上腕骨骨折	2	(0.8)	0	0
皮下血腫	2	(0.8)	0	0
熱傷	2	(0.8)	0	0
動物咬傷	1	(0.4)	0	0
背部損傷	1	(0.4)	0	0
第２度熱傷	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症					
眼挫傷	1 (0.4)	1 (0.4)	0	0	0
眼外傷	1 (0.4)	1 (0.4)	0	0	0
顔面損傷	1 (0.4)	1 (0.4)	0	0	0
足骨折	1 (0.4)	0	1 (0.5)	0	0
骨折	1 (0.4)	0	0	0	0
損傷	1 (0.4)	0	0	0	0
関節脱臼	1 (0.4)	0	1 (0.5)	0	0
筋断裂	1 (0.4)	0	1 (0.5)	0	0
肉離れ	1 (0.4)	0	1 (0.5)	0	0
処置による疼痛	1 (0.4)	0	0	0	0
肋骨骨折	1 (0.4)	0	0	1 (0.5)	0
交通事故	1 (0.4)	0	0	0	0
刺創	1 (0.4)	0	0	0	0
硬膜下血腫	1 (0.4)	0	0	0	0
各種物質毒性	1 (0.4)	1 (0.4)	0	0	0
外傷性頭蓋内出血	1 (0.4)	0	0	0	0
創傷	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症					
眼挫傷	1 (0.4)	0	0	0	0
眼外傷	1 (0.4)	0	0	0	0
顔面損傷	1 (0.4)	0	0	0	0
足骨折	1 (0.4)	0	0	0	0
骨折	1 (0.4)	0	1 (0.8)	0	0
損傷	1 (0.4)	0	0	1 (0.9)	0
関節脱臼	1 (0.4)	0	0	0	0
筋断裂	1 (0.4)	0	0	0	0
肉離れ	1 (0.4)	0	0	0	0
処置による疼痛	1 (0.4)	1 (0.7)	0	0	0
肋骨骨折	1 (0.4)	0	0	0	0
交通事故	1 (0.4)	0	0	0	0
刺創	1 (0.4)	0	0	1 (0.9)	0
硬膜下血腫	1 (0.4)	0	0	0	0
各種物質毒性	1 (0.4)	0	0	0	0
外傷性頭蓋内出血	1 (0.4)	0	0	0	0
創傷	1 (0.4)	0	0	1 (0.9)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症					
眼挫傷	1 (0.4)	0	0	0	0
眼外傷	1 (0.4)	0	0	0	0
顔面損傷	1 (0.4)	0	0	0	0
足骨折	1 (0.4)	0	0	0	0
骨折	1 (0.4)	0	0	0	0
損傷	1 (0.4)	0	0	0	0
関節脱臼	1 (0.4)	0	0	0	0
筋断裂	1 (0.4)	0	0	0	0
肉離れ	1 (0.4)	0	0	0	0
処置による疼痛	1 (0.4)	0	0	0	0
肋骨骨折	1 (0.4)	0	0	0	0
交通事故	1 (0.4)	1 (1.2)	0	0	0
刺創	1 (0.4)	0	0	0	0
硬膜下血腫	1 (0.4)	0	1 (1.6)	0	0
各種物質毒性	1 (0.4)	0	0	0	0
外傷性頭蓋内出血	1 (0.4)	0	1 (1.6)	0	0
創傷	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
傷害、中毒および処置合併症				
眼挫傷	1	(0.4)	0	0
眼外傷	1	(0.4)	0	0
顔面損傷	1	(0.4)	0	0
足骨折	1	(0.4)	0	0
骨折	1	(0.4)	0	0
損傷	1	(0.4)	0	0
関節脱臼	1	(0.4)	0	0
筋断裂	1	(0.4)	0	0
肉離れ	1	(0.4)	0	0
処置による疼痛	1	(0.4)	0	0
肋骨骨折	1	(0.4)	0	0
交通事故	1	(0.4)	0	0
刺創	1	(0.4)	0	0
硬膜下血腫	1	(0.4)	0	0
各種物質毒性	1	(0.4)	0	0
外傷性頭蓋内出血	1	(0.4)	0	0
創傷	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
手首関節骨折	1	(0.4)	1	(0.4)	0		0		0	
臨床検査	30	(11.8)	9	(3.5)	6	(2.8)	5	(2.5)	4	(2.4)
アラニンアミノトランスフェラーゼ増加	7	(2.7)	2	(0.8)	2	(0.9)	1	(0.5)	0	
γ－グルタミルトランスフェラーゼ増加	5	(2.0)	1	(0.4)	0		0		1	(0.6)
体重減少	5	(2.0)	0		1	(0.5)	1	(0.5)	3	(1.8)
アスパラギン酸アミノトランスフェラーゼ増加	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
血圧上昇	2	(0.8)	1	(0.4)	0		1	(0.5)	0	
尿中蛋白陽性	2	(0.8)	2	(0.8)	0		0		0	
体重増加	2	(0.8)	1	(0.4)	0		0		0	
血中アルカリホスファターゼ増加	1	(0.4)	1	(0.4)	0		0		0	
血中ブドウ糖増加	1	(0.4)	0		0		0		0	
拡張期血圧上昇	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
手首関節骨折	1	(0.4)	0		0		0		0	
臨床検査	30	(11.8)	1	(0.7)	4	(3.1)	0		2	(2.1)
アラニンアミノトランスフェラーゼ増加	7	(2.7)	0		2	(1.6)	0		0	
γ－グルタミルトランスフェラーゼ増加	5	(2.0)	0		1	(0.8)	0		1	(1.0)
体重減少	5	(2.0)	0		0		0		0	
アスパラギン酸アミノトランスフェラーゼ増加	2	(0.8)	0		0		0		0	
血圧上昇	2	(0.8)	0		0		0		0	
尿中蛋白陽性	2	(0.8)	0		0		0		0	
体重増加	2	(0.8)	1	(0.7)	0		0		0	
血中アルカリホスファターゼ増加	1	(0.4)	0		0		0		0	
血中ブドウ糖増加	1	(0.4)	0		1	(0.8)	0		0	
拡張期血圧上昇	1	(0.4)	0		1	(0.8)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
手首関節骨折	1	(0.4)	0		0		0		0	
臨床検査	30	(11.8)	0		0		1	(2.2)	0	
アラニンアミノトランスフェラーゼ増加	7	(2.7)	0		0		0		0	
γ－グルタミルトランスフェラーゼ増加	5	(2.0)	0		0		1	(2.2)	0	
体重減少	5	(2.0)	0		0		0		0	
アスパラギン酸アミノトランスフェラーゼ増加	2	(0.8)	0		0		0		0	
血圧上昇	2	(0.8)	0		0		0		0	
尿中蛋白陽性	2	(0.8)	0		0		0		0	
体重増加	2	(0.8)	0		0		0		0	
血中アルカリホスファターゼ増加	1	(0.4)	0		0		0		0	
血中ブドウ糖増加	1	(0.4)	0		0		0		0	
拡張期血圧上昇	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
傷害、中毒および処置合併症				
手首関節骨折	1	(0.4)	0	0
臨床検査	30	(11.8)	0	0
アラニンアミノトランスフェラーゼ増加	7	(2.7)	0	0
γ－グルタミルトランスフェラーゼ増加	5	(2.0)	0	0
体重減少	5	(2.0)	0	0
アスパラギン酸アミノトランスフェラーゼ増加	2	(0.8)	0	0
血圧上昇	2	(0.8)	0	0
尿中蛋白陽性	2	(0.8)	0	0
体重増加	2	(0.8)	0	0
血中アルカリホスファターゼ増加	1	(0.4)	0	0
血中ブドウ糖増加	1	(0.4)	0	0
拡張期血圧上昇	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
血中トリグリセリド増加	1	(0.4)	0		0		0		0	
血中尿酸増加	1	(0.4)	1	(0.4)	0		0		0	
薬物濃度増加	1	(0.4)	0		0		1	(0.5)	0	
心電図ＰＲ延長	1	(0.4)	0		0		1	(0.5)	0	
好酸球数増加	1	(0.4)	0		1	(0.5)	0		0	
肝機能検査異常	1	(0.4)	1	(0.4)	0		0		0	
サイロキシン減少	1	(0.4)	0		1	(0.5)	0		0	
トランスアミナーゼ上昇	1	(0.4)	0		1	(0.5)	0		0	
トリヨードチロニン減少	1	(0.4)	0		1	(0.5)	0		0	
白血球数増加	1	(0.4)	0		0		0		0	
代謝および栄養障害	13	(5.1)	5	(2.0)	0		3	(1.5)	2	(1.2)
糖尿病	3	(1.2)	1	(0.4)	0		0		1	(0.6)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
臨床検査					
血中トリグリセリド増加	1 (0.4)	0	1 (0.8)	0	0
血中尿酸増加	1 (0.4)	0	0	0	0
薬物濃度増加	1 (0.4)	0	0	0	0
心電図ＰＲ延長	1 (0.4)	0	0	0	0
好酸球数増加	1 (0.4)	0	0	0	0
肝機能検査異常	1 (0.4)	0	0	0	0
サイロキシン減少	1 (0.4)	0	0	0	0
トランスアミナーゼ上昇	1 (0.4)	0	0	0	0
トリヨードチロニン減少	1 (0.4)	0	0	0	0
白血球数増加	1 (0.4)	0	0	0	1 (1.0)
代謝および栄養障害	13 (5.1)	0	0	2 (1.8)	0
糖尿病	3 (1.2)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1　Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
血中トリグリセリド増加	1	(0.4)	0		0		0		0	
血中尿酸増加	1	(0.4)	0		0		0		0	
薬物濃度増加	1	(0.4)	0		0		0		0	
心電図ＰＲ延長	1	(0.4)	0		0		0		0	
好酸球数増加	1	(0.4)	0		0		0		0	
肝機能検査異常	1	(0.4)	0		0		0		0	
サイロキシン減少	1	(0.4)	0		0		0		0	
トランスアミナーゼ上昇	1	(0.4)	0		0		0		0	
トリヨードチロニン減少	1	(0.4)	0		0		0		0	
白血球数増加	1	(0.4)	0		0		0		0	
代謝および栄養障害	13	(5.1)	1	(1.2)	0		0		0	
糖尿病	3	(1.2)	1	(1.2)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
臨床検査				
血中トリグリセリド増加	1	(0.4)	0	0
血中尿酸増加	1	(0.4)	0	0
薬物濃度増加	1	(0.4)	0	0
心電図ＰＲ延長	1	(0.4)	0	0
好酸球数増加	1	(0.4)	0	0
肝機能検査異常	1	(0.4)	0	0
サイロキシン減少	1	(0.4)	0	0
トランスアミナーゼ上昇	1	(0.4)	0	0
トリヨードチロニン減少	1	(0.4)	0	0
白血球数増加	1	(0.4)	0	0
代謝および栄養障害	13	(5.1)	0	0
糖尿病	3	(1.2)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
代謝および栄養障害										
ビタミンD欠乏	3	(1.2)	1	(0.4)	0		2	(1.0)	0	
脱水	2	(0.8)	0		0		0		1	(0.6)
鉄欠乏	2	(0.8)	2	(0.8)	0		0		0	
食欲減退	1	(0.4)	1	(0.4)	0		0		0	
高アンモニア血症	1	(0.4)	0		0		0		0	
高尿酸血症	1	(0.4)	1	(0.4)	0		0		0	
低カリウム血症	1	(0.4)	1	(0.4)	0		0		0	
低ナトリウム血症	1	(0.4)	1	(0.4)	0		0		0	
肥満	1	(0.4)	1	(0.4)	0		0		0	
過体重	1	(0.4)	0		0		1	(0.5)	0	
ビタミンA欠乏	1	(0.4)	1	(0.4)	0		0		0	
筋骨格系および結合組織障害	28	(11.0)	14	(5.5)	3	(1.4)	3	(1.5)	1	(0.6)
背部痛	10	(3.9)	2	(0.8)	3	(1.4)	2	(1.0)	1	(0.6)
関節痛	6	(2.4)	3	(1.2)	0		1	(0.5)	0	
四肢痛	3	(1.2)	2	(0.8)	0		0		0	
筋肉痛	2	(0.8)	1	(0.4)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
代謝および栄養障害										
ビタミンD欠乏	3	(1.2)	0		0		0		0	
脱水	2	(0.8)	0		0		1	(0.9)	0	
鉄欠乏	2	(0.8)	0		0		0		0	
食欲減退	1	(0.4)	0		0		0		0	
高アンモニア血症	1	(0.4)	0		0		1	(0.9)	0	
高尿酸血症	1	(0.4)	0		0		0		0	
低カリウム血症	1	(0.4)	0		0		0		0	
低ナトリウム血症	1	(0.4)	0		0		0		0	
肥満	1	(0.4)	0		0		0		0	
過体重	1	(0.4)	0		0		0		0	
ビタミンA欠乏	1	(0.4)	0		0		0		0	
筋骨格系および結合組織障害	28	(11.0)	1	(0.7)	1	(0.8)	1	(0.9)	1	(1.0)
背部痛	10	(3.9)	0		0		0		0	
関節痛	6	(2.4)	1	(0.7)	0		0		0	
四肢痛	3	(1.2)	0		0		0		0	
筋肉痛	2	(0.8)	0		0		1	(0.9)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
代謝および栄養障害										
ビタミンD欠乏	3	(1.2)	0		0		0		0	
脱水	2	(0.8)	0		0		0		0	
鉄欠乏	2	(0.8)	0		0		0		0	
食欲減退	1	(0.4)	0		0		0		0	
高アンモニア血症	1	(0.4)	0		0		0		0	
高尿酸血症	1	(0.4)	0		0		0		0	
低カリウム血症	1	(0.4)	0		0		0		0	
低ナトリウム血症	1	(0.4)	0		0		0		0	
肥満	1	(0.4)	0		0		0		0	
過体重	1	(0.4)	0		0		0		0	
ビタミンA欠乏	1	(0.4)	0		0		0		0	
筋骨格系および結合組織障害	28	(11.0)	2	(2.5)	2	(3.1)	1	(2.2)	0	
背部痛	10	(3.9)	0		2	(3.1)	0		0	
関節痛	6	(2.4)	0		0		1	(2.2)	0	
四肢痛	3	(1.2)	1	(1.2)	0		0		0	
筋肉痛	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
代謝および栄養障害				
ビタミンD欠乏	3	(1.2)	0	0
脱水	2	(0.8)	0	0
鉄欠乏	2	(0.8)	0	0
食欲減退	1	(0.4)	0	0
高アンモニア血症	1	(0.4)	0	0
高尿酸血症	1	(0.4)	0	0
低カリウム血症	1	(0.4)	0	0
低ナトリウム血症	1	(0.4)	0	0
肥満	1	(0.4)	0	0
過体重	1	(0.4)	0	0
ビタミンA欠乏	1	(0.4)	0	0
筋骨格系および結合組織障害	28	(11.0)	0	0
背部痛	10	(3.9)	0	0
関節痛	6	(2.4)	0	0
四肢痛	3	(1.2)	0	0
筋肉痛	2	(0.8)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
筋骨格系および結合組織障害										
側腹部痛	1	(0.4)	1	(0.4)	0		0		0	
関節拘縮	1	(0.4)	1	(0.4)	0		0		0	
関節腫脹	1	(0.4)	1	(0.4)	0		0		0	
筋肉疲労	1	(0.4)	0		0		0		0	
筋骨格系胸痛	1	(0.4)	1	(0.4)	0		0		0	
筋骨格痛	1	(0.4)	0		0		0		0	
ミオキミア	1	(0.4)	1	(0.4)	0		0		0	
頚部痛	1	(0.4)	1	(0.4)	0		0		0	
変形性関節症	1	(0.4)	1	(0.4)	0		0		0	
滑液嚢腫	1	(0.4)	0		0		0		0	
腱鞘炎	1	(0.4)	1	(0.4)	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）	4	(1.6)	0		1	(0.5)	2	(1.0)	0	
乳腺線維腺腫	2	(0.8)	0		1	(0.5)	1	(0.5)	0	
膀胱癌	1	(0.4)	0		0		0		0	
脂肪腫	1	(0.4)	0		0		1	(0.5)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
			n	(%)	n	(%)	n	(%)	n	(%)
筋骨格系および結合組織障害										
側腹部痛	1	(0.4)	0		0		0		0	
関節拘縮	1	(0.4)	0		0		0		0	
関節腫脹	1	(0.4)	0		0		0		0	
筋肉疲労	1	(0.4)	0		1	(0.8)	0		0	
筋骨格系胸痛	1	(0.4)	0		0		0		0	
筋骨格痛	1	(0.4)	0		0		0		0	
ミオキミア	1	(0.4)	0		0		0		0	
頚部痛	1	(0.4)	0		0		0		0	
変形性関節症	1	(0.4)	0		0		0		0	
滑液嚢腫	1	(0.4)	0		0		0		1	(1.0)
腱鞘炎	1	(0.4)	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）	4	(1.6)	0		0		1	(0.9)	0	
乳腺線維腺腫	2	(0.8)	0		0		0		0	
膀胱癌	1	(0.4)	0		0		1	(0.9)	0	
脂肪腫	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
筋骨格系および結合組織障害										
側腹部痛	1	(0.4)	0		0		0		0	
関節拘縮	1	(0.4)	0		0		0		0	
関節腫脹	1	(0.4)	0		0		0		0	
筋肉疲労	1	(0.4)	0		0		0		0	
筋骨格系胸痛	1	(0.4)	0		0		0		0	
筋骨格痛	1	(0.4)	1	(1.2)	0		0		0	
ミオキミア	1	(0.4)	0		0		0		0	
頚部痛	1	(0.4)	0		0		0		0	
変形性関節症	1	(0.4)	0		0		0		0	
滑液嚢腫	1	(0.4)	0		0		0		0	
腱鞘炎	1	(0.4)	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）	4	(1.6)	0		0		0		0	
乳腺線維腺腫	2	(0.8)	0		0		0		0	
膀胱癌	1	(0.4)	0		0		0		0	
脂肪腫	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
筋骨格系および結合組織障害				
側腹部痛	1	(0.4)	0	0
関節拘縮	1	(0.4)	0	0
関節腫脹	1	(0.4)	0	0
筋肉疲労	1	(0.4)	0	0
筋骨格系胸痛	1	(0.4)	0	0
筋骨格痛	1	(0.4)	0	0
ミオキミア	1	(0.4)	0	0
頚部痛	1	(0.4)	0	0
変形性関節症	1	(0.4)	0	0
滑液嚢腫	1	(0.4)	0	0
腱鞘炎	1	(0.4)	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）	4	(1.6)	0	0
乳腺線維腺腫	2	(0.8)	0	0
膀胱癌	1	(0.4)	0	0
脂肪腫	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
			n	(%)	n	(%)	n	(%)	n	(%)
神経系障害	146	(57.3)	110	(43.1)	27	(12.4)	26	(12.9)	12	(7.3)
浮動性めまい	64	(25.1)	47	(18.4)	5	(2.3)	4	(2.0)	4	(2.4)
頭痛	52	(20.4)	26	(10.2)	10	(4.6)	5	(2.5)	6	(3.7)
傾眠	45	(17.6)	33	(12.9)	4	(1.8)	3	(1.5)	2	(1.2)
大発作痙攣	13	(5.1)	6	(2.4)	1	(0.5)	1	(0.5)	0	
片頭痛	10	(3.9)	5	(2.0)	2	(0.9)	0		0	
ミオクローヌス性てんかん	8	(3.1)	5	(2.0)	0		0		0	
錯感覚	8	(3.1)	5	(2.0)	0		3	(1.5)	0	
振戦	8	(3.1)	5	(2.0)	0		0		0	
平衡障害	7	(2.7)	5	(2.0)	0		2	(1.0)	0	
健忘	6	(2.4)	6	(2.4)	0		0		0	
運動失調	6	(2.4)	5	(2.0)	0		0		0	
注意力障害	6	(2.4)	5	(2.0)	0		0		0	
痙攣	5	(2.0)	1	(0.4)	1	(0.5)	1	(0.5)	1	(0.6)
小発作てんかん	5	(2.0)	2	(0.8)	1	(0.5)	1	(0.5)	0	
感覚鈍麻	4	(1.6)	1	(0.4)	1	(0.5)	2	(1.0)	0	
てんかん重積状態	4	(1.6)	2	(0.8)	0		1	(0.5)	0	
失語症	3	(1.2)	2	(0.8)	0		1	(0.5)	0	
認知障害	2	(0.8)	0		0		2	(1.0)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
			n	(%)	n	(%)	n	(%)	n	(%)
神経系障害	146	(57.3)	10	(6.8)	7	(5.5)	5	(4.4)	3	(3.1)
浮動性めまい	64	(25.1)	2	(1.4)	0		0		0	
頭痛	52	(20.4)	3	(2.0)	0		1	(0.9)	1	(1.0)
傾眠	45	(17.6)	0		2	(1.6)	0		1	(1.0)
大発作痙攣	13	(5.1)	1	(0.7)	3	(2.3)	1	(0.9)	0	
片頭痛	10	(3.9)	1	(0.7)	1	(0.8)	0		0	
ミオクローヌス性てんかん	8	(3.1)	0		1	(0.8)	1	(0.9)	0	
錯感覚	8	(3.1)	0		0		0		0	
振戦	8	(3.1)	1	(0.7)	1	(0.8)	0		0	
平衡障害	7	(2.7)	0		0		0		0	
健忘	6	(2.4)	0		0		0		0	
運動失調	6	(2.4)	0		0		0		1	(1.0)
注意力障害	6	(2.4)	0		0		0		0	
痙攣	5	(2.0)	0		0		1	(0.9)	0	
小発作てんかん	5	(2.0)	1	(0.7)	0		0		0	
感覚鈍麻	4	(1.6)	0		0		0		0	
てんかん重積状態	4	(1.6)	1	(0.7)	0		0		0	
失語症	3	(1.2)	0		0		0		0	
認知障害	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
神経系障害	146	(57.3)	1	(1.2)	0		2	(4.3)	1	(2.7)
浮動性めまい	64	(25.1)	0		0		0		1	(2.7)
頭痛	52	(20.4)	0		0		0		0	
傾眠	45	(17.6)	0		0		0		0	
大発作痙攣	13	(5.1)	0		0		0		0	
片頭痛	10	(3.9)	1	(1.2)	0		0		0	
ミオクローヌス性てんかん	8	(3.1)	0		0		1	(2.2)	0	
錯感覚	8	(3.1)	0		0		0		0	
振戦	8	(3.1)	0		0		1	(2.2)	0	
平衡障害	7	(2.7)	0		0		0		0	
健忘	6	(2.4)	0		0		0		0	
運動失調	6	(2.4)	0		0		0		0	
注意力障害	6	(2.4)	0		0		0		0	
痙攣	5	(2.0)	0		0		0		0	
小発作てんかん	5	(2.0)	0		0		0		0	
感覚鈍麻	4	(1.6)	0		0		0		0	
てんかん重積状態	4	(1.6)	0		0		0		0	
失語症	3	(1.2)	0		0		0		0	
認知障害	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)		>39 - <=42 n (%)
神経系障害	146	(57.3)	1	(8.3)	0
浮動性めまい	64	(25.1)	1	(8.3)	0
頭痛	52	(20.4)	0		0
傾眠	45	(17.6)	0		0
大発作痙攣	13	(5.1)	0		0
片頭痛	10	(3.9)	0		0
ミオクローヌス性てんかん	8	(3.1)	0		0
錯感覚	8	(3.1)	0		0
振戦	8	(3.1)	0		0
平衡障害	7	(2.7)	0		0
健忘	6	(2.4)	0		0
運動失調	6	(2.4)	0		0
注意力障害	6	(2.4)	1	(8.3)	0
痙攣	5	(2.0)	0		0
小発作てんかん	5	(2.0)	0		0
感覚鈍麻	4	(1.6)	0		0
てんかん重積状態	4	(1.6)	0		0
失語症	3	(1.2)	0		0
認知障害	2	(0.8)	0		0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
神経系障害					
嗜眠	2 (0.8)	2 (0.8)	0	0	0
意識消失	2 (0.8)	1 (0.4)	0	0	0
記憶障害	2 (0.8)	1 (0.4)	0	0	0
ミオクローヌス	2 (0.8)	2 (0.8)	0	0	0
咬舌	2 (0.8)	0	1 (0.5)	1 (0.5)	0
良性頭蓋内圧亢進	1 (0.4)	0	0	1 (0.5)	0
脳血腫	1 (0.4)	1 (0.4)	0	0	0
複雑部分発作	1 (0.4)	1 (0.4)	0	0	0
協調運動異常	1 (0.4)	0	0	0	0
よだれ	1 (0.4)	1 (0.4)	0	0	0
構語障害	1 (0.4)	1 (0.4)	0	0	0
味覚異常	1 (0.4)	1 (0.4)	0	0	0
統合運動障害	1 (0.4)	0	0	1 (0.5)	0
てんかん	1 (0.4)	0	1 (0.5)	0	0
反射亢進	1 (0.4)	1 (0.4)	0	0	0
反射減弱	1 (0.4)	0	1 (0.5)	0	0
発作後頭痛	1 (0.4)	0	0	0	1 (0.6)
姿勢時振戦	1 (0.4)	1 (0.4)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
		n (%)	n (%)	n (%)	n (%)
神経系障害					
嗜眠	2 (0.8)	0	0	0	0
意識消失	2 (0.8)	1 (0.7)	0	0	0
記憶障害	2 (0.8)	0	0	1 (0.9)	0
ミオクローヌス	2 (0.8)	0	0	0	0
咬舌	2 (0.8)	0	0	0	0
良性頭蓋内圧亢進	1 (0.4)	0	0	0	0
脳血腫	1 (0.4)	0	0	0	0
複雑部分発作	1 (0.4)	0	0	0	0
協調運動異常	1 (0.4)	0	0	0	0
よだれ	1 (0.4)	0	0	0	0
構語障害	1 (0.4)	0	0	0	0
味覚異常	1 (0.4)	0	0	0	0
統合運動障害	1 (0.4)	0	0	0	0
てんかん	1 (0.4)	0	0	0	0
反射亢進	1 (0.4)	0	0	0	0
反射減弱	1 (0.4)	0	0	0	0
発作後頭痛	1 (0.4)	0	0	0	0
姿勢時振戦	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
神経系障害						
嗜眠	2	(0.8)	0	0	0	0
意識消失	2	(0.8)	0	0	0	0
記憶障害	2	(0.8)	0	0	0	0
ミオクローヌス	2	(0.8)	0	0	0	0
咬舌	2	(0.8)	0	0	0	0
良性頭蓋内圧亢進	1	(0.4)	0	0	0	0
脳血腫	1	(0.4)	0	0	0	0
複雑部分発作	1	(0.4)	0	0	0	0
協調運動異常	1	(0.4)	0	0	0	0
よだれ	1	(0.4)	0	0	0	0
構語障害	1	(0.4)	0	0	0	0
味覚異常	1	(0.4)	0	0	0	0
統合運動障害	1	(0.4)	0	0	0	0
てんかん	1	(0.4)	0	0	0	0
反射亢進	1	(0.4)	0	0	0	0
反射減弱	1	(0.4)	0	0	0	0
発作後頭痛	1	(0.4)	0	0	0	0
姿勢時振戦	1	(0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)		>39 - <=42 n (%)	
神経系障害						
嗜眠	2	(0.8)	0		0	
意識消失	2	(0.8)	0		0	
記憶障害	2	(0.8)	0		0	
ミオクローヌス	2	(0.8)	0		0	
咬舌	2	(0.8)	0		0	
良性頭蓋内圧亢進	1	(0.4)	0		0	
脳血腫	1	(0.4)	0		0	
複雑部分発作	1	(0.4)	0		0	
協調運動異常	1	(0.4)	1	(8.3)	0	
よだれ	1	(0.4)	0		0	
構語障害	1	(0.4)	0		0	
味覚異常	1	(0.4)	0		0	
統合運動障害	1	(0.4)	0		0	
てんかん	1	(0.4)	0		0	
反射亢進	1	(0.4)	0		0	
反射減弱	1	(0.4)	0		0	
発作後頭痛	1	(0.4)	0		0	
姿勢時振戦	1	(0.4)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
神経系障害										
鎮静	1	(0.4)	1	(0.4)	0		0		0	
単純部分発作	1	(0.4)	1	(0.4)	0		0		0	
会話障害	1	(0.4)	1	(0.4)	0		0		0	
失神	1	(0.4)	0		0		1	(0.5)	0	
緊張性頭痛	1	(0.4)	1	(0.4)	0		0		0	
強直性痙攣	1	(0.4)	0		1	(0.5)	0		0	
精神障害	36	(14.1)	23	(9.0)	4	(1.8)	3	(1.5)	2	(1.2)
不安	7	(2.7)	6	(2.4)	1	(0.5)	0		0	
不眠症	7	(2.7)	3	(1.2)	2	(0.9)	0		0	
うつ病	4	(1.6)	2	(0.8)	0		1	(0.5)	1	(0.6)
自殺念慮	4	(1.6)	3	(1.2)	0		0		0	
心因性発作	3	(1.2)	2	(0.8)	0		0		0	
攻撃性	2	(0.8)	1	(0.4)	0		1	(0.5)	0	
抑うつ気分	2	(0.8)	2	(0.8)	0		0		0	
失見当識	2	(0.8)	1	(0.4)	0		0		0	
睡眠障害	2	(0.8)	0		1	(0.5)	1	(0.5)	0	
怒り	1	(0.4)	1	(0.4)	0		0		0	
精神緩慢	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
鎮静	1	(0.4)	0		0		0		0	
単純部分発作	1	(0.4)	0		0		0		0	
会話障害	1	(0.4)	0		0		0		0	
失神	1	(0.4)	0		0		0		0	
緊張性頭痛	1	(0.4)	0		0		0		0	
強直性痙攣	1	(0.4)	0		0		0		0	
精神障害	36	(14.1)	1	(0.7)	1	(0.8)	1	(0.9)	1	(1.0)
不安	7	(2.7)	0		0		0		0	
不眠症	7	(2.7)	0		0		0		0	
うつ病	4	(1.6)	0		0		0		0	
自殺念慮	4	(1.6)	1	(0.7)	0		0		0	
心因性発作	3	(1.2)	0		0		0		1	(1.0)
攻撃性	2	(0.8)	0		0		0		0	
抑うつ気分	2	(0.8)	0		0		0		0	
失見当識	2	(0.8)	0		0		1	(0.9)	0	
睡眠障害	2	(0.8)	0		0		0		0	
怒り	1	(0.4)	0		0		0		0	
精神緩慢	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
神経系障害										
鎮静	1	(0.4)	0		0		0		0	
単純部分発作	1	(0.4)	0		0		0		0	
会話障害	1	(0.4)	0		0		0		0	
失神	1	(0.4)	0		0		0		0	
緊張性頭痛	1	(0.4)	0		0		0		0	
強直性痙攣	1	(0.4)	0		0		0		0	
精神障害	36	(14.1)	2	(2.5)	0		0		2	(5.4)
不安	7	(2.7)	0		0		0		0	
不眠症	7	(2.7)	2	(2.5)	0		0		0	
うつ病	4	(1.6)	0		0		0		0	
自殺念慮	4	(1.6)	0		0		0		0	
心因性発作	3	(1.2)	0		0		0		0	
攻撃性	2	(0.8)	0		0		0		0	
抑うつ気分	2	(0.8)	0		0		0		0	
失見当識	2	(0.8)	0		0		0		0	
睡眠障害	2	(0.8)	0		0		0		0	
怒り	1	(0.4)	0		0		0		0	
精神緩慢	1	(0.4)	0		0		0		1	(2.7)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
神経系障害				
鎮静	1	(0.4)	0	0
単純部分発作	1	(0.4)	0	0
会話障害	1	(0.4)	0	0
失神	1	(0.4)	0	0
緊張性頭痛	1	(0.4)	0	0
強直性痙攣	1	(0.4)	0	0
精神障害	36	(14.1)	0	0
不安	7	(2.7)	0	0
不眠症	7	(2.7)	0	0
うつ病	4	(1.6)	0	0
自殺念慮	4	(1.6)	0	0
心因性発作	3	(1.2)	0	0
攻撃性	2	(0.8)	0	0
抑うつ気分	2	(0.8)	0	0
失見当識	2	(0.8)	0	0
睡眠障害	2	(0.8)	0	0
怒り	1	(0.4)	0	0
精神緩慢	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
			n	(%)	n	(%)	n	(%)	n	(%)
精神障害										
妄想	1	(0.4)	0		0		0		0	
ディスフェミア	1	(0.4)	1	(0.4)	0		0		0	
学習障害	1	(0.4)	1	(0.4)	0		0		0	
精神状態変化	1	(0.4)	0		0		0		1	(0.6)
パニック発作	1	(0.4)	1	(0.4)	0		0		0	
精神運動制止遅滞	1	(0.4)	1	(0.4)	0		0		0	
睡眠時驚愕	1	(0.4)	0		0		0		0	
身体表現性障害	1	(0.4)	0		0		0		0	
ストレス	1	(0.4)	1	(0.4)	0		0		0	
早朝覚醒型不眠症	1	(0.4)	1	(0.4)	0		0		0	
思考異常	1	(0.4)	1	(0.4)	0		0		0	
腎および尿路障害	2	(0.8)	1	(0.4)	0		0		1	(0.6)
排尿困難	1	(0.4)	1	(0.4)	0		0		0	
糖尿	1	(0.4)	1	(0.4)	0		0		0	
腎不全	1	(0.4)	0		0		0		1	(0.6)
生殖系および乳房障害	12	(4.7)	4	(1.6)	3	(1.4)	3	(1.5)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
			n	(%)	n	(%)	n	(%)	n	(%)
精神障害										
妄想	1	(0.4)	0		0		1	(0.9)	0	
ディスフェミア	1	(0.4)	0		0		0		0	
学習障害	1	(0.4)	0		0		0		0	
精神状態変化	1	(0.4)	0		0		0		0	
パニック発作	1	(0.4)	0		0		0		0	
精神運動制止遅滞	1	(0.4)	0		0		0		0	
睡眠時驚愕	1	(0.4)	0		1	(0.8)	0		0	
身体表現性障害	1	(0.4)	0		0		0		0	
ストレス	1	(0.4)	0		0		0		0	
早朝覚醒型不眠症	1	(0.4)	0		0		0		0	
思考異常	1	(0.4)	0		0		0		0	
腎および尿路障害	2	(0.8)	0		0		0		0	
排尿困難	1	(0.4)	0		0		0		0	
糖尿	1	(0.4)	0		0		0		0	
腎不全	1	(0.4)	0		0		0		0	
生殖系および乳房障害	12	(4.7)	0		1	(0.8)	1	(0.9)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
		n (%)	n (%)	n (%)	n (%)
精神障害					
妄想	1 (0.4)	0	0	0	0
ディスフェミア	1 (0.4)	0	0	0	0
学習障害	1 (0.4)	0	0	0	0
精神状態変化	1 (0.4)	0	0	0	0
パニック発作	1 (0.4)	0	0	0	0
精神運動制止遅滞	1 (0.4)	0	0	0	0
睡眠時驚愕	1 (0.4)	0	0	0	0
身体表現性障害	1 (0.4)	0	0	0	1 (2.7)
ストレス	1 (0.4)	0	0	0	0
早朝覚醒型不眠症	1 (0.4)	0	0	0	0
思考異常	1 (0.4)	0	0	0	0
腎および尿路障害	2 (0.8)	0	0	0	0
排尿困難	1 (0.4)	0	0	0	0
糖尿	1 (0.4)	0	0	0	0
腎不全	1 (0.4)	0	0	0	0
生殖系および乳房障害	12 (4.7)	1 (1.2)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
精神障害				
妄想	1	(0.4)	0	0
ディスフェミア	1	(0.4)	0	0
学習障害	1	(0.4)	0	0
精神状態変化	1	(0.4)	0	0
パニック発作	1	(0.4)	0	0
精神運動制止遅滞	1	(0.4)	0	0
睡眠時驚愕	1	(0.4)	0	0
身体表現性障害	1	(0.4)	0	0
ストレス	1	(0.4)	0	0
早朝覚醒型不眠症	1	(0.4)	0	0
思考異常	1	(0.4)	0	0
腎および尿路障害	2	(0.8)	0	0
排尿困難	1	(0.4)	0	0
糖尿	1	(0.4)	0	0
腎不全	1	(0.4)	0	0
生殖系および乳房障害	12	(4.7)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
生殖系および乳房障害										
月経困難症	4	(1.6)	1	(0.4)	1	(0.5)	2	(1.0)	0	
不規則月経	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
卵巣嚢胞	2	(0.8)	0		1	(0.5)	0		0	
乳房痛	1	(0.4)	1	(0.4)	0		0		0	
月経過多	1	(0.4)	0		0		0		0	
前立腺腫大	1	(0.4)	0		0		0		0	
性機能不全	1	(0.4)	0		0		1	(0.5)	0	
子宮出血	1	(0.4)	1	(0.4)	0		0		0	
呼吸器、胸郭および縦隔障害	23	(9.0)	10	(3.9)	6	(2.8)	3	(1.5)	2	(1.2)
口腔咽頭痛	7	(2.7)	4	(1.6)	1	(0.5)	1	(0.5)	1	(0.6)
咳嗽	5	(2.0)	2	(0.8)	2	(0.9)	0		0	
鼻出血	4	(1.6)	1	(0.4)	2	(0.9)	0		0	
過換気	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
誤嚥性肺炎	2	(0.8)	0		0		1	(0.5)	0	
急性呼吸不全	1	(0.4)	0		0		0		0	
喘息	1	(0.4)	1	(0.4)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
生殖系および乳房障害										
月経困難症	4	(1.6)	0		0		0		0	
不規則月経	2	(0.8)	0		0		0		0	
卵巣嚢胞	2	(0.8)	0		0		1	(0.9)	0	
乳房痛	1	(0.4)	0		0		0		0	
月経過多	1	(0.4)	0		1	(0.8)	0		0	
前立腺腫大	1	(0.4)	0		0		0		0	
性機能不全	1	(0.4)	0		0		0		0	
子宮出血	1	(0.4)	0		0		0		0	
呼吸器、胸郭および縦隔障害	23	(9.0)	1	(0.7)	0		2	(1.8)	2	(2.1)
口腔咽頭痛	7	(2.7)	0		0		0		0	
咳嗽	5	(2.0)	0		0		0		1	(1.0)
鼻出血	4	(1.6)	0		0		1	(0.9)	0	
過換気	2	(0.8)	0		0		0		0	
誤嚥性肺炎	2	(0.8)	1	(0.7)	0		0		0	
急性呼吸不全	1	(0.4)	1	(0.7)	0		0		0	
喘息	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
生殖系および乳房障害										
月経困難症	4	(1.6)	0		0		0		0	
不規則月経	2	(0.8)	0		0		0		0	
卵巣嚢胞	2	(0.8)	0		0		0		0	
乳房痛	1	(0.4)	0		0		0		0	
月経過多	1	(0.4)	0		0		0		0	
前立腺腫大	1	(0.4)	1	(1.2)	0		0		0	
性機能不全	1	(0.4)	0		0		0		0	
子宮出血	1	(0.4)	0		0		0		0	
呼吸器、胸郭および縦隔障害	23	(9.0)	0		0		0		0	
口腔咽頭痛	7	(2.7)	0		0		0		0	
咳嗽	5	(2.0)	0		0		0		0	
鼻出血	4	(1.6)	0		0		0		0	
過換気	2	(0.8)	0		0		0		0	
誤嚥性肺炎	2	(0.8)	0		0		0		0	
急性呼吸不全	1	(0.4)	0		0		0		0	
喘息	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
生殖系および乳房障害				
月経困難症	4	(1.6)	0	0
不規則月経	2	(0.8)	0	0
卵巣嚢胞	2	(0.8)	0	0
乳房痛	1	(0.4)	0	0
月経過多	1	(0.4)	0	0
前立腺腫大	1	(0.4)	0	0
性機能不全	1	(0.4)	0	0
子宮出血	1	(0.4)	0	0
呼吸器、胸郭および縦隔障害	23	(9.0)	0	0
口腔咽頭痛	7	(2.7)	0	0
咳嗽	5	(2.0)	0	0
鼻出血	4	(1.6)	0	0
過換気	2	(0.8)	0	0
誤嚥性肺炎	2	(0.8)	0	0
急性呼吸不全	1	(0.4)	0	0
喘息	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
			n	(%)	n	(%)	n	(%)	n	(%)
呼吸器、胸郭および縦隔障害										
鼻閉	1	(0.4)	0		1	(0.5)	0		0	
呼吸時疼痛	1	(0.4)	0		0		1	(0.5)	0	
湿性咳嗽	1	(0.4)	0		0		0		0	
呼吸障害	1	(0.4)	0		0		0		0	
鼻痛	1	(0.4)	1	(0.4)	0		0		0	
鼻漏	1	(0.4)	1	(0.4)	0		0		0	
いびき	1	(0.4)	0		0		0		1	(0.6)
皮膚および皮下組織障害	21	(8.2)	10	(3.9)	4	(1.8)	2	(1.0)	0	
脱毛症	4	(1.6)	2	(0.8)	2	(0.9)	0		0	
湿疹	3	(1.2)	1	(0.4)	0		1	(0.5)	0	
発疹	3	(1.2)	3	(1.2)	0		0		0	
皮膚炎	2	(0.8)	0		0		0		0	
紅斑	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
嵌入爪	2	(0.8)	0		0		0		0	
そう痒症	2	(0.8)	2	(0.8)	0		0		0	
ざ瘡	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
呼吸器、胸郭および縦隔障害										
鼻閉	1	(0.4)	0		0		0		0	
呼吸時疼痛	1	(0.4)	0		0		0		0	
湿性咳嗽	1	(0.4)	0		0		1	(0.9)	0	
呼吸障害	1	(0.4)	0		0		0		1	(1.0)
鼻痛	1	(0.4)	0		0		0		0	
鼻漏	1	(0.4)	0		0		0		0	
いびき	1	(0.4)	0		0		0		0	
皮膚および皮下組織障害	21	(8.2)	1	(0.7)	3	(2.3)	1	(0.9)	0	
脱毛症	4	(1.6)	0		0		0		0	
湿疹	3	(1.2)	0		1	(0.8)	0		0	
発疹	3	(1.2)	0		0		0		0	
皮膚炎	2	(0.8)	0		1	(0.8)	0		0	
紅斑	2	(0.8)	0		0		0		0	
嵌入爪	2	(0.8)	1	(0.7)	0		1	(0.9)	0	
そう痒症	2	(0.8)	0		0		0		0	
ざ瘡	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
呼吸器、胸郭および縦隔障害										
鼻閉	1	(0.4)	0		0		0		0	
呼吸時疼痛	1	(0.4)	0		0		0		0	
湿性咳嗽	1	(0.4)	0		0		0		0	
呼吸障害	1	(0.4)	0		0		0		0	
鼻痛	1	(0.4)	0		0		0		0	
鼻漏	1	(0.4)	0		0		0		0	
いびき	1	(0.4)	0		0		0		0	
皮膚および皮下組織障害	21	(8.2)	2	(2.5)	0		1	(2.2)	0	
脱毛症	4	(1.6)	0		0		0		0	
湿疹	3	(1.2)	0		0		0		0	
発疹	3	(1.2)	0		0		0		0	
皮膚炎	2	(0.8)	1	(1.2)	0		0		0	
紅斑	2	(0.8)	0		0		0		0	
嵌入爪	2	(0.8)	0		0		0		0	
そう痒症	2	(0.8)	0		0		0		0	
ざ瘡	1	(0.4)	1	(1.2)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
呼吸器、胸郭および縦隔障害				
鼻閉	1	(0.4)	0	0
呼吸時疼痛	1	(0.4)	0	0
湿性咳嗽	1	(0.4)	0	0
呼吸障害	1	(0.4)	0	0
鼻痛	1	(0.4)	0	0
鼻漏	1	(0.4)	0	0
いびき	1	(0.4)	0	0
皮膚および皮下組織障害	21	(8.2)	0	0
脱毛症	4	(1.6)	0	0
湿疹	3	(1.2)	0	0
発疹	3	(1.2)	0	0
皮膚炎	2	(0.8)	0	0
紅斑	2	(0.8)	0	0
嵌入爪	2	(0.8)	0	0
そう痒症	2	(0.8)	0	0
ざ瘡	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
皮膚および皮下組織障害										
接触性皮膚炎	1	(0.4)	0		0		1	(0.5)	0	
皮膚乾燥	1	(0.4)	0		0		0		0	
異汗性湿疹	1	(0.4)	1	(0.4)	0		0		0	
逆むけ	1	(0.4)	0		1	(0.5)	0		0	
多汗症	1	(0.4)	1	(0.4)	0		0		0	
爪破損	1	(0.4)	0		1	(0.5)	0		0	
顔面腫脹	1	(0.4)	1	(0.4)	0		0		0	
蕁麻疹	1	(0.4)	0		0		0		0	
外科および内科処置	1	(0.4)	0		0		1	(0.5)	0	
人工流産	1	(0.4)	0		0		1	(0.5)	0	
血管障害	12	(4.7)	4	(1.6)	2	(0.9)	2	(1.0)	0	
高血圧	7	(2.7)	2	(0.8)	2	(0.9)	2	(1.0)	0	
潮紅	1	(0.4)	1	(0.4)	0		0		0	
低血圧	1	(0.4)	1	(0.4)	0		0		0	
起立性低血圧	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
皮膚および皮下組織障害										
接触性皮膚炎	1	(0.4)	0		0		0		0	
皮膚乾燥	1	(0.4)	0		1	(0.8)	0		0	
異汗性湿疹	1	(0.4)	0		0		0		0	
逆むけ	1	(0.4)	0		0		0		0	
多汗症	1	(0.4)	0		0		0		0	
爪破損	1	(0.4)	0		0		0		0	
顔面腫脹	1	(0.4)	0		0		0		0	
蕁麻疹	1	(0.4)	0		0		0		0	
外科および内科処置	1	(0.4)	0		0		0		0	
人工流産	1	(0.4)	0		0		0		0	
血管障害	12	(4.7)	1	(0.7)	0		1	(0.9)	0	
高血圧	7	(2.7)	0		0		0		0	
潮紅	1	(0.4)	0		0		0		0	
低血圧	1	(0.4)	0		0		0		0	
起立性低血圧	1	(0.4)	1	(0.7)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
皮膚および皮下組織障害										
接触性皮膚炎	1	(0.4)	0		0		0		0	
皮膚乾燥	1	(0.4)	0		0		0		0	
異汗性湿疹	1	(0.4)	0		0		0		0	
逆むけ	1	(0.4)	0		0		0		0	
多汗症	1	(0.4)	0		0		0		0	
爪破損	1	(0.4)	0		0		0		0	
顔面腫脹	1	(0.4)	0		0		0		0	
蕁麻疹	1	(0.4)	0		0		1	(2.2)	0	
外科および内科処置	1	(0.4)	0		0		0		0	
人工流産	1	(0.4)	0		0		0		0	
血管障害	12	(4.7)	0		1	(1.6)	1	(2.2)	0	
高血圧	7	(2.7)	0		1	(1.6)	0		0	
潮紅	1	(0.4)	0		0		0		0	
低血圧	1	(0.4)	0		0		0		0	
起立性低血圧	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
皮膚および皮下組織障害				
接触性皮膚炎	1	(0.4)	0	0
皮膚乾燥	1	(0.4)	0	0
異汗性湿疹	1	(0.4)	0	0
逆むけ	1	(0.4)	0	0
多汗症	1	(0.4)	0	0
爪破損	1	(0.4)	0	0
顔面腫脹	1	(0.4)	0	0
蕁麻疹	1	(0.4)	0	0
外科および内科処置	1	(0.4)	0	0
人工流産	1	(0.4)	0	0
血管障害	12	(4.7)	0	0
高血圧	7	(2.7)	0	0
潮紅	1	(0.4)	0	0
低血圧	1	(0.4)	0	0
起立性低血圧	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
血管障害					
末梢性虚血	1 (0.4)	0	0	0	0
血管炎	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1　Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
血管障害					
末梢性虚血	1 (0.4)	0	0	0	0
血管炎	1 (0.4)	0	0	1 (0.9)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
血管障害					
末梢性虚血	1 (0.4)	0	0	1 (2.2)	0
血管炎	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	All Subjects	n (%)	n (%)
血管障害			
末梢性虚血	1 (0.4)	0	0
血管炎	1 (0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class		>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics	n	(%)	n	(%)	n	(%)	n	(%)
Number evaluated	50	50		48		43		32	
Any TEAE	41 (82.0)	35	(70.0)	18	(37.5)	17	(39.5)	7	(21.9)
血液およびリンパ系障害	1 (2.0)	1	(2.0)	0		0		0	
鉄欠乏性貧血	1 (2.0)	1	(2.0)	0		0		0	
心臓障害	4 (8.0)	3	(6.0)	0		1	(2.3)	0	
右脚ブロック	2 (4.0)	1	(2.0)	0		1	(2.3)	0	
第一度房室ブロック	1 (2.0)	1	(2.0)	0		0		0	
動悸	1 (2.0)	1	(2.0)	0		0		0	
耳および迷路障害	2 (4.0)	1	(2.0)	0		1	(2.3)	0	
回転性めまい	2 (4.0)	1	(2.0)	0		1	(2.3)	0	
眼障害	2 (4.0)	1	(2.0)	0		0		0	
複視	1 (2.0)	1	(2.0)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Pediatrics		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
Number evaluated	50		28		24		21		19	
Any TEAE	41	(82.0)	5	(17.9)	6	(25.0)	2	(9.5)	1	(5.3)
血液およびリンパ系障害	1	(2.0)	0		0		0		0	
鉄欠乏性貧血	1	(2.0)	0		0		0		0	
心臓障害	4	(8.0)	0		0		0		0	
右脚ブロック	2	(4.0)	0		0		0		0	
第一度房室ブロック	1	(2.0)	0		0		0		0	
動悸	1	(2.0)	0		0		0		0	
耳および迷路障害	2	(4.0)	0		0		0		0	
回転性めまい	2	(4.0)	0		0		0		0	
眼障害	2	(4.0)	0		0		0		0	
複視	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Pediatrics	Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
Number evaluated	50	16	12	9	7
Any TEAE	41 (82.0)	1 (6.3)	0	1 (11.1)	1 (14.3)
血液およびリンパ系障害	1 (2.0)	0	0	0	0
鉄欠乏性貧血	1 (2.0)	0	0	0	0
心臓障害	4 (8.0)	0	0	0	0
右脚ブロック	2 (4.0)	0	0	0	0
第一度房室ブロック	1 (2.0)	0	0	0	0
動悸	1 (2.0)	0	0	0	0
耳および迷路障害	2 (4.0)	0	0	0	0
回転性めまい	2 (4.0)	0	0	0	0
眼障害	2 (4.0)	0	0	1 (11.1)	0
複視	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
Number evaluated	50		3	0
Any TEAE	41	(82.0)	0	0
血液およびリンパ系障害	1	(2.0)	0	0
鉄欠乏性貧血	1	(2.0)	0	0
心臓障害	4	(8.0)	0	0
右脚ブロック	2	(4.0)	0	0
第一度房室ブロック	1	(2.0)	0	0
動悸	1	(2.0)	0	0
耳および迷路障害	2	(4.0)	0	0
回転性めまい	2	(4.0)	0	0
眼障害	2	(4.0)	0	0
複視	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
眼障害										
眼瞼湿疹	1	(2.0)	0		0		0		0	
胃腸障害	19	(38.0)	10	(20.0)	3	(6.3)	1	(2.3)	1	(3.1)
悪心	6	(12.0)	5	(10.0)	0		0		1	(3.1)
嘔吐	5	(10.0)	2	(4.0)	1	(2.1)	1	(2.3)	0	
上腹部痛	3	(6.0)	1	(2.0)	0		0		0	
下痢	3	(6.0)	0		0		0		0	
口内炎	2	(4.0)	0		0		0		0	
腹痛	1	(2.0)	0		1	(2.1)	0		0	
下腹部痛	1	(2.0)	1	(2.0)	0		0		0	
便秘	1	(2.0)	0		1	(2.1)	0		0	
胃炎	1	(2.0)	1	(2.0)	0		0		0	
一般・全身障害および投与部位の状態	9	(18.0)	3	(6.0)	3	(6.3)	0		1	(3.1)
疲労	3	(6.0)	1	(2.0)	1	(2.1)	0		0	
発熱	3	(6.0)	1	(2.0)	1	(2.1)	0		1	(3.1)
易刺激性	1	(2.0)	1	(2.0)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Pediatrics		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
眼障害										
眼瞼湿疹	1	(2.0)	0		0		0		0	
胃腸障害	19	(38.0)	2	(7.1)	1	(4.2)	1	(4.8)	1	(5.3)
悪心	6	(12.0)	0		0		0		0	
嘔吐	5	(10.0)	0		0		1	(4.8)	0	
上腹部痛	3	(6.0)	0		0		1	(4.8)	1	(5.3)
下痢	3	(6.0)	1	(3.6)	0		0		1	(5.3)
口内炎	2	(4.0)	1	(3.6)	1	(4.2)	0		0	
腹痛	1	(2.0)	0		0		0		0	
下腹部痛	1	(2.0)	0		0		0		0	
便秘	1	(2.0)	0		0		0		0	
胃炎	1	(2.0)	0		0		0		0	
一般・全身障害および投与部位の状態	9	(18.0)	0		1	(4.2)	1	(4.8)	0	
疲労	3	(6.0)	0		1	(4.2)	0		0	
発熱	3	(6.0)	0		0		0		0	
易刺激性	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Pediatrics	Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
眼障害					
眼瞼湿疹	1 (2.0)	0	0	1 (11.1)	0
胃腸障害	19 (38.0)	1 (6.3)	0	0	0
悪心	6 (12.0)	0	0	0	0
嘔吐	5 (10.0)	0	0	0	0
上腹部痛	3 (6.0)	0	0	0	0
下痢	3 (6.0)	1 (6.3)	0	0	0
口内炎	2 (4.0)	0	0	0	0
腹痛	1 (2.0)	0	0	0	0
下腹部痛	1 (2.0)	0	0	0	0
便秘	1 (2.0)	0	0	0	0
胃炎	1 (2.0)	0	0	0	0
一般・全身障害および投与部位の状態	9 (18.0)	0	0	0	0
疲労	3 (6.0)	0	0	0	0
発熱	3 (6.0)	0	0	0	0
易刺激性	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Pediatrics		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
眼障害				
眼瞼湿疹	1	(2.0)	0	0
胃腸障害	19	(38.0)	0	0
悪心	6	(12.0)	0	0
嘔吐	5	(10.0)	0	0
上腹部痛	3	(6.0)	0	0
下痢	3	(6.0)	0	0
口内炎	2	(4.0)	0	0
腹痛	1	(2.0)	0	0
下腹部痛	1	(2.0)	0	0
便秘	1	(2.0)	0	0
胃炎	1	(2.0)	0	0
一般・全身障害および投与部位の状態	9	(18.0)	0	0
疲労	3	(6.0)	0	0
発熱	3	(6.0)	0	0
易刺激性	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class		>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics	n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態									
非心臓性胸痛	1 (2.0)	0		0		0		0	
末梢性浮腫	1 (2.0)	0		1	(2.1)	0		0	
感染症および寄生虫症	26 (52.0)	14	(28.0)	6	(12.5)	8	(18.6)	4	(12.5)
鼻咽頭炎	14 (28.0)	4	(8.0)	3	(6.3)	4	(9.3)	2	(6.3)
上気道感染	5 (10.0)	2	(4.0)	0		2	(4.7)	1	(3.1)
インフルエンザ	4 (8.0)	2	(4.0)	1	(2.1)	0		0	
尿路感染	2 (4.0)	1	(2.0)	0		0		0	
急性扁桃炎	1 (2.0)	0		0		1	(2.3)	0	
ウイルス性胃炎	1 (2.0)	0		0		0		0	
胃腸炎	1 (2.0)	1	(2.0)	0		0		0	
歯肉炎	1 (2.0)	0		0		1	(2.3)	0	
膿痂疹	1 (2.0)	1	(2.0)	0		0		0	
歯周炎	1 (2.0)	0		0		0		1	(3.1)
咽頭炎	1 (2.0)	0		0		0		0	
咽頭扁桃炎	1 (2.0)	1	(2.0)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
非心臓性胸痛	1	(2.0)	0		0		1	(4.8)	0	
末梢性浮腫	1	(2.0)	0		0		0		0	
感染症および寄生虫症	26	(52.0)	1	(3.6)	2	(8.3)	1	(4.8)	0	
鼻咽頭炎	14	(28.0)	1	(3.6)	0		0		0	
上気道感染	5	(10.0)	0		0		0		0	
インフルエンザ	4	(8.0)	0		1	(4.2)	0		0	
尿路感染	2	(4.0)	0		0		1	(4.8)	0	
急性扁桃炎	1	(2.0)	0		0		0		0	
ウイルス性胃炎	1	(2.0)	0		0		1	(4.8)	0	
胃腸炎	1	(2.0)	0		0		0		0	
歯肉炎	1	(2.0)	0		0		0		0	
膿痂疹	1	(2.0)	0		0		0		0	
歯周炎	1	(2.0)	0		0		0		0	
咽頭炎	1	(2.0)	0		1	(4.2)	0		0	
咽頭扁桃炎	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態						
非心臓性胸痛	1	(2.0)	0	0	0	0
末梢性浮腫	1	(2.0)	0	0	0	0
感染症および寄生虫症	26	(52.0)	0	0	0	0
鼻咽頭炎	14	(28.0)	0	0	0	0
上気道感染	5	(10.0)	0	0	0	0
インフルエンザ	4	(8.0)	0	0	0	0
尿路感染	2	(4.0)	0	0	0	0
急性扁桃炎	1	(2.0)	0	0	0	0
ウイルス性胃炎	1	(2.0)	0	0	0	0
胃腸炎	1	(2.0)	0	0	0	0
歯肉炎	1	(2.0)	0	0	0	0
膿痂疹	1	(2.0)	0	0	0	0
歯周炎	1	(2.0)	0	0	0	0
咽頭炎	1	(2.0)	0	0	0	0
咽頭扁桃炎	1	(2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
一般・全身障害および投与部位の状態				
非心臓性胸痛	1	(2.0)	0	0
末梢性浮腫	1	(2.0)	0	0
感染症および寄生虫症	26	(52.0)	0	0
鼻咽頭炎	14	(28.0)	0	0
上気道感染	5	(10.0)	0	0
インフルエンザ	4	(8.0)	0	0
尿路感染	2	(4.0)	0	0
急性扁桃炎	1	(2.0)	0	0
ウイルス性胃炎	1	(2.0)	0	0
胃腸炎	1	(2.0)	0	0
歯肉炎	1	(2.0)	0	0
膿痂疹	1	(2.0)	0	0
歯周炎	1	(2.0)	0	0
咽頭炎	1	(2.0)	0	0
咽頭扁桃炎	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
肺炎	1	(2.0)	0		1	(2.1)	0		0	
ウイルス性気道感染	1	(2.0)	1	(2.0)	0		0		0	
鼻炎	1	(2.0)	1	(2.0)	0		0		0	
ウイルス性上気道感染	1	(2.0)	0		1	(2.1)	0		0	
傷害、中毒および処置合併症	9	(18.0)	3	(6.0)	4	(8.3)	3	(7.0)	0	
挫傷	6	(12.0)	1	(2.0)	3	(6.3)	1	(2.3)	0	
頭部損傷	3	(6.0)	2	(4.0)	0		0		0	
転倒	2	(4.0)	0		1	(2.1)	1	(2.3)	0	
歯牙破折	2	(4.0)	0		0		1	(2.3)	0	
裂傷	1	(2.0)	0		0		1	(2.3)	0	
皮下血腫	1	(2.0)	1	(2.0)	0		0		0	
臨床検査	5	(10.0)	1	(2.0)	2	(4.2)	0		0	
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0		1	(2.1)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Pediatrics		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
感染症および寄生虫症										
肺炎	1	(2.0)	0		0		0		0	
ウイルス性気道感染	1	(2.0)	0		0		0		0	
鼻炎	1	(2.0)	0		0		0		0	
ウイルス性上気道感染	1	(2.0)	0		0		0		0	
傷害、中毒および処置合併症	9	(18.0)	1	(3.6)	1	(4.2)	0		0	
挫傷	6	(12.0)	1	(3.6)	0		0		0	
頭部損傷	3	(6.0)	1	(3.6)	0		0		0	
転倒	2	(4.0)	0		0		0		0	
歯牙破折	2	(4.0)	0		1	(4.2)	0		0	
裂傷	1	(2.0)	0		0		0		0	
皮下血腫	1	(2.0)	0		0		0		0	
臨床検査	5	(10.0)	1	(3.6)	1	(4.2)	0		0	
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0		1	(4.2)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Pediatrics		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
感染症および寄生虫症						
肺炎	1	(2.0)	0	0	0	0
ウイルス性気道感染	1	(2.0)	0	0	0	0
鼻炎	1	(2.0)	0	0	0	0
ウイルス性上気道感染	1	(2.0)	0	0	0	0
傷害、中毒および処置合併症	9	(18.0)	0	0	0	0
挫傷	6	(12.0)	0	0	0	0
頭部損傷	3	(6.0)	0	0	0	0
転倒	2	(4.0)	0	0	0	0
歯牙破折	2	(4.0)	0	0	0	0
裂傷	1	(2.0)	0	0	0	0
皮下血腫	1	(2.0)	0	0	0	0
臨床検査	5	(10.0)	0	0	0	0
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
感染症および寄生虫症				
肺炎	1	(2.0)	0	0
ウイルス性気道感染	1	(2.0)	0	0
鼻炎	1	(2.0)	0	0
ウイルス性上気道感染	1	(2.0)	0	0
傷害、中毒および処置合併症	9	(18.0)	0	0
挫傷	6	(12.0)	0	0
頭部損傷	3	(6.0)	0	0
転倒	2	(4.0)	0	0
歯牙破折	2	(4.0)	0	0
裂傷	1	(2.0)	0	0
皮下血腫	1	(2.0)	0	0
臨床検査	5	(10.0)	0	0
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
血中アルカリホスファターゼ増加	1	(2.0)	1	(2.0)	0		0		0	
血中トリグリセリド増加	1	(2.0)	0		0		0		0	
トランスアミナーゼ上昇	1	(2.0)	0		1	(2.1)	0		0	
体重増加	1	(2.0)	0		0		0		0	
代謝および栄養障害	3	(6.0)	0		0		1	(2.3)	0	
脱水	1	(2.0)	0		0		0		0	
高アンモニア血症	1	(2.0)	0		0		0		0	
過体重	1	(2.0)	0		0		1	(2.3)	0	
筋骨格系および結合組織障害	2	(4.0)	2	(4.0)	0		0		0	
四肢痛	1	(2.0)	1	(2.0)	0		0		0	
腱鞘炎	1	(2.0)	1	(2.0)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
血中アルカリホスファターゼ増加	1	(2.0)	0		0		0		0	
血中トリグリセリド増加	1	(2.0)	0		1	(4.2)	0		0	
トランスアミナーゼ上昇	1	(2.0)	0		0		0		0	
体重増加	1	(2.0)	1	(3.6)	0		0		0	
代謝および栄養障害	3	(6.0)	0		0		2	(9.5)	0	
脱水	1	(2.0)	0		0		1	(4.8)	0	
高アンモニア血症	1	(2.0)	0		0		1	(4.8)	0	
過体重	1	(2.0)	0		0		0		0	
筋骨格系および結合組織障害	2	(4.0)	0		0		0		0	
四肢痛	1	(2.0)	0		0		0		0	
腱鞘炎	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
臨床検査						
血中アルカリホスファターゼ増加	1	(2.0)	0	0	0	0
血中トリグリセリド増加	1	(2.0)	0	0	0	0
トランスアミナーゼ上昇	1	(2.0)	0	0	0	0
体重増加	1	(2.0)	0	0	0	0
代謝および栄養障害	3	(6.0)	0	0	0	0
脱水	1	(2.0)	0	0	0	0
高アンモニア血症	1	(2.0)	0	0	0	0
過体重	1	(2.0)	0	0	0	0
筋骨格系および結合組織障害	2	(4.0)	0	0	0	0
四肢痛	1	(2.0)	0	0	0	0
腱鞘炎	1	(2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
臨床検査				
血中アルカリホスファターゼ増加	1	(2.0)	0	0
血中トリグリセリド増加	1	(2.0)	0	0
トランスアミナーゼ上昇	1	(2.0)	0	0
体重増加	1	(2.0)	0	0
代謝および栄養障害	3	(6.0)	0	0
脱水	1	(2.0)	0	0
高アンモニア血症	1	(2.0)	0	0
過体重	1	(2.0)	0	0
筋骨格系および結合組織障害	2	(4.0)	0	0
四肢痛	1	(2.0)	0	0
腱鞘炎	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
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	(2.0)	0		1	(2.1)	0		0	
乳腺線維腺腫	1	(2.0)	0		1	(2.1)	0		0	
神経系障害	27	(54.0)	20	(40.0)	8	(16.7)	3	(7.0)	4	(12.5)
傾眠	13	(26.0)	8	(16.0)	3	(6.3)	1	(2.3)	1	(3.1)
浮動性めまい	11	(22.0)	9	(18.0)	1	(2.1)	0		1	(3.1)
頭痛	9	(18.0)	5	(10.0)	1	(2.1)	0		2	(6.3)
痙攣	3	(6.0)	1	(2.0)	1	(2.1)	0		1	(3.1)
大発作痙攣	2	(4.0)	1	(2.0)	0		0		0	
小発作てんかん	2	(4.0)	1	(2.0)	1	(2.1)	0		0	
運動失調	1	(2.0)	1	(2.0)	0		0		0	
平衡障害	1	(2.0)	1	(2.0)	0		0		0	
脳血腫	1	(2.0)	1	(2.0)	0		0		0	
複雑部分発作	1	(2.0)	1	(2.0)	0		0		0	
意識消失	1	(2.0)	0		0		0		0	
てんかん重積状態	1	(2.0)	0		0		1	(2.3)	0	
失神	1	(2.0)	0		0		1	(2.3)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
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	(2.0)	0		0		0		0	
乳腺線維腺腫	1	(2.0)	0		0		0		0	
神経系障害	27	(54.0)	1	(3.6)	1	(4.2)	1	(4.8)	0	
傾眠	13	(26.0)	0		0		0		0	
浮動性めまい	11	(22.0)	0		0		0		0	
頭痛	9	(18.0)	0		0		1	(4.8)	0	
痙攣	3	(6.0)	0		0		0		0	
大発作痙攣	2	(4.0)	0		1	(4.2)	0		0	
小発作てんかん	2	(4.0)	0		0		0		0	
運動失調	1	(2.0)	0		0		0		0	
平衡障害	1	(2.0)	0		0		0		0	
脳血腫	1	(2.0)	0		0		0		0	
複雑部分発作	1	(2.0)	0		0		0		0	
意識消失	1	(2.0)	1	(3.6)	0		0		0	
てんかん重積状態	1	(2.0)	0		0		0		0	
失神	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
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	(2.0)	0	0	0	0
乳腺線維腺腫	1	(2.0)	0	0	0	0
神経系障害	27	(54.0)	0	0	0	0
傾眠	13	(26.0)	0	0	0	0
浮動性めまい	11	(22.0)	0	0	0	0
頭痛	9	(18.0)	0	0	0	0
痙攣	3	(6.0)	0	0	0	0
大発作痙攣	2	(4.0)	0	0	0	0
小発作てんかん	2	(4.0)	0	0	0	0
運動失調	1	(2.0)	0	0	0	0
平衡障害	1	(2.0)	0	0	0	0
脳血腫	1	(2.0)	0	0	0	0
複雑部分発作	1	(2.0)	0	0	0	0
意識消失	1	(2.0)	0	0	0	0
てんかん重積状態	1	(2.0)	0	0	0	0
失神	1	(2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
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	(2.0)	0	0
乳腺線維腺腫	1	(2.0)	0	0
神経系障害	27	(54.0)	0	0
傾眠	13	(26.0)	0	0
浮動性めまい	11	(22.0)	0	0
頭痛	9	(18.0)	0	0
痙攣	3	(6.0)	0	0
大発作痙攣	2	(4.0)	0	0
小発作てんかん	2	(4.0)	0	0
運動失調	1	(2.0)	0	0
平衡障害	1	(2.0)	0	0
脳血腫	1	(2.0)	0	0
複雑部分発作	1	(2.0)	0	0
意識消失	1	(2.0)	0	0
てんかん重積状態	1	(2.0)	0	0
失神	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
神経系障害					
強直性痙攣	1 (2.0)	0	1 (2.1)	0	0
精神障害	6 (12.0)	3 (6.0)	2 (4.2)	1 (2.3)	0
攻撃性	1 (2.0)	0	0	1 (2.3)	0
不安	1 (2.0)	1 (2.0)	0	0	0
ディスフェミア	1 (2.0)	1 (2.0)	0	0	0
不眠症	1 (2.0)	0	1 (2.1)	0	0
学習障害	1 (2.0)	1 (2.0)	0	0	0
心因性発作	1 (2.0)	1 (2.0)	0	0	0
睡眠障害	1 (2.0)	0	1 (2.1)	0	0
睡眠時驚愕	1 (2.0)	0	0	0	0
身体表現性障害	1 (2.0)	0	0	0	0
生殖系および乳房障害	2 (4.0)	0	1 (2.1)	1 (2.3)	0
月経困難症	1 (2.0)	0	0	1 (2.3)	0
卵巣嚢胞	1 (2.0)	0	1 (2.1)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
神経系障害					
強直性痙攣	1 (2.0)	0	0	0	0
精神障害	6 (12.0)	0	1 (4.2)	0	0
攻撃性	1 (2.0)	0	0	0	0
不安	1 (2.0)	0	0	0	0
ディスフェミア	1 (2.0)	0	0	0	0
不眠症	1 (2.0)	0	0	0	0
学習障害	1 (2.0)	0	0	0	0
心因性発作	1 (2.0)	0	0	0	0
睡眠障害	1 (2.0)	0	0	0	0
睡眠時驚愕	1 (2.0)	0	1 (4.2)	0	0
身体表現性障害	1 (2.0)	0	0	0	0
生殖系および乳房障害	2 (4.0)	0	0	0	0
月経困難症	1 (2.0)	0	0	0	0
卵巣嚢胞	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
神経系障害					
強直性痙攣	1 (2.0)	0	0	0	0
精神障害	6 (12.0)	0	0	0	1 (14.3)
攻撃性	1 (2.0)	0	0	0	0
不安	1 (2.0)	0	0	0	0
ディスフェミア	1 (2.0)	0	0	0	0
不眠症	1 (2.0)	0	0	0	0
学習障害	1 (2.0)	0	0	0	0
心因性発作	1 (2.0)	0	0	0	0
睡眠障害	1 (2.0)	0	0	0	0
睡眠時驚愕	1 (2.0)	0	0	0	0
身体表現性障害	1 (2.0)	0	0	0	1 (14.3)
生殖系および乳房障害	2 (4.0)	0	0	0	0
月経困難症	1 (2.0)	0	0	0	0
卵巣嚢胞	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
神経系障害				
強直性痙攣	1	(2.0)	0	0
精神障害	6	(12.0)	0	0
攻撃性	1	(2.0)	0	0
不安	1	(2.0)	0	0
ディスフェミア	1	(2.0)	0	0
不眠症	1	(2.0)	0	0
学習障害	1	(2.0)	0	0
心因性発作	1	(2.0)	0	0
睡眠障害	1	(2.0)	0	0
睡眠時驚愕	1	(2.0)	0	0
身体表現性障害	1	(2.0)	0	0
生殖系および乳房障害	2	(4.0)	0	0
月経困難症	1	(2.0)	0	0
卵巣嚢胞	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
呼吸器、胸郭および縦隔障害	6	(12.0)	4	(8.0)	2	(4.2)	0		0	
咳嗽	2	(4.0)	1	(2.0)	1	(2.1)	0		0	
過換気	2	(4.0)	1	(2.0)	1	(2.1)	0		0	
鼻出血	1	(2.0)	1	(2.0)	0		0		0	
鼻閉	1	(2.0)	0		1	(2.1)	0		0	
鼻痛	1	(2.0)	1	(2.0)	0		0		0	
鼻漏	1	(2.0)	1	(2.0)	0		0		0	
皮膚および皮下組織障害	2	(4.0)	1	(2.0)	0		1	(2.3)	0	
異汗性湿疹	1	(2.0)	1	(2.0)	0		0		0	
湿疹	1	(2.0)	0		0		1	(2.3)	0	
外科および内科処置	1	(2.0)	0		0		1	(2.3)	0	
人工流産	1	(2.0)	0		0		1	(2.3)	0	
血管障害	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害	6 (12.0)	0	0	0	0
咳嗽	2 (4.0)	0	0	0	0
過換気	2 (4.0)	0	0	0	0
鼻出血	1 (2.0)	0	0	0	0
鼻閉	1 (2.0)	0	0	0	0
鼻痛	1 (2.0)	0	0	0	0
鼻漏	1 (2.0)	0	0	0	0
皮膚および皮下組織障害	2 (4.0)	0	0	0	0
異汗性湿疹	1 (2.0)	0	0	0	0
湿疹	1 (2.0)	0	0	0	0
外科および内科処置	1 (2.0)	0	0	0	0
人工流産	1 (2.0)	0	0	0	0
血管障害	1 (2.0)	1 (3.6)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害	6	(12.0)	0	0	0	0
咳嗽	2	(4.0)	0	0	0	0
過換気	2	(4.0)	0	0	0	0
鼻出血	1	(2.0)	0	0	0	0
鼻閉	1	(2.0)	0	0	0	0
鼻痛	1	(2.0)	0	0	0	0
鼻漏	1	(2.0)	0	0	0	0
皮膚および皮下組織障害	2	(4.0)	0	0	0	0
異汗性湿疹	1	(2.0)	0	0	0	0
湿疹	1	(2.0)	0	0	0	0
外科および内科処置	1	(2.0)	0	0	0	0
人工流産	1	(2.0)	0	0	0	0
血管障害	1	(2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
呼吸器、胸郭および縦隔障害	6	(12.0)	0	0
咳嗽	2	(4.0)	0	0
過換気	2	(4.0)	0	0
鼻出血	1	(2.0)	0	0
鼻閉	1	(2.0)	0	0
鼻痛	1	(2.0)	0	0
鼻漏	1	(2.0)	0	0
皮膚および皮下組織障害	2	(4.0)	0	0
異汗性湿疹	1	(2.0)	0	0
湿疹	1	(2.0)	0	0
外科および内科処置	1	(2.0)	0	0
人工流産	1	(2.0)	0	0
血管障害	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1　Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
血管障害					
起立性低血圧	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
血管障害					
起立性低血圧	1 (2.0)	1 (3.6)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1　Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
血管障害					
起立性低血圧	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	Pediatrics	n (%)	n (%)
血管障害			
起立性低血圧	1 (2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	205	170	158	132
Any TEAE	178 (86.8)	145 (70.7)	57 (33.5)	57 (36.1)	35 (26.5)
血液およびリンパ系障害	7 (3.4)	2 (1.0)	2 (1.2)	1 (0.6)	0
貧血	2 (1.0)	0	0	1 (0.6)	0
白血球減少症	2 (1.0)	1 (0.5)	0	0	0
好中球減少症	2 (1.0)	1 (0.5)	0	0	0
好酸球増加症	1 (0.5)	1 (0.5)	0	0	0
鉄欠乏性貧血	1 (0.5)	0	0	0	0
リンパ球減少症	1 (0.5)	0	1 (0.6)	0	0
血小板減少症	1 (0.5)	0	1 (0.6)	0	0
心臓障害	8 (3.9)	4 (2.0)	3 (1.8)	1 (0.6)	0
洞性頻脈	2 (1.0)	1 (0.5)	1 (0.6)	0	0
不整脈	1 (0.5)	1 (0.5)	0	0	0
第一度房室ブロック	1 (0.5)	0	1 (0.6)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	119	104	93	78
Any TEAE	178 (86.8)	26 (21.8)	23 (22.1)	23 (24.7)	13 (16.7)
血液およびリンパ系障害	7 (3.4)	1 (0.8)	0	1 (1.1)	1 (1.3)
貧血	2 (1.0)	0	0	1 (1.1)	0
白血球減少症	2 (1.0)	1 (0.8)	0	0	0
好中球減少症	2 (1.0)	1 (0.8)	0	0	0
好酸球増加症	1 (0.5)	0	0	0	0
鉄欠乏性貧血	1 (0.5)	0	0	0	1 (1.3)
リンパ球減少症	1 (0.5)	0	0	0	0
血小板減少症	1 (0.5)	0	0	0	0
心臓障害	8 (3.9)	0	0	0	0
洞性頻脈	2 (1.0)	0	0	0	0
不整脈	1 (0.5)	0	0	0	0
第一度房室ブロック	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
Number evaluated	205		65		52		37		30	
Any TEAE	178	(86.8)	14	(21.5)	9	(17.3)	10	(27.0)	2	(6.7)
血液およびリンパ系障害	7	(3.4)	0		0		0		0	
貧血	2	(1.0)	0		0		0		0	
白血球減少症	2	(1.0)	0		0		0		0	
好中球減少症	2	(1.0)	0		0		0		0	
好酸球増加症	1	(0.5)	0		0		0		0	
鉄欠乏性貧血	1	(0.5)	0		0		0		0	
リンパ球減少症	1	(0.5)	0		0		0		0	
血小板減少症	1	(0.5)	0		0		0		0	
心臓障害	8	(3.9)	0		0		0		0	
洞性頻脈	2	(1.0)	0		0		0		0	
不整脈	1	(0.5)	0		0		0		0	
第一度房室ブロック	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	Adults		n	(%)	n	(%)
Number evaluated	205		9		3	
Any TEAE	178	(86.8)	1	(11.1)	1	(33.3)
血液およびリンパ系障害	7	(3.4)	0		0	
貧血	2	(1.0)	0		0	
白血球減少症	2	(1.0)	0		0	
好中球減少症	2	(1.0)	0		0	
好酸球増加症	1	(0.5)	0		0	
鉄欠乏性貧血	1	(0.5)	0		0	
リンパ球減少症	1	(0.5)	0		0	
血小板減少症	1	(0.5)	0		0	
心臓障害	8	(3.9)	0		0	
洞性頻脈	2	(1.0)	0		0	
不整脈	1	(0.5)	0		0	
第一度房室ブロック	1	(0.5)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
心臓障害										
徐脈	1	(0.5)	1	(0.5)	0		0		0	
右脚ブロック	1	(0.5)	0		1	(0.6)	0		0	
動悸	1	(0.5)	0		0		1	(0.6)	0	
洞性徐脈	1	(0.5)	1	(0.5)	0		0		0	
耳および迷路障害	23	(11.2)	15	(7.3)	1	(0.6)	4	(2.5)	2	(1.5)
回転性めまい	21	(10.2)	13	(6.3)	1	(0.6)	3	(1.9)	2	(1.5)
耳痛	1	(0.5)	0		0		1	(0.6)	0	
乗物酔い	1	(0.5)	1	(0.5)	0		0		0	
耳鳴	1	(0.5)	1	(0.5)	0		0		0	
眼障害	21	(10.2)	15	(7.3)	3	(1.8)	1	(0.6)	2	(1.5)
複視	8	(3.9)	4	(2.0)	1	(0.6)	1	(0.6)	1	(0.8)
霧視	7	(3.4)	7	(3.4)	0		0		0	
視力障害	4	(2.0)	1	(0.5)	1	(0.6)	0		1	(0.8)
眼乾燥	1	(0.5)	0		0		0		0	
眼刺激	1	(0.5)	1	(0.5)	0		0		0	
流涙増加	1	(0.5)	1	(0.5)	0		0		0	
変視症	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
心臓障害										
徐脈	1	(0.5)	0		0		0		0	
右脚ブロック	1	(0.5)	0		0		0		0	
動悸	1	(0.5)	0		0		0		0	
洞性徐脈	1	(0.5)	0		0		0		0	
耳および迷路障害	23	(11.2)	0		0		2	(2.2)	0	
回転性めまい	21	(10.2)	0		0		2	(2.2)	0	
耳痛	1	(0.5)	0		0		0		0	
乗物酔い	1	(0.5)	0		0		0		0	
耳鳴	1	(0.5)	0		0		0		0	
眼障害	21	(10.2)	1	(0.8)	1	(1.0)	1	(1.1)	0	
複視	8	(3.9)	1	(0.8)	0		0		0	
霧視	7	(3.4)	0		0		0		0	
視力障害	4	(2.0)	0		1	(1.0)	0		0	
眼乾燥	1	(0.5)	0		0		0		0	
眼刺激	1	(0.5)	0		0		0		0	
流涙増加	1	(0.5)	0		0		0		0	
変視症	1	(0.5)	0		0		1	(1.1)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
心臓障害							
徐脈	1	(0.5)	0		0	0	0
右脚ブロック	1	(0.5)	0		0	0	0
動悸	1	(0.5)	0		0	0	0
洞性徐脈	1	(0.5)	0		0	0	0
耳および迷路障害	23	(11.2)	0		0	0	0
回転性めまい	21	(10.2)	0		0	0	0
耳痛	1	(0.5)	0		0	0	0
乗物酔い	1	(0.5)	0		0	0	0
耳鳴	1	(0.5)	0		0	0	0
眼障害	21	(10.2)	1	(1.5)	0	0	0
複視	8	(3.9)	0		0	0	0
霧視	7	(3.4)	0		0	0	0
視力障害	4	(2.0)	0		0	0	0
眼乾燥	1	(0.5)	1	(1.5)	0	0	0
眼刺激	1	(0.5)	0		0	0	0
流涙増加	1	(0.5)	0		0	0	0
変視症	1	(0.5)	0		0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
心臓障害				
徐脈	1	(0.5)	0	0
右脚ブロック	1	(0.5)	0	0
動悸	1	(0.5)	0	0
洞性徐脈	1	(0.5)	0	0
耳および迷路障害	23	(11.2)	0	0
回転性めまい	21	(10.2)	0	0
耳痛	1	(0.5)	0	0
乗物酔い	1	(0.5)	0	0
耳鳴	1	(0.5)	0	0
眼障害	21	(10.2)	0	0
複視	8	(3.9)	0	0
霧視	7	(3.4)	0	0
視力障害	4	(2.0)	0	0
眼乾燥	1	(0.5)	0	0
眼刺激	1	(0.5)	0	0
流涙増加	1	(0.5)	0	0
変視症	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
眼障害										
視神経乳頭浮腫	1	(0.5)	0		1	(0.6)	0		0	
光視症	1	(0.5)	1	(0.5)	0		0		0	
斜視	1	(0.5)	0		0		0		0	
視力低下	1	(0.5)	0		1	(0.6)	0		0	
胃腸障害	47	(22.9)	29	(14.1)	4	(2.4)	8	(5.1)	4	(3.0)
悪心	18	(8.8)	11	(5.4)	0		5	(3.2)	0	
嘔吐	13	(6.3)	7	(3.4)	2	(1.2)	2	(1.3)	1	(0.8)
下痢	11	(5.4)	4	(2.0)	0		1	(0.6)	2	(1.5)
腹痛	6	(2.9)	3	(1.5)	0		0		0	
齲歯	4	(2.0)	2	(1.0)	1	(0.6)	0		0	
口内乾燥	4	(2.0)	4	(2.0)	0		0		0	
腹部不快感	3	(1.5)	1	(0.5)	0		2	(1.3)	0	
便秘	3	(1.5)	3	(1.5)	0		0		0	
胃炎	3	(1.5)	1	(0.5)	1	(0.6)	0		1	(0.8)
下腹部痛	2	(1.0)	1	(0.5)	0		0		0	
口の感覚鈍麻	2	(1.0)	1	(0.5)	0		0		0	
口の錯感覚	2	(1.0)	2	(1.0)	0		0		0	
上腹部痛	1	(0.5)	1	(0.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
眼障害										
視神経乳頭浮腫	1	(0.5)	0		0		0		0	
光視症	1	(0.5)	0		0		0		0	
斜視	1	(0.5)	0		0		1	(1.1)	0	
視力低下	1	(0.5)	0		0		0		0	
胃腸障害	47	(22.9)	2	(1.7)	5	(4.8)	0		2	(2.6)
悪心	18	(8.8)	1	(0.8)	0		0		0	
嘔吐	13	(6.3)	0		0		0		0	
下痢	11	(5.4)	1	(0.8)	1	(1.0)	0		1	(1.3)
腹痛	6	(2.9)	0		0		0		1	(1.3)
齲歯	4	(2.0)	0		1	(1.0)	0		0	
口内乾燥	4	(2.0)	0		0		0		0	
腹部不快感	3	(1.5)	0		0		0		0	
便秘	3	(1.5)	0		0		0		0	
胃炎	3	(1.5)	0		0		0		0	
下腹部痛	2	(1.0)	0		1	(1.0)	0		0	
口の感覚鈍麻	2	(1.0)	0		1	(1.0)	0		0	
口の錯感覚	2	(1.0)	0		0		0		0	
上腹部痛	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
眼障害										
視神経乳頭浮腫	1	(0.5)	0		0		0		0	
光視症	1	(0.5)	0		0		0		0	
斜視	1	(0.5)	0		0		0		0	
視力低下	1	(0.5)	0		0		0		0	
胃腸障害	47	(22.9)	7	(10.8)	0		0		0	
悪心	18	(8.8)	1	(1.5)	0		0		0	
嘔吐	13	(6.3)	1	(1.5)	0		0		0	
下痢	11	(5.4)	1	(1.5)	0		0		0	
腹痛	6	(2.9)	2	(3.1)	0		0		0	
齲歯	4	(2.0)	0		0		0		0	
口内乾燥	4	(2.0)	0		0		0		0	
腹部不快感	3	(1.5)	0		0		0		0	
便秘	3	(1.5)	0		0		0		0	
胃炎	3	(1.5)	0		0		0		0	
下腹部痛	2	(1.0)	0		0		0		0	
口の感覚鈍麻	2	(1.0)	0		0		0		0	
口の錯感覚	2	(1.0)	0		0		0		0	
上腹部痛	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
眼障害				
視神経乳頭浮腫	1	(0.5)	0	0
光視症	1	(0.5)	0	0
斜視	1	(0.5)	0	0
視力低下	1	(0.5)	0	0
胃腸障害	47	(22.9)	0	0
悪心	18	(8.8)	0	0
嘔吐	13	(6.3)	0	0
下痢	11	(5.4)	0	0
腹痛	6	(2.9)	0	0
齲歯	4	(2.0)	0	0
口内乾燥	4	(2.0)	0	0
腹部不快感	3	(1.5)	0	0
便秘	3	(1.5)	0	0
胃炎	3	(1.5)	0	0
下腹部痛	2	(1.0)	0	0
口の感覚鈍麻	2	(1.0)	0	0
口の錯感覚	2	(1.0)	0	0
上腹部痛	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
胃腸障害										
口唇炎	1	(0.5)	0		0		0		0	
セリアック病	1	(0.5)	0		0		0		0	
鼓腸	1	(0.5)	1	(0.5)	0		0		0	
胃食道逆流性疾患	1	(0.5)	0		1	(0.6)	0		0	
痔核	1	(0.5)	0		0		0		0	
歯周病	1	(0.5)	0		0		0		0	
レッチング	1	(0.5)	1	(0.5)	0		0		0	
小腸穿孔	1	(0.5)	0		0		0		0	
舌障害	1	(0.5)	1	(0.5)	0		0		0	
埋伏歯	1	(0.5)	0		0		0		0	
歯の脱落	1	(0.5)	0		0		0		0	
歯痛	1	(0.5)	0		0		0		0	
一般・全身障害および投与部位の状態	40	(19.5)	23	(11.2)	2	(1.2)	3	(1.9)	6	(4.5)
疲労	13	(6.3)	9	(4.4)	0		1	(0.6)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
胃腸障害										
口唇炎	1	(0.5)	0		0		0		0	
セリアック病	1	(0.5)	0		0		0		0	
鼓腸	1	(0.5)	0		0		0		0	
胃食道逆流性疾患	1	(0.5)	0		0		0		0	
痔核	1	(0.5)	0		1	(1.0)	0		0	
歯周病	1	(0.5)	0		1	(1.0)	0		0	
レッチング	1	(0.5)	0		0		0		0	
小腸穿孔	1	(0.5)	0		0		0		0	
舌障害	1	(0.5)	0		0		0		0	
埋伏歯	1	(0.5)	0		1	(1.0)	0		0	
歯の脱落	1	(0.5)	0		0		0		0	
歯痛	1	(0.5)	0		0		0		0	
一般・全身障害および投与部位の状態	40	(19.5)	6	(5.0)	2	(1.9)	0		0	
疲労	13	(6.3)	2	(1.7)	1	(1.0)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
胃腸障害										
口唇炎	1	(0.5)	1	(1.5)	0		0		0	
セリアック病	1	(0.5)	1	(1.5)	0		0		0	
鼓腸	1	(0.5)	0		0		0		0	
胃食道逆流性疾患	1	(0.5)	0		0		0		0	
痔核	1	(0.5)	0		0		0		0	
歯周病	1	(0.5)	0		0		0		0	
レッチング	1	(0.5)	0		0		0		0	
小腸穿孔	1	(0.5)	1	(1.5)	0		0		0	
舌障害	1	(0.5)	0		0		0		0	
埋伏歯	1	(0.5)	0		0		0		0	
歯の脱落	1	(0.5)	1	(1.5)	0		0		0	
歯痛	1	(0.5)	1	(1.5)	0		0		0	
一般・全身障害および投与部位の状態	40	(19.5)	0		1	(1.9)	3	(8.1)	0	
疲労	13	(6.3)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
胃腸障害				
口唇炎	1	(0.5)	0	0
セリアック病	1	(0.5)	0	0
鼓腸	1	(0.5)	0	0
胃食道逆流性疾患	1	(0.5)	0	0
痔核	1	(0.5)	0	0
歯周病	1	(0.5)	0	0
レッチング	1	(0.5)	0	0
小腸穿孔	1	(0.5)	0	0
舌障害	1	(0.5)	0	0
埋伏歯	1	(0.5)	0	0
歯の脱落	1	(0.5)	0	0
歯痛	1	(0.5)	0	0
一般・全身障害および投与部位の状態	40	(19.5)	0	0
疲労	13	(6.3)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class		>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults	n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態									
発熱	7 (3.4)	2	(1.0)	2	(1.2)	0		0	
易刺激性	5 (2.4)	3	(1.5)	0		1	(0.6)	1	(0.8)
無力症	3 (1.5)	2	(1.0)	0		0		1	(0.8)
悪寒	3 (1.5)	2	(1.0)	0		0		0	
評価不能の事象	3 (1.5)	2	(1.0)	0		1	(0.6)	0	
局所腫脹	2 (1.0)	0		0		0		0	
倦怠感	2 (1.0)	2	(1.0)	0		0		0	
非心臓性胸痛	2 (1.0)	0		0		0		1	(0.8)
胸痛	1 (0.5)	0		0		0		1	(0.8)
活力増進	1 (0.5)	1	(0.5)	0		0		0	
酩酊感	1 (0.5)	1	(0.5)	0		0		0	
熱感	1 (0.5)	1	(0.5)	0		0		0	
歩行障害	1 (0.5)	1	(0.5)	0		0		0	
低体温	1 (0.5)	0		0		0		1	(0.8)
炎症	1 (0.5)	0		0		0		0	
インフルエンザ様疾患	1 (0.5)	1	(0.5)	0		0		0	
粘膜びらん	1 (0.5)	0		0		0		1	(0.8)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
一般・全身障害および投与部位の状態										
発熱	7	(3.4)	1	(0.8)	0		0		0	
易刺激性	5	(2.4)	0		0		0		0	
無力症	3	(1.5)	0		0		0		0	
悪寒	3	(1.5)	1	(0.8)	0		0		0	
評価不能の事象	3	(1.5)	0		0		0		0	
局所腫脹	2	(1.0)	1	(0.8)	0		0		0	
倦怠感	2	(1.0)	0		0		0		0	
非心臓性胸痛	2	(1.0)	0		0		0		0	
胸痛	1	(0.5)	0		0		0		0	
活力増進	1	(0.5)	0		0		0		0	
酩酊感	1	(0.5)	0		0		0		0	
熱感	1	(0.5)	0		0		0		0	
歩行障害	1	(0.5)	0		0		0		0	
低体温	1	(0.5)	0		0		0		0	
炎症	1	(0.5)	0		1	(1.0)	0		0	
インフルエンザ様疾患	1	(0.5)	0		0		0		0	
粘膜びらん	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
発熱	7	(3.4)	0		0		2	(5.4)	0	
易刺激性	5	(2.4)	0		0		0		0	
無力症	3	(1.5)	0		0		0		0	
悪寒	3	(1.5)	0		0		0		0	
評価不能の事象	3	(1.5)	0		0		0		0	
局所腫脹	2	(1.0)	0		0		1	(2.7)	0	
倦怠感	2	(1.0)	0		0		0		0	
非心臓性胸痛	2	(1.0)	0		1	(1.9)	0		0	
胸痛	1	(0.5)	0		0		0		0	
活力増進	1	(0.5)	0		0		0		0	
酩酊感	1	(0.5)	0		0		0		0	
熱感	1	(0.5)	0		0		0		0	
歩行障害	1	(0.5)	0		0		0		0	
低体温	1	(0.5)	0		0		0		0	
炎症	1	(0.5)	0		0		0		0	
インフルエンザ様疾患	1	(0.5)	0		0		0		0	
粘膜びらん	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
一般・全身障害および投与部位の状態				
発熱	7	(3.4)	0	0
易刺激性	5	(2.4)	0	0
無力症	3	(1.5)	0	0
悪寒	3	(1.5)	0	0
評価不能の事象	3	(1.5)	0	0
局所腫脹	2	(1.0)	0	0
倦怠感	2	(1.0)	0	0
非心臓性胸痛	2	(1.0)	0	0
胸痛	1	(0.5)	0	0
活力増進	1	(0.5)	0	0
酩酊感	1	(0.5)	0	0
熱感	1	(0.5)	0	0
歩行障害	1	(0.5)	0	0
低体温	1	(0.5)	0	0
炎症	1	(0.5)	0	0
インフルエンザ様疾患	1	(0.5)	0	0
粘膜びらん	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疼痛	1	(0.5)	0		0		0		0	
口渇	1	(0.5)	1	(0.5)	0		0		0	
肝胆道系障害	2	(1.0)	1	(0.5)	0		0		0	
脂肪肝	2	(1.0)	1	(0.5)	0		0		0	
免疫系障害	4	(2.0)	1	(0.5)	1	(0.6)	0		0	
季節性アレルギー	2	(1.0)	0		1	(0.6)	0		0	
薬物過敏症	1	(0.5)	0		0		0		0	
過敏症	1	(0.5)	1	(0.5)	0		0		0	
感染症および寄生虫症	79	(38.5)	33	(16.1)	16	(9.4)	13	(8.2)	16	(12.1)
鼻咽頭炎	29	(14.1)	11	(5.4)	5	(2.9)	4	(2.5)	5	(3.8)
上気道感染	12	(5.9)	6	(2.9)	1	(0.6)	2	(1.3)	1	(0.8)
インフルエンザ	7	(3.4)	1	(0.5)	1	(0.6)	1	(0.6)	4	(3.0)
胃腸炎	6	(2.9)	1	(0.5)	2	(1.2)	1	(0.6)	2	(1.5)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疼痛	1	(0.5)	1	(0.8)	0		0		0	
口渇	1	(0.5)	0		0		0		0	
肝胆道系障害	2	(1.0)	0		1	(1.0)	0		0	
脂肪肝	2	(1.0)	0		1	(1.0)	0		0	
免疫系障害	4	(2.0)	0		0		0		0	
季節性アレルギー	2	(1.0)	0		0		0		0	
薬物過敏症	1	(0.5)	0		0		0		0	
過敏症	1	(0.5)	0		0		0		0	
感染症および寄生虫症	79	(38.5)	7	(5.9)	2	(1.9)	6	(6.5)	1	(1.3)
鼻咽頭炎	29	(14.1)	0		1	(1.0)	0		0	
上気道感染	12	(5.9)	2	(1.7)	0		0		0	
インフルエンザ	7	(3.4)	0		0		0		0	
胃腸炎	6	(2.9)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疼痛	1	(0.5)	0		0		0		0	
口渇	1	(0.5)	0		0		0		0	
肝胆道系障害	2	(1.0)	0		0		0		0	
脂肪肝	2	(1.0)	0		0		0		0	
免疫系障害	4	(2.0)	2	(3.1)	0		0		0	
季節性アレルギー	2	(1.0)	1	(1.5)	0		0		0	
薬物過敏症	1	(0.5)	1	(1.5)	0		0		0	
過敏症	1	(0.5)	0		0		0		0	
感染症および寄生虫症	79	(38.5)	2	(3.1)	2	(3.8)	3	(8.1)	0	
鼻咽頭炎	29	(14.1)	0		1	(1.9)	1	(2.7)	0	
上気道感染	12	(5.9)	0		0		0		0	
インフルエンザ	7	(3.4)	0		0		0		0	
胃腸炎	6	(2.9)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	Adults		n	(%)	n	(%)
一般・全身障害および投与部位の状態						
疼痛	1	(0.5)	0		0	
口渇	1	(0.5)	0		0	
肝胆道系障害	2	(1.0)	0		0	
脂肪肝	2	(1.0)	0		0	
免疫系障害	4	(2.0)	0		0	
季節性アレルギー	2	(1.0)	0		0	
薬物過敏症	1	(0.5)	0		0	
過敏症	1	(0.5)	0		0	
感染症および寄生虫症	79	(38.5)	0		1	(33.3)
鼻咽頭炎	29	(14.1)	0		1	(33.3)
上気道感染	12	(5.9)	0		0	
インフルエンザ	7	(3.4)	0		0	
胃腸炎	6	(2.9)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
尿路感染	6	(2.9)	1	(0.5)	1	(0.6)	1	(0.6)	0	
咽頭炎	4	(2.0)	1	(0.5)	0		1	(0.6)	1	(0.8)
気管支炎	3	(1.5)	0		1	(0.6)	1	(0.6)	0	
ウイルス性気道感染	3	(1.5)	1	(0.5)	2	(1.2)	0		0	
鼻炎	3	(1.5)	1	(0.5)	0		0		0	
蜂巣炎	2	(1.0)	0		1	(0.6)	0		0	
膀胱炎	2	(1.0)	0		1	(0.6)	0		1	(0.8)
耳感染	2	(1.0)	1	(0.5)	0		0		0	
ライム病	2	(1.0)	1	(0.5)	1	(0.6)	0		0	
肺炎	2	(1.0)	0		0		0		0	
気道感染	2	(1.0)	0		0		0		1	(0.8)
皮下組織膿瘍	2	(1.0)	0		1	(0.6)	0		1	(0.8)
四肢膿瘍	1	(0.5)	0		0		0		1	(0.8)
急性扁桃炎	1	(0.5)	0		0		1	(0.6)	0	
カンジダ感染	1	(0.5)	1	(0.5)	0		0		0	
大腸菌性尿路感染	1	(0.5)	1	(0.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
尿路感染	6	(2.9)	2	(1.7)	0		0		0	
咽頭炎	4	(2.0)	0		0		1	(1.1)	0	
気管支炎	3	(1.5)	1	(0.8)	0		0		0	
ウイルス性気道感染	3	(1.5)	0		0		0		0	
鼻炎	3	(1.5)	0		0		2	(2.2)	0	
蜂巣炎	2	(1.0)	0		0		0		0	
膀胱炎	2	(1.0)	0		0		0		0	
耳感染	2	(1.0)	0		0		1	(1.1)	0	
ライム病	2	(1.0)	0		0		0		0	
肺炎	2	(1.0)	0		0		1	(1.1)	0	
気道感染	2	(1.0)	1	(0.8)	0		0		0	
皮下組織膿瘍	2	(1.0)	0		0		0		0	
四肢膿瘍	1	(0.5)	0		0		0		0	
急性扁桃炎	1	(0.5)	0		0		0		0	
カンジダ感染	1	(0.5)	0		0		0		0	
大腸菌性尿路感染	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
尿路感染	6	(2.9)	0		0		1	(2.7)	0	
咽頭炎	4	(2.0)	0		0		0		0	
気管支炎	3	(1.5)	0		0		0		0	
ウイルス性気道感染	3	(1.5)	0		0		0		0	
鼻炎	3	(1.5)	0		0		0		0	
蜂巣炎	2	(1.0)	0		0		1	(2.7)	0	
膀胱炎	2	(1.0)	0		0		0		0	
耳感染	2	(1.0)	0		0		0		0	
ライム病	2	(1.0)	0		0		0		0	
肺炎	2	(1.0)	0		0		1	(2.7)	0	
気道感染	2	(1.0)	0		0		0		0	
皮下組織膿瘍	2	(1.0)	0		0		0		0	
四肢膿瘍	1	(0.5)	0		0		0		0	
急性扁桃炎	1	(0.5)	0		0		0		0	
カンジダ感染	1	(0.5)	0		0		0		0	
大腸菌性尿路感染	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
感染症および寄生虫症				
尿路感染	6	(2.9)	0	0
咽頭炎	4	(2.0)	0	0
気管支炎	3	(1.5)	0	0
ウイルス性気道感染	3	(1.5)	0	0
鼻炎	3	(1.5)	0	0
蜂巣炎	2	(1.0)	0	0
膀胱炎	2	(1.0)	0	0
耳感染	2	(1.0)	0	0
ライム病	2	(1.0)	0	0
肺炎	2	(1.0)	0	0
気道感染	2	(1.0)	0	0
皮下組織膿瘍	2	(1.0)	0	0
四肢膿瘍	1	(0.5)	0	0
急性扁桃炎	1	(0.5)	0	0
カンジダ感染	1	(0.5)	0	0
大腸菌性尿路感染	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症					
眼瞼毛包炎	1 (0.5)	1 (0.5)	0	0	0
ウイルス性胃腸炎	1 (0.5)	0	1 (0.6)	0	0
消化管感染	1 (0.5)	0	0	0	0
鼠径部膿瘍	1 (0.5)	0	0	0	1 (0.8)
帯状疱疹	1 (0.5)	1 (0.5)	0	0	0
麦粒腫	1 (0.5)	0	0	0	0
腎感染	1 (0.5)	1 (0.5)	0	0	0
喉頭炎	1 (0.5)	1 (0.5)	0	0	0
大葉性肺炎	1 (0.5)	0	0	0	0
口腔カンジダ症	1 (0.5)	0	0	1 (0.6)	0
外耳炎	1 (0.5)	0	0	0	0
中耳炎	1 (0.5)	0	0	0	1 (0.8)
乳頭腫ウイルス感染	1 (0.5)	0	0	0	0
爪囲炎	1 (0.5)	1 (0.5)	0	0	0
歯冠周囲炎	1 (0.5)	0	0	0	1 (0.8)
咽頭扁桃炎	1 (0.5)	1 (0.5)	0	0	0
毛巣嚢胞	1 (0.5)	1 (0.5)	0	0	0
副鼻腔炎	1 (0.5)	1 (0.5)	0	0	0
皮膚細菌感染	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症					
眼瞼毛包炎	1 (0.5)	0	0	0	0
ウイルス性胃腸炎	1 (0.5)	0	0	0	0
消化管感染	1 (0.5)	0	0	0	0
鼠径部膿瘍	1 (0.5)	0	0	0	0
帯状疱疹	1 (0.5)	0	0	0	0
麦粒腫	1 (0.5)	0	0	0	1 (1.3)
腎感染	1 (0.5)	0	0	0	0
喉頭炎	1 (0.5)	0	0	0	0
大葉性肺炎	1 (0.5)	0	1 (1.0)	0	0
口腔カンジダ症	1 (0.5)	0	0	0	0
外耳炎	1 (0.5)	0	0	0	0
中耳炎	1 (0.5)	0	0	0	0
乳頭腫ウイルス感染	1 (0.5)	0	0	1 (1.1)	0
爪囲炎	1 (0.5)	0	0	0	0
歯冠周囲炎	1 (0.5)	0	0	0	0
咽頭扁桃炎	1 (0.5)	0	0	0	0
毛巣嚢胞	1 (0.5)	0	0	0	0
副鼻腔炎	1 (0.5)	0	0	0	0
皮膚細菌感染	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
感染症および寄生虫症										
眼瞼毛包炎	1	(0.5)	0		0		0		0	
ウイルス性胃腸炎	1	(0.5)	0		0		0		0	
消化管感染	1	(0.5)	1	(1.5)	0		0		0	
肛径部膿瘍	1	(0.5)	0		0		0		0	
帯状疱疹	1	(0.5)	0		0		0		0	
麦粒腫	1	(0.5)	0		0		0		0	
腎感染	1	(0.5)	0		0		0		0	
喉頭炎	1	(0.5)	0		0		0		0	
大葉性肺炎	1	(0.5)	0		0		0		0	
口腔カンジダ症	1	(0.5)	0		0		0		0	
外耳炎	1	(0.5)	0		1	(1.9)	0		0	
中耳炎	1	(0.5)	0		0		0		0	
乳頭腫ウイルス感染	1	(0.5)	0		0		0		0	
爪囲炎	1	(0.5)	0		0		0		0	
歯冠周囲炎	1	(0.5)	0		0		0		0	
咽頭扁桃炎	1	(0.5)	0		0		0		0	
毛巣嚢胞	1	(0.5)	0		0		0		0	
副鼻腔炎	1	(0.5)	0		0		0		0	
皮膚細菌感染	1	(0.5)	1	(1.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
感染症および寄生虫症				
眼瞼毛包炎	1	(0.5)	0	0
ウイルス性胃腸炎	1	(0.5)	0	0
消化管感染	1	(0.5)	0	0
鼠径部膿瘍	1	(0.5)	0	0
帯状疱疹	1	(0.5)	0	0
麦粒腫	1	(0.5)	0	0
腎感染	1	(0.5)	0	0
喉頭炎	1	(0.5)	0	0
大葉性肺炎	1	(0.5)	0	0
口腔カンジダ症	1	(0.5)	0	0
外耳炎	1	(0.5)	0	0
中耳炎	1	(0.5)	0	0
乳頭腫ウイルス感染	1	(0.5)	0	0
爪囲炎	1	(0.5)	0	0
歯冠周囲炎	1	(0.5)	0	0
咽頭扁桃炎	1	(0.5)	0	0
毛巣嚢胞	1	(0.5)	0	0
副鼻腔炎	1	(0.5)	0	0
皮膚細菌感染	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
感染症および寄生虫症										
細菌性扁桃炎	1	(0.5)	1	(0.5)	0		0		0	
歯膿瘍	1	(0.5)	0		0		1	(0.6)	0	
歯感染	1	(0.5)	0		0		0		1	(0.8)
腟感染	1	(0.5)	1	(0.5)	0		0		0	
ウイルス感染	1	(0.5)	0		0		1	(0.6)	0	
外陰腟真菌感染	1	(0.5)	0		0		0		0	
外陰部腟炎	1	(0.5)	1	(0.5)	0		0		0	
創傷感染	1	(0.5)	1	(0.5)	0		0		0	
傷害、中毒および処置合併症	52	(25.4)	15	(7.3)	10	(5.9)	10	(6.3)	5	(3.8)
挫傷	11	(5.4)	4	(2.0)	2	(1.2)	2	(1.3)	1	(0.8)
頭部損傷	7	(3.4)	2	(1.0)	0		3	(1.9)	1	(0.8)
裂傷	6	(2.9)	0		2	(1.2)	0		0	
靭帯捻挫	6	(2.9)	3	(1.5)	0		2	(1.3)	0	
転倒	4	(2.0)	2	(1.0)	1	(0.6)	0		0	
擦過傷	3	(1.5)	0		0		0		1	(0.8)
顔面骨骨折	3	(1.5)	1	(0.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
感染症および寄生虫症										
細菌性扁桃炎	1	(0.5)	0		0		0		0	
歯膿瘍	1	(0.5)	0		0		0		0	
歯感染	1	(0.5)	0		0		0		0	
腟感染	1	(0.5)	0		0		0		0	
ウイルス感染	1	(0.5)	0		0		0		0	
外陰腟真菌感染	1	(0.5)	1	(0.8)	0		0		0	
外陰部腟炎	1	(0.5)	0		0		0		0	
創傷感染	1	(0.5)	0		0		0		0	
傷害、中毒および処置合併症	52	(25.4)	4	(3.4)	3	(2.9)	7	(7.5)	2	(2.6)
挫傷	11	(5.4)	0		0		1	(1.1)	0	
頭部損傷	7	(3.4)	0		1	(1.0)	0		0	
裂傷	6	(2.9)	0		0		1	(1.1)	2	(2.6)
靭帯捻挫	6	(2.9)	0		0		0		0	
転倒	4	(2.0)	1	(0.8)	0		0		0	
擦過傷	3	(1.5)	2	(1.7)	0		0		0	
顔面骨骨折	3	(1.5)	0		0		1	(1.1)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
感染症および寄生虫症										
細菌性扁桃炎	1	(0.5)	0		0		0		0	
歯膿瘍	1	(0.5)	0		0		0		0	
歯感染	1	(0.5)	0		0		0		0	
腟感染	1	(0.5)	0		0		0		0	
ウイルス感染	1	(0.5)	0		0		0		0	
外陰腟真菌感染	1	(0.5)	0		0		0		0	
外陰部腟炎	1	(0.5)	0		0		0		0	
創傷感染	1	(0.5)	0		0		0		0	
傷害、中毒および処置合併症	52	(25.4)	3	(4.6)	3	(5.8)	2	(5.4)	0	
挫傷	11	(5.4)	0		1	(1.9)	0		0	
頭部損傷	7	(3.4)	0		0		0		0	
裂傷	6	(2.9)	0		1	(1.9)	0		0	
靭帯捻挫	6	(2.9)	1	(1.5)	0		0		0	
転倒	4	(2.0)	0		0		0		0	
擦過傷	3	(1.5)	0		0		0		0	
顔面骨骨折	3	(1.5)	0		1	(1.9)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
感染症および寄生虫症				
細菌性扁桃炎	1	(0.5)	0	0
歯膿瘍	1	(0.5)	0	0
歯感染	1	(0.5)	0	0
腟感染	1	(0.5)	0	0
ウイルス感染	1	(0.5)	0	0
外陰腟真菌感染	1	(0.5)	0	0
外陰部腟炎	1	(0.5)	0	0
創傷感染	1	(0.5)	0	0
傷害、中毒および処置合併症	52	(25.4)	0	0
挫傷	11	(5.4)	0	0
頭部損傷	7	(3.4)	0	0
裂傷	6	(2.9)	0	0
靭帯捻挫	6	(2.9)	0	0
転倒	4	(2.0)	0	0
擦過傷	3	(1.5)	0	0
顔面骨骨折	3	(1.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class		>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults	n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症									
手骨折	3 (1.5)	1	(0.5)	0		0		1	(0.8)
関節損傷	3 (1.5)	1	(0.5)	0		0		0	
歯牙破折	3 (1.5)	1	(0.5)	0		1	(0.6)	0	
節足動物咬傷	2 (1.0)	0		1	(0.6)	0		0	
上腕骨骨折	2 (1.0)	1	(0.5)	1	(0.6)	0		0	
熱傷	2 (1.0)	1	(0.5)	0		1	(0.6)	0	
動物咬傷	1 (0.5)	0		0		0		0	
背部損傷	1 (0.5)	1	(0.5)	0		0		0	
第２度熱傷	1 (0.5)	0		0		0		1	(0.8)
眼挫傷	1 (0.5)	1	(0.5)	0		0		0	
眼外傷	1 (0.5)	1	(0.5)	0		0		0	
顔面損傷	1 (0.5)	1	(0.5)	0		0		0	
足骨折	1 (0.5)	0		1	(0.6)	0		0	
骨折	1 (0.5)	0		0		0		0	
損傷	1 (0.5)	0		0		0		0	
関節脱臼	1 (0.5)	0		1	(0.6)	0		0	
筋断裂	1 (0.5)	0		1	(0.6)	0		0	
肉離れ	1 (0.5)	0		1	(0.6)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
傷害、中毒および処置合併症										
手骨折	3	(1.5)	0		0		0		0	
関節損傷	3	(1.5)	0		1	(1.0)	0		0	
歯牙破折	3	(1.5)	0		0		1	(1.1)	0	
節足動物咬傷	2	(1.0)	0		0		0		0	
上腕骨骨折	2	(1.0)	0		0		0		0	
熱傷	2	(1.0)	0		0		0		0	
動物咬傷	1	(0.5)	1	(0.8)	0		0		0	
背部損傷	1	(0.5)	0		0		0		0	
第２度熱傷	1	(0.5)	0		0		0		0	
眼挫傷	1	(0.5)	0		0		0		0	
眼外傷	1	(0.5)	0		0		0		0	
顔面損傷	1	(0.5)	0		0		0		0	
足骨折	1	(0.5)	0		0		0		0	
骨折	1	(0.5)	0		1	(1.0)	0		0	
損傷	1	(0.5)	0		0		1	(1.1)	0	
関節脱臼	1	(0.5)	0		0		0		0	
筋断裂	1	(0.5)	0		0		0		0	
肉離れ	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症					
手骨折	3 (1.5)	1 (1.5)	0	0	0
関節損傷	3 (1.5)	0	0	1 (2.7)	0
歯牙破折	3 (1.5)	0	0	0	0
節足動物咬傷	2 (1.0)	0	0	1 (2.7)	0
上腕骨骨折	2 (1.0)	0	0	0	0
熱傷	2 (1.0)	0	0	0	0
動物咬傷	1 (0.5)	0	0	0	0
背部損傷	1 (0.5)	0	0	0	0
第２度熱傷	1 (0.5)	0	0	0	0
眼挫傷	1 (0.5)	0	0	0	0
眼外傷	1 (0.5)	0	0	0	0
顔面損傷	1 (0.5)	0	0	0	0
足骨折	1 (0.5)	0	0	0	0
骨折	1 (0.5)	0	0	0	0
損傷	1 (0.5)	0	0	0	0
関節脱臼	1 (0.5)	0	0	0	0
筋断裂	1 (0.5)	0	0	0	0
肉離れ	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
傷害、中毒および処置合併症				
手骨折	3	(1.5)	0	0
関節損傷	3	(1.5)	0	0
歯牙破折	3	(1.5)	0	0
節足動物咬傷	2	(1.0)	0	0
上腕骨骨折	2	(1.0)	0	0
熱傷	2	(1.0)	0	0
動物咬傷	1	(0.5)	0	0
背部損傷	1	(0.5)	0	0
第２度熱傷	1	(0.5)	0	0
眼挫傷	1	(0.5)	0	0
眼外傷	1	(0.5)	0	0
顔面損傷	1	(0.5)	0	0
足骨折	1	(0.5)	0	0
骨折	1	(0.5)	0	0
損傷	1	(0.5)	0	0
関節脱臼	1	(0.5)	0	0
筋断裂	1	(0.5)	0	0
肉離れ	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
処置による疼痛	1	(0.5)	0		0		0		0	
肋骨骨折	1	(0.5)	0		0		1	(0.6)	0	
交通事故	1	(0.5)	0		0		0		0	
刺創	1	(0.5)	0		0		0		0	
皮下血腫	1	(0.5)	0		0		0		1	(0.8)
硬膜下血腫	1	(0.5)	0		0		0		0	
各種物質毒性	1	(0.5)	1	(0.5)	0		0		0	
外傷性頭蓋内出血	1	(0.5)	0		0		0		0	
創傷	1	(0.5)	0		0		0		0	
手首関節骨折	1	(0.5)	1	(0.5)	0		0		0	
臨床検査	25	(12.2)	8	(3.9)	4	(2.4)	5	(3.2)	4	(3.0)
アラニンアミノトランスフェラーゼ増加	5	(2.4)	2	(1.0)	1	(0.6)	1	(0.6)	0	
γ－グルタミルトランスフェラーゼ増加	5	(2.4)	1	(0.5)	0		0		1	(0.8)
体重減少	5	(2.4)	0		1	(0.6)	1	(0.6)	3	(2.3)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
処置による疼痛	1	(0.5)	1	(0.8)	0		0		0	
肋骨骨折	1	(0.5)	0		0		0		0	
交通事故	1	(0.5)	0		0		0		0	
刺創	1	(0.5)	0		0		1	(1.1)	0	
皮下血腫	1	(0.5)	0		0		0		0	
硬膜下血腫	1	(0.5)	0		0		0		0	
各種物質毒性	1	(0.5)	0		0		0		0	
外傷性頭蓋内出血	1	(0.5)	0		0		0		0	
創傷	1	(0.5)	0		0		1	(1.1)	0	
手首関節骨折	1	(0.5)	0		0		0		0	
臨床検査	25	(12.2)	0		3	(2.9)	0		2	(2.6)
アラニンアミノトランスフェラーゼ増加	5	(2.4)	0		1	(1.0)	0		0	
γ－グルタミルトランスフェラーゼ増加	5	(2.4)	0		1	(1.0)	0		1	(1.3)
体重減少	5	(2.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
傷害、中毒および処置合併症										
処置による疼痛	1	(0.5)	0		0		0		0	
肋骨骨折	1	(0.5)	0		0		0		0	
交通事故	1	(0.5)	1	(1.5)	0		0		0	
刺創	1	(0.5)	0		0		0		0	
皮下血腫	1	(0.5)	0		0		0		0	
硬膜下血腫	1	(0.5)	0		1	(1.9)	0		0	
各種物質毒性	1	(0.5)	0		0		0		0	
外傷性頭蓋内出血	1	(0.5)	0		1	(1.9)	0		0	
創傷	1	(0.5)	0		0		0		0	
手首関節骨折	1	(0.5)	0		0		0		0	
臨床検査	25	(12.2)	0		0		1	(2.7)	0	
アラニンアミノトランスフェラーゼ増加	5	(2.4)	0		0		0		0	
γ－グルタミルトランスフェラーゼ増加	5	(2.4)	0		0		1	(2.7)	0	
体重減少	5	(2.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
傷害、中毒および処置合併症				
処置による疼痛	1	(0.5)	0	0
肋骨骨折	1	(0.5)	0	0
交通事故	1	(0.5)	0	0
刺創	1	(0.5)	0	0
皮下血腫	1	(0.5)	0	0
硬膜下血腫	1	(0.5)	0	0
各種物質毒性	1	(0.5)	0	0
外傷性頭蓋内出血	1	(0.5)	0	0
創傷	1	(0.5)	0	0
手首関節骨折	1	(0.5)	0	0
臨床検査	25	(12.2)	0	0
アラニンアミノトランスフェラーゼ増加	5	(2.4)	0	0
γ－グルタミルトランスフェラーゼ増加	5	(2.4)	0	0
体重減少	5	(2.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
アスパラギン酸アミノトランスフェラーゼ増加	2	(1.0)	1	(0.5)	1	(0.6)	0		0	
血圧上昇	2	(1.0)	1	(0.5)	0		1	(0.6)	0	
尿中蛋白陽性	2	(1.0)	2	(1.0)	0		0		0	
血中ブドウ糖増加	1	(0.5)	0		0		0		0	
拡張期血圧上昇	1	(0.5)	0		0		0		0	
血中尿酸増加	1	(0.5)	1	(0.5)	0		0		0	
薬物濃度増加	1	(0.5)	0		0		1	(0.6)	0	
心電図ＰＲ延長	1	(0.5)	0		0		1	(0.6)	0	
好酸球数増加	1	(0.5)	0		1	(0.6)	0		0	
肝機能検査異常	1	(0.5)	1	(0.5)	0		0		0	
サイロキシン減少	1	(0.5)	0		1	(0.6)	0		0	
トリヨードチロニン減少	1	(0.5)	0		1	(0.6)	0		0	
体重増加	1	(0.5)	1	(0.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults		n (%)	n (%)	n (%)	n (%)
臨床検査						
アスパラギン酸アミノトランスフェラーゼ増加	2	(1.0)	0	0	0	0
血圧上昇	2	(1.0)	0	0	0	0
尿中蛋白陽性	2	(1.0)	0	0	0	0
血中ブドウ糖増加	1	(0.5)	0	1 (1.0)	0	0
拡張期血圧上昇	1	(0.5)	0	1 (1.0)	0	0
血中尿酸増加	1	(0.5)	0	0	0	0
薬物濃度増加	1	(0.5)	0	0	0	0
心電図ＰＲ延長	1	(0.5)	0	0	0	0
好酸球数増加	1	(0.5)	0	0	0	0
肝機能検査異常	1	(0.5)	0	0	0	0
サイロキシン減少	1	(0.5)	0	0	0	0
トリヨードチロニン減少	1	(0.5)	0	0	0	0
体重増加	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults		n (%)	n (%)	n (%)	n (%)
臨床検査						
アスパラギン酸アミノトランスフェラーゼ増加	2	(1.0)	0	0	0	0
血圧上昇	2	(1.0)	0	0	0	0
尿中蛋白陽性	2	(1.0)	0	0	0	0
血中ブドウ糖増加	1	(0.5)	0	0	0	0
拡張期血圧上昇	1	(0.5)	0	0	0	0
血中尿酸増加	1	(0.5)	0	0	0	0
薬物濃度増加	1	(0.5)	0	0	0	0
心電図ＰＲ延長	1	(0.5)	0	0	0	0
好酸球数増加	1	(0.5)	0	0	0	0
肝機能検査異常	1	(0.5)	0	0	0	0
サイロキシン減少	1	(0.5)	0	0	0	0
トリヨードチロニン減少	1	(0.5)	0	0	0	0
体重増加	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
臨床検査				
アスパラギン酸アミノトランスフェラーゼ増加	2	(1.0)	0	0
血圧上昇	2	(1.0)	0	0
尿中蛋白陽性	2	(1.0)	0	0
血中ブドウ糖増加	1	(0.5)	0	0
拡張期血圧上昇	1	(0.5)	0	0
血中尿酸増加	1	(0.5)	0	0
薬物濃度増加	1	(0.5)	0	0
心電図ＰＲ延長	1	(0.5)	0	0
好酸球数増加	1	(0.5)	0	0
肝機能検査異常	1	(0.5)	0	0
サイロキシン減少	1	(0.5)	0	0
トリヨードチロニン減少	1	(0.5)	0	0
体重増加	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
白血球数増加	1	(0.5)	0		0		0		0	
代謝および栄養障害	10	(4.9)	5	(2.4)	0		2	(1.3)	2	(1.5)
糖尿病	3	(1.5)	1	(0.5)	0		0		1	(0.8)
ビタミンD欠乏	3	(1.5)	1	(0.5)	0		2	(1.3)	0	
鉄欠乏	2	(1.0)	2	(1.0)	0		0		0	
食欲減退	1	(0.5)	1	(0.5)	0		0		0	
脱水	1	(0.5)	0		0		0		1	(0.8)
高尿酸血症	1	(0.5)	1	(0.5)	0		0		0	
低カリウム血症	1	(0.5)	1	(0.5)	0		0		0	
低ナトリウム血症	1	(0.5)	1	(0.5)	0		0		0	
肥満	1	(0.5)	1	(0.5)	0		0		0	
ビタミンA欠乏	1	(0.5)	1	(0.5)	0		0		0	
筋骨格系および結合組織障害	26	(12.7)	12	(5.9)	3	(1.8)	3	(1.9)	1	(0.8)
背部痛	10	(4.9)	2	(1.0)	3	(1.8)	2	(1.3)	1	(0.8)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
白血球数増加	1	(0.5)	0		0		0		1	(1.3)
代謝および栄養障害	10	(4.9)	0		0		0		0	
糖尿病	3	(1.5)	0		0		0		0	
ビタミンD欠乏	3	(1.5)	0		0		0		0	
鉄欠乏	2	(1.0)	0		0		0		0	
食欲減退	1	(0.5)	0		0		0		0	
脱水	1	(0.5)	0		0		0		0	
高尿酸血症	1	(0.5)	0		0		0		0	
低カリウム血症	1	(0.5)	0		0		0		0	
低ナトリウム血症	1	(0.5)	0		0		0		0	
肥満	1	(0.5)	0		0		0		0	
ビタミンA欠乏	1	(0.5)	0		0		0		0	
筋骨格系および結合組織障害	26	(12.7)	1	(0.8)	1	(1.0)	1	(1.1)	1	(1.3)
背部痛	10	(4.9)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
臨床検査										
白血球数増加	1	(0.5)	0		0		0		0	
代謝および栄養障害	10	(4.9)	1	(1.5)	0		0		0	
糖尿病	3	(1.5)	1	(1.5)	0		0		0	
ビタミンD欠乏	3	(1.5)	0		0		0		0	
鉄欠乏	2	(1.0)	0		0		0		0	
食欲減退	1	(0.5)	0		0		0		0	
脱水	1	(0.5)	0		0		0		0	
高尿酸血症	1	(0.5)	0		0		0		0	
低カリウム血症	1	(0.5)	0		0		0		0	
低ナトリウム血症	1	(0.5)	0		0		0		0	
肥満	1	(0.5)	0		0		0		0	
ビタミンA欠乏	1	(0.5)	0		0		0		0	
筋骨格系および結合組織障害	26	(12.7)	2	(3.1)	2	(3.8)	1	(2.7)	0	
背部痛	10	(4.9)	0		2	(3.8)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
臨床検査				
白血球数増加	1	(0.5)	0	0
代謝および栄養障害	10	(4.9)	0	0
糖尿病	3	(1.5)	0	0
ビタミンD欠乏	3	(1.5)	0	0
鉄欠乏	2	(1.0)	0	0
食欲減退	1	(0.5)	0	0
脱水	1	(0.5)	0	0
高尿酸血症	1	(0.5)	0	0
低カリウム血症	1	(0.5)	0	0
低ナトリウム血症	1	(0.5)	0	0
肥満	1	(0.5)	0	0
ビタミンA欠乏	1	(0.5)	0	0
筋骨格系および結合組織障害	26	(12.7)	0	0
背部痛	10	(4.9)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
筋骨格系および結合組織障害										
関節痛	6	(2.9)	3	(1.5)	0		1	(0.6)	0	
筋肉痛	2	(1.0)	1	(0.5)	0		0		0	
四肢痛	2	(1.0)	1	(0.5)	0		0		0	
側腹部痛	1	(0.5)	1	(0.5)	0		0		0	
関節拘縮	1	(0.5)	1	(0.5)	0		0		0	
関節腫脹	1	(0.5)	1	(0.5)	0		0		0	
筋肉疲労	1	(0.5)	0		0		0		0	
筋骨格系胸痛	1	(0.5)	1	(0.5)	0		0		0	
筋骨格痛	1	(0.5)	0		0		0		0	
ミオキミア	1	(0.5)	1	(0.5)	0		0		0	
頚部痛	1	(0.5)	1	(0.5)	0		0		0	
変形性関節症	1	(0.5)	1	(0.5)	0		0		0	
滑液嚢腫	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）	3	(1.5)	0		0		2	(1.3)	0	
膀胱癌	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
筋骨格系および結合組織障害										
関節痛	6	(2.9)	1	(0.8)	0		0		0	
筋肉痛	2	(1.0)	0		0		1	(1.1)	0	
四肢痛	2	(1.0)	0		0		0		0	
側腹部痛	1	(0.5)	0		0		0		0	
関節拘縮	1	(0.5)	0		0		0		0	
関節腫脹	1	(0.5)	0		0		0		0	
筋肉疲労	1	(0.5)	0		1	(1.0)	0		0	
筋骨格系胸痛	1	(0.5)	0		0		0		0	
筋骨格痛	1	(0.5)	0		0		0		0	
ミオキミア	1	(0.5)	0		0		0		0	
頚部痛	1	(0.5)	0		0		0		0	
変形性関節症	1	(0.5)	0		0		0		0	
滑液嚢腫	1	(0.5)	0		0		0		1	(1.3)
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）	3	(1.5)	0		0		1	(1.1)	0	
膀胱癌	1	(0.5)	0		0		1	(1.1)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
筋骨格系および結合組織障害										
関節痛	6	(2.9)	0		0		1	(2.7)	0	
筋肉痛	2	(1.0)	0		0		0		0	
四肢痛	2	(1.0)	1	(1.5)	0		0		0	
側腹部痛	1	(0.5)	0		0		0		0	
関節拘縮	1	(0.5)	0		0		0		0	
関節腫脹	1	(0.5)	0		0		0		0	
筋肉疲労	1	(0.5)	0		0		0		0	
筋骨格系胸痛	1	(0.5)	0		0		0		0	
筋骨格痛	1	(0.5)	1	(1.5)	0		0		0	
ミオキミア	1	(0.5)	0		0		0		0	
頚部痛	1	(0.5)	0		0		0		0	
変形性関節症	1	(0.5)	0		0		0		0	
滑液嚢腫	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）	3	(1.5)	0		0		0		0	
膀胱癌	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
筋骨格系および結合組織障害				
関節痛	6	(2.9)	0	0
筋肉痛	2	(1.0)	0	0
四肢痛	2	(1.0)	0	0
側腹部痛	1	(0.5)	0	0
関節拘縮	1	(0.5)	0	0
関節腫脹	1	(0.5)	0	0
筋肉疲労	1	(0.5)	0	0
筋骨格系胸痛	1	(0.5)	0	0
筋骨格痛	1	(0.5)	0	0
ミオキミア	1	(0.5)	0	0
頚部痛	1	(0.5)	0	0
変形性関節症	1	(0.5)	0	0
滑液嚢腫	1	(0.5)	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）	3	(1.5)	0	0
膀胱癌	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class		>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults	n	(%)	n	(%)	n	(%)	n	(%)
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）									
乳腺線維腺腫	1 (0.5)	0		0		1	(0.6)	0	
脂肪腫	1 (0.5)	0		0		1	(0.6)	0	
神経系障害	119 (58.0)	90	(43.9)	19	(11.2)	23	(14.6)	8	(6.1)
浮動性めまい	53 (25.9)	38	(18.5)	4	(2.4)	4	(2.5)	3	(2.3)
頭痛	43 (21.0)	21	(10.2)	9	(5.3)	5	(3.2)	4	(3.0)
傾眠	32 (15.6)	25	(12.2)	1	(0.6)	2	(1.3)	1	(0.8)
大発作痙攣	11 (5.4)	5	(2.4)	1	(0.6)	1	(0.6)	0	
片頭痛	10 (4.9)	5	(2.4)	2	(1.2)	0		0	
ミオクローヌス性てんかん	8 (3.9)	5	(2.4)	0		0		0	
錯感覚	8 (3.9)	5	(2.4)	0		3	(1.9)	0	
振戦	8 (3.9)	5	(2.4)	0		0		0	
健忘	6 (2.9)	6	(2.9)	0		0		0	
平衡障害	6 (2.9)	4	(2.0)	0		2	(1.3)	0	
注意力障害	6 (2.9)	5	(2.4)	0		0		0	
運動失調	5 (2.4)	4	(2.0)	0		0		0	
感覚鈍麻	4 (2.0)	1	(0.5)	1	(0.6)	2	(1.3)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
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）										
乳腺線維腺腫	1	(0.5)	0		0		0		0	
脂肪腫	1	(0.5)	0		0		0		0	
神経系障害	119	(58.0)	9	(7.6)	6	(5.8)	4	(4.3)	3	(3.8)
浮動性めまい	53	(25.9)	2	(1.7)	0		0		0	
頭痛	43	(21.0)	3	(2.5)	0		0		1	(1.3)
傾眠	32	(15.6)	0		2	(1.9)	0		1	(1.3)
大発作痙攣	11	(5.4)	1	(0.8)	2	(1.9)	1	(1.1)	0	
片頭痛	10	(4.9)	1	(0.8)	1	(1.0)	0		0	
ミオクローヌス性てんかん	8	(3.9)	0		1	(1.0)	1	(1.1)	0	
錯感覚	8	(3.9)	0		0		0		0	
振戦	8	(3.9)	1	(0.8)	1	(1.0)	0		0	
健忘	6	(2.9)	0		0		0		0	
平衡障害	6	(2.9)	0		0		0		0	
注意力障害	6	(2.9)	0		0		0		0	
運動失調	5	(2.4)	0		0		0		1	(1.3)
感覚鈍麻	4	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
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）										
乳腺線維腺腫	1	(0.5)	0		0		0		0	
脂肪腫	1	(0.5)	0		0		0		0	
神経系障害	119	(58.0)	1	(1.5)	0		2	(5.4)	1	(3.3)
浮動性めまい	53	(25.9)	0		0		0		1	(3.3)
頭痛	43	(21.0)	0		0		0		0	
傾眠	32	(15.6)	0		0		0		0	
大発作痙攣	11	(5.4)	0		0		0		0	
片頭痛	10	(4.9)	1	(1.5)	0		0		0	
ミオクローヌス性てんかん	8	(3.9)	0		0		1	(2.7)	0	
錯感覚	8	(3.9)	0		0		0		0	
振戦	8	(3.9)	0		0		1	(2.7)	0	
健忘	6	(2.9)	0		0		0		0	
平衡障害	6	(2.9)	0		0		0		0	
注意力障害	6	(2.9)	0		0		0		0	
運動失調	5	(2.4)	0		0		0		0	
感覚鈍麻	4	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	Adults		n	(%)	n	(%)
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）						
乳腺線維腺腫	1	(0.5)	0		0	
脂肪腫	1	(0.5)	0		0	
神経系障害	119	(58.0)	1	(11.1)	0	
浮動性めまい	53	(25.9)	1	(11.1)	0	
頭痛	43	(21.0)	0		0	
傾眠	32	(15.6)	0		0	
大発作痙攣	11	(5.4)	0		0	
片頭痛	10	(4.9)	0		0	
ミオクローヌス性てんかん	8	(3.9)	0		0	
錯感覚	8	(3.9)	0		0	
振戦	8	(3.9)	0		0	
健忘	6	(2.9)	0		0	
平衡障害	6	(2.9)	0		0	
注意力障害	6	(2.9)	1	(11.1)	0	
運動失調	5	(2.4)	0		0	
感覚鈍麻	4	(2.0)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
失語症	3	(1.5)	2	(1.0)	0		1	(0.6)	0	
小発作てんかん	3	(1.5)	1	(0.5)	0		1	(0.6)	0	
てんかん重積状態	3	(1.5)	2	(1.0)	0		0		0	
認知障害	2	(1.0)	0		0		2	(1.3)	0	
痙攣	2	(1.0)	0		0		1	(0.6)	0	
嗜眠	2	(1.0)	2	(1.0)	0		0		0	
記憶障害	2	(1.0)	1	(0.5)	0		0		0	
ミオクローヌス	2	(1.0)	2	(1.0)	0		0		0	
咬舌	2	(1.0)	0		1	(0.6)	1	(0.6)	0	
良性頭蓋内圧亢進	1	(0.5)	0		0		1	(0.6)	0	
協調運動異常	1	(0.5)	0		0		0		0	
よだれ	1	(0.5)	1	(0.5)	0		0		0	
構語障害	1	(0.5)	1	(0.5)	0		0		0	
味覚異常	1	(0.5)	1	(0.5)	0		0		0	
統合運動障害	1	(0.5)	0		0		1	(0.6)	0	
てんかん	1	(0.5)	0		1	(0.6)	0		0	
反射亢進	1	(0.5)	1	(0.5)	0		0		0	
反射減弱	1	(0.5)	0		1	(0.6)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
神経系障害										
失語症	3	(1.5)	0		0		0		0	
小発作てんかん	3	(1.5)	1	(0.8)	0		0		0	
てんかん重積状態	3	(1.5)	1	(0.8)	0		0		0	
認知障害	2	(1.0)	0		0		0		0	
痙攣	2	(1.0)	0		0		1	(1.1)	0	
嗜眠	2	(1.0)	0		0		0		0	
記憶障害	2	(1.0)	0		0		1	(1.1)	0	
ミオクローヌス	2	(1.0)	0		0		0		0	
咬舌	2	(1.0)	0		0		0		0	
良性頭蓋内圧亢進	1	(0.5)	0		0		0		0	
協調運動異常	1	(0.5)	0		0		0		0	
よだれ	1	(0.5)	0		0		0		0	
構語障害	1	(0.5)	0		0		0		0	
味覚異常	1	(0.5)	0		0		0		0	
統合運動障害	1	(0.5)	0		0		0		0	
てんかん	1	(0.5)	0		0		0		0	
反射亢進	1	(0.5)	0		0		0		0	
反射減弱	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
神経系障害						
失語症	3	(1.5)	0	0	0	0
小発作てんかん	3	(1.5)	0	0	0	0
てんかん重積状態	3	(1.5)	0	0	0	0
認知障害	2	(1.0)	0	0	0	0
痙攣	2	(1.0)	0	0	0	0
嗜眠	2	(1.0)	0	0	0	0
記憶障害	2	(1.0)	0	0	0	0
ミオクローヌス	2	(1.0)	0	0	0	0
咬舌	2	(1.0)	0	0	0	0
良性頭蓋内圧亢進	1	(0.5)	0	0	0	0
協調運動異常	1	(0.5)	0	0	0	0
よだれ	1	(0.5)	0	0	0	0
構語障害	1	(0.5)	0	0	0	0
味覚異常	1	(0.5)	0	0	0	0
統合運動障害	1	(0.5)	0	0	0	0
てんかん	1	(0.5)	0	0	0	0
反射亢進	1	(0.5)	0	0	0	0
反射減弱	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)		>39 - <=42 n (%)	
神経系障害						
失語症	3	(1.5)	0		0	
小発作てんかん	3	(1.5)	0		0	
てんかん重積状態	3	(1.5)	0		0	
認知障害	2	(1.0)	0		0	
痙攣	2	(1.0)	0		0	
嗜眠	2	(1.0)	0		0	
記憶障害	2	(1.0)	0		0	
ミオクローヌス	2	(1.0)	0		0	
咬舌	2	(1.0)	0		0	
良性頭蓋内圧亢進	1	(0.5)	0		0	
協調運動異常	1	(0.5)	1	(11.1)	0	
よだれ	1	(0.5)	0		0	
構語障害	1	(0.5)	0		0	
味覚異常	1	(0.5)	0		0	
統合運動障害	1	(0.5)	0		0	
てんかん	1	(0.5)	0		0	
反射亢進	1	(0.5)	0		0	
反射減弱	1	(0.5)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
意識消失	1	(0.5)	1	(0.5)	0		0		0	
発作後頭痛	1	(0.5)	0		0		0		1	(0.8)
姿勢時振戦	1	(0.5)	1	(0.5)	0		0		0	
鎮静	1	(0.5)	1	(0.5)	0		0		0	
単純部分発作	1	(0.5)	1	(0.5)	0		0		0	
会話障害	1	(0.5)	1	(0.5)	0		0		0	
緊張性頭痛	1	(0.5)	1	(0.5)	0		0		0	
精神障害	30	(14.6)	20	(9.8)	2	(1.2)	2	(1.3)	2	(1.5)
不安	6	(2.9)	5	(2.4)	1	(0.6)	0		0	
不眠症	6	(2.9)	3	(1.5)	1	(0.6)	0		0	
うつ病	4	(2.0)	2	(1.0)	0		1	(0.6)	1	(0.8)
自殺念慮	4	(2.0)	3	(1.5)	0		0		0	
抑うつ気分	2	(1.0)	2	(1.0)	0		0		0	
失見当識	2	(1.0)	1	(0.5)	0		0		0	
心因性発作	2	(1.0)	1	(0.5)	0		0		0	
攻撃性	1	(0.5)	1	(0.5)	0		0		0	
怒り	1	(0.5)	1	(0.5)	0		0		0	
精神緩慢	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
神経系障害										
意識消失	1	(0.5)	0		0		0		0	
発作後頭痛	1	(0.5)	0		0		0		0	
姿勢時振戦	1	(0.5)	0		0		0		0	
鎮静	1	(0.5)	0		0		0		0	
単純部分発作	1	(0.5)	0		0		0		0	
会話障害	1	(0.5)	0		0		0		0	
緊張性頭痛	1	(0.5)	0		0		0		0	
精神障害	30	(14.6)	1	(0.8)	0		1	(1.1)	1	(1.3)
不安	6	(2.9)	0		0		0		0	
不眠症	6	(2.9)	0		0		0		0	
うつ病	4	(2.0)	0		0		0		0	
自殺念慮	4	(2.0)	1	(0.8)	0		0		0	
抑うつ気分	2	(1.0)	0		0		0		0	
失見当識	2	(1.0)	0		0		1	(1.1)	0	
心因性発作	2	(1.0)	0		0		0		1	(1.3)
攻撃性	1	(0.5)	0		0		0		0	
怒り	1	(0.5)	0		0		0		0	
精神緩慢	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
神経系障害										
意識消失	1	(0.5)	0		0		0		0	
発作後頭痛	1	(0.5)	0		0		0		0	
姿勢時振戦	1	(0.5)	0		0		0		0	
鎮静	1	(0.5)	0		0		0		0	
単純部分発作	1	(0.5)	0		0		0		0	
会話障害	1	(0.5)	0		0		0		0	
緊張性頭痛	1	(0.5)	0		0		0		0	
精神障害	30	(14.6)	2	(3.1)	0		0		1	(3.3)
不安	6	(2.9)	0		0		0		0	
不眠症	6	(2.9)	2	(3.1)	0		0		0	
うつ病	4	(2.0)	0		0		0		0	
自殺念慮	4	(2.0)	0		0		0		0	
抑うつ気分	2	(1.0)	0		0		0		0	
失見当識	2	(1.0)	0		0		0		0	
心因性発作	2	(1.0)	0		0		0		0	
攻撃性	1	(0.5)	0		0		0		0	
怒り	1	(0.5)	0		0		0		0	
精神緩慢	1	(0.5)	0		0		0		1	(3.3)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
神経系障害				
意識消失	1	(0.5)	0	0
発作後頭痛	1	(0.5)	0	0
姿勢時振戦	1	(0.5)	0	0
鎮静	1	(0.5)	0	0
単純部分発作	1	(0.5)	0	0
会話障害	1	(0.5)	0	0
緊張性頭痛	1	(0.5)	0	0
精神障害	30	(14.6)	0	0
不安	6	(2.9)	0	0
不眠症	6	(2.9)	0	0
うつ病	4	(2.0)	0	0
自殺念慮	4	(2.0)	0	0
抑うつ気分	2	(1.0)	0	0
失見当識	2	(1.0)	0	0
心因性発作	2	(1.0)	0	0
攻撃性	1	(0.5)	0	0
怒り	1	(0.5)	0	0
精神緩慢	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
精神障害										
妄想	1	(0.5)	0		0		0		0	
精神状態変化	1	(0.5)	0		0		0		1	(0.8)
パニック発作	1	(0.5)	1	(0.5)	0		0		0	
精神運動制止遅滞	1	(0.5)	1	(0.5)	0		0		0	
睡眠障害	1	(0.5)	0		0		1	(0.6)	0	
ストレス	1	(0.5)	1	(0.5)	0		0		0	
早朝覚醒型不眠症	1	(0.5)	1	(0.5)	0		0		0	
思考異常	1	(0.5)	1	(0.5)	0		0		0	
腎および尿路障害	2	(1.0)	1	(0.5)	0		0		1	(0.8)
排尿困難	1	(0.5)	1	(0.5)	0		0		0	
糖尿	1	(0.5)	1	(0.5)	0		0		0	
腎不全	1	(0.5)	0		0		0		1	(0.8)
生殖系および乳房障害	10	(4.9)	4	(2.0)	2	(1.2)	2	(1.3)	0	
月経困難症	3	(1.5)	1	(0.5)	1	(0.6)	1	(0.6)	0	
不規則月経	2	(1.0)	1	(0.5)	1	(0.6)	0		0	
乳房痛	1	(0.5)	1	(0.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
精神障害										
妄想	1	(0.5)	0		0		1	(1.1)	0	
精神状態変化	1	(0.5)	0		0		0		0	
パニック発作	1	(0.5)	0		0		0		0	
精神運動制止遅滞	1	(0.5)	0		0		0		0	
睡眠障害	1	(0.5)	0		0		0		0	
ストレス	1	(0.5)	0		0		0		0	
早朝覚醒型不眠症	1	(0.5)	0		0		0		0	
思考異常	1	(0.5)	0		0		0		0	
腎および尿路障害	2	(1.0)	0		0		0		0	
排尿困難	1	(0.5)	0		0		0		0	
糖尿	1	(0.5)	0		0		0		0	
腎不全	1	(0.5)	0		0		0		0	
生殖系および乳房障害	10	(4.9)	0		1	(1.0)	1	(1.1)	0	
月経困難症	3	(1.5)	0		0		0		0	
不規則月経	2	(1.0)	0		0		0		0	
乳房痛	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
精神障害							
妄想	1	(0.5)	0		0	0	0
精神状態変化	1	(0.5)	0		0	0	0
パニック発作	1	(0.5)	0		0	0	0
精神運動制止遅滞	1	(0.5)	0		0	0	0
睡眠障害	1	(0.5)	0		0	0	0
ストレス	1	(0.5)	0		0	0	0
早朝覚醒型不眠症	1	(0.5)	0		0	0	0
思考異常	1	(0.5)	0		0	0	0
腎および尿路障害	2	(1.0)	0		0	0	0
排尿困難	1	(0.5)	0		0	0	0
糖尿	1	(0.5)	0		0	0	0
腎不全	1	(0.5)	0		0	0	0
生殖系および乳房障害	10	(4.9)	1	(1.5)	0	0	0
月経困難症	3	(1.5)	0		0	0	0
不規則月経	2	(1.0)	0		0	0	0
乳房痛	1	(0.5)	0		0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
精神障害				
妄想	1	(0.5)	0	0
精神状態変化	1	(0.5)	0	0
パニック発作	1	(0.5)	0	0
精神運動制止遅滞	1	(0.5)	0	0
睡眠障害	1	(0.5)	0	0
ストレス	1	(0.5)	0	0
早朝覚醒型不眠症	1	(0.5)	0	0
思考異常	1	(0.5)	0	0
腎および尿路障害	2	(1.0)	0	0
排尿困難	1	(0.5)	0	0
糖尿	1	(0.5)	0	0
腎不全	1	(0.5)	0	0
生殖系および乳房障害	10	(4.9)	0	0
月経困難症	3	(1.5)	0	0
不規則月経	2	(1.0)	0	0
乳房痛	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
生殖系および乳房障害										
月経過多	1	(0.5)	0		0		0		0	
卵巣嚢胞	1	(0.5)	0		0		0		0	
前立腺腫大	1	(0.5)	0		0		0		0	
性機能不全	1	(0.5)	0		0		1	(0.6)	0	
子宮出血	1	(0.5)	1	(0.5)	0		0		0	
呼吸器、胸郭および縦隔障害	17	(8.3)	6	(2.9)	4	(2.4)	3	(1.9)	2	(1.5)
口腔咽頭痛	7	(3.4)	4	(2.0)	1	(0.6)	1	(0.6)	1	(0.8)
咳嗽	3	(1.5)	1	(0.5)	1	(0.6)	0		0	
鼻出血	3	(1.5)	0		2	(1.2)	0		0	
誤嚥性肺炎	2	(1.0)	0		0		1	(0.6)	0	
急性呼吸不全	1	(0.5)	0		0		0		0	
喘息	1	(0.5)	1	(0.5)	0		0		0	
呼吸時疼痛	1	(0.5)	0		0		1	(0.6)	0	
湿性咳嗽	1	(0.5)	0		0		0		0	
呼吸障害	1	(0.5)	0		0		0		0	
いびき	1	(0.5)	0		0		0		1	(0.8)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
生殖系および乳房障害										
月経過多	1	(0.5)	0		1	(1.0)	0		0	
卵巣嚢胞	1	(0.5)	0		0		1	(1.1)	0	
前立腺腫大	1	(0.5)	0		0		0		0	
性機能不全	1	(0.5)	0		0		0		0	
子宮出血	1	(0.5)	0		0		0		0	
呼吸器、胸郭および縦隔障害	17	(8.3)	1	(0.8)	0		2	(2.2)	2	(2.6)
口腔咽頭痛	7	(3.4)	0		0		0		0	
咳嗽	3	(1.5)	0		0		0		1	(1.3)
鼻出血	3	(1.5)	0		0		1	(1.1)	0	
誤嚥性肺炎	2	(1.0)	1	(0.8)	0		0		0	
急性呼吸不全	1	(0.5)	1	(0.8)	0		0		0	
喘息	1	(0.5)	0		0		0		0	
呼吸時疼痛	1	(0.5)	0		0		0		0	
湿性咳嗽	1	(0.5)	0		0		1	(1.1)	0	
呼吸障害	1	(0.5)	0		0		0		1	(1.3)
いびき	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
生殖系および乳房障害						
月経過多	1	(0.5)	0	0	0	0
卵巣嚢胞	1	(0.5)	0	0	0	0
前立腺腫大	1	(0.5)	1 (1.5)	0	0	0
性機能不全	1	(0.5)	0	0	0	0
子宮出血	1	(0.5)	0	0	0	0
呼吸器、胸郭および縦隔障害	17	(8.3)	0	0	0	0
口腔咽頭痛	7	(3.4)	0	0	0	0
咳嗽	3	(1.5)	0	0	0	0
鼻出血	3	(1.5)	0	0	0	0
誤嚥性肺炎	2	(1.0)	0	0	0	0
急性呼吸不全	1	(0.5)	0	0	0	0
喘息	1	(0.5)	0	0	0	0
呼吸時疼痛	1	(0.5)	0	0	0	0
湿性咳嗽	1	(0.5)	0	0	0	0
呼吸障害	1	(0.5)	0	0	0	0
いびき	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
生殖系および乳房障害				
月経過多	1	(0.5)	0	0
卵巣嚢胞	1	(0.5)	0	0
前立腺腫大	1	(0.5)	0	0
性機能不全	1	(0.5)	0	0
子宮出血	1	(0.5)	0	0
呼吸器、胸郭および縦隔障害	17	(8.3)	0	0
口腔咽頭痛	7	(3.4)	0	0
咳嗽	3	(1.5)	0	0
鼻出血	3	(1.5)	0	0
誤嚥性肺炎	2	(1.0)	0	0
急性呼吸不全	1	(0.5)	0	0
喘息	1	(0.5)	0	0
呼吸時疼痛	1	(0.5)	0	0
湿性咳嗽	1	(0.5)	0	0
呼吸障害	1	(0.5)	0	0
いびき	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
皮膚および皮下組織障害	19	(9.3)	9	(4.4)	4	(2.4)	1	(0.6)	0	
脱毛症	4	(2.0)	2	(1.0)	2	(1.2)	0		0	
発疹	3	(1.5)	3	(1.5)	0		0		0	
皮膚炎	2	(1.0)	0		0		0		0	
湿疹	2	(1.0)	1	(0.5)	0		0		0	
紅斑	2	(1.0)	1	(0.5)	1	(0.6)	0		0	
嵌入爪	2	(1.0)	0		0		0		0	
そう痒症	2	(1.0)	2	(1.0)	0		0		0	
ざ瘡	1	(0.5)	0		0		0		0	
接触性皮膚炎	1	(0.5)	0		0		1	(0.6)	0	
皮膚乾燥	1	(0.5)	0		0		0		0	
逆むけ	1	(0.5)	0		1	(0.6)	0		0	
多汗症	1	(0.5)	1	(0.5)	0		0		0	
爪破損	1	(0.5)	0		1	(0.6)	0		0	
顔面腫脹	1	(0.5)	1	(0.5)	0		0		0	
蕁麻疹	1	(0.5)	0		0		0		0	
血管障害	11	(5.4)	4	(2.0)	2	(1.2)	2	(1.3)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
皮膚および皮下組織障害	19	(9.3)	1	(0.8)	3	(2.9)	1	(1.1)	0	
脱毛症	4	(2.0)	0		0		0		0	
発疹	3	(1.5)	0		0		0		0	
皮膚炎	2	(1.0)	0		1	(1.0)	0		0	
湿疹	2	(1.0)	0		1	(1.0)	0		0	
紅斑	2	(1.0)	0		0		0		0	
嵌入爪	2	(1.0)	1	(0.8)	0		1	(1.1)	0	
そう痒症	2	(1.0)	0		0		0		0	
ざ瘡	1	(0.5)	0		0		0		0	
接触性皮膚炎	1	(0.5)	0		0		0		0	
皮膚乾燥	1	(0.5)	0		1	(1.0)	0		0	
逆むけ	1	(0.5)	0		0		0		0	
多汗症	1	(0.5)	0		0		0		0	
爪破損	1	(0.5)	0		0		0		0	
顔面腫脹	1	(0.5)	0		0		0		0	
蕁麻疹	1	(0.5)	0		0		0		0	
血管障害	11	(5.4)	0		0		1	(1.1)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
皮膚および皮下組織障害	19	(9.3)	2	(3.1)	0		1	(2.7)	0	
脱毛症	4	(2.0)	0		0		0		0	
発疹	3	(1.5)	0		0		0		0	
皮膚炎	2	(1.0)	1	(1.5)	0		0		0	
湿疹	2	(1.0)	0		0		0		0	
紅斑	2	(1.0)	0		0		0		0	
嵌入爪	2	(1.0)	0		0		0		0	
そう痒症	2	(1.0)	0		0		0		0	
ざ瘡	1	(0.5)	1	(1.5)	0		0		0	
接触性皮膚炎	1	(0.5)	0		0		0		0	
皮膚乾燥	1	(0.5)	0		0		0		0	
逆むけ	1	(0.5)	0		0		0		0	
多汗症	1	(0.5)	0		0		0		0	
爪破損	1	(0.5)	0		0		0		0	
顔面腫脹	1	(0.5)	0		0		0		0	
蕁麻疹	1	(0.5)	0		0		1	(2.7)	0	
血管障害	11	(5.4)	0		1	(1.9)	1	(2.7)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
皮膚および皮下組織障害	19	(9.3)	0	0
脱毛症	4	(2.0)	0	0
発疹	3	(1.5)	0	0
皮膚炎	2	(1.0)	0	0
湿疹	2	(1.0)	0	0
紅斑	2	(1.0)	0	0
嵌入爪	2	(1.0)	0	0
そう痒症	2	(1.0)	0	0
ざ瘡	1	(0.5)	0	0
接触性皮膚炎	1	(0.5)	0	0
皮膚乾燥	1	(0.5)	0	0
逆むけ	1	(0.5)	0	0
多汗症	1	(0.5)	0	0
爪破損	1	(0.5)	0	0
顔面腫脹	1	(0.5)	0	0
蕁麻疹	1	(0.5)	0	0
血管障害	11	(5.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
血管障害					
高血圧	7 (3.4)	2 (1.0)	2 (1.2)	2 (1.3)	0
潮紅	1 (0.5)	1 (0.5)	0	0	0
低血圧	1 (0.5)	1 (0.5)	0	0	0
末梢性虚血	1 (0.5)	0	0	0	0
血管炎	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
血管障害					
高血圧	7 (3.4)	0	0	0	0
潮紅	1 (0.5)	0	0	0	0
低血圧	1 (0.5)	0	0	0	0
末梢性虚血	1 (0.5)	0	0	0	0
血管炎	1 (0.5)	0	0	1 (1.1)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
血管障害					
高血圧	7 (3.4)	0	1 (1.9)	0	0
潮紅	1 (0.5)	0	0	0	0
低血圧	1 (0.5)	0	0	0	0
末梢性虚血	1 (0.5)	0	0	1 (2.7)	0
血管炎	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-1　LCM 曝露期間に発現した有害事象［Pool SGTC-1］（続き）

Table 5.1.1 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
血管障害				
高血圧	7	(3.4)	0	0
潮紅	1	(0.5)	0	0
低血圧	1	(0.5)	0	0
末梢性虚血	1	(0.5)	0	0
血管炎	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
Number evaluated	255	255	218	201	164
Any TEAE	192 (75.3)	147 (57.6)	49 (22.5)	51 (25.4)	29 (17.7)
耳および迷路障害	23 (9.0)	14 (5.5)	1 (0.5)	4 (2.0)	2 (1.2)
回転性めまい	23 (9.0)	14 (5.5)	1 (0.5)	4 (2.0)	2 (1.2)
眼障害	16 (6.3)	12 (4.7)	1 (0.5)	1 (0.5)	1 (0.6)
複視	9 (3.5)	5 (2.0)	1 (0.5)	1 (0.5)	1 (0.6)
霧視	7 (2.7)	7 (2.7)	0	0	0
胃腸障害	49 (19.2)	25 (9.8)	4 (1.8)	7 (3.5)	4 (2.4)
悪心	24 (9.4)	16 (6.3)	0	5 (2.5)	1 (0.6)
嘔吐	18 (7.1)	9 (3.5)	3 (1.4)	3 (1.5)	1 (0.6)
下痢	14 (5.5)	4 (1.6)	0	1 (0.5)	2 (1.2)
腹痛	7 (2.7)	3 (1.2)	1 (0.5)	0	0
一般・全身障害および投与部位の状態	30 (11.8)	15 (5.9)	4 (1.8)	2 (1.0)	2 (1.2)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
Number evaluated	255	147	128	114	97
Any TEAE	192 (75.3)	18 (12.2)	14 (10.9)	7 (6.1)	7 (7.2)
耳および迷路障害	23 (9.0)	0	0	2 (1.8)	0
回転性めまい	23 (9.0)	0	0	2 (1.8)	0
眼障害	16 (6.3)	1 (0.7)	0	0	0
複視	9 (3.5)	1 (0.7)	0	0	0
霧視	7 (2.7)	0	0	0	0
胃腸障害	49 (19.2)	3 (2.0)	1 (0.8)	1 (0.9)	3 (3.1)
悪心	24 (9.4)	1 (0.7)	0	0	0
嘔吐	18 (7.1)	0	0	1 (0.9)	0
下痢	14 (5.5)	2 (1.4)	1 (0.8)	0	2 (2.1)
腹痛	7 (2.7)	0	0	0	1 (1.0)
一般・全身障害および投与部位の状態	30 (11.8)	3 (2.0)	2 (1.6)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
Number evaluated	255	81	64	46	37
Any TEAE	192 (75.3)	7 (8.6)	6 (9.4)	6 (13.0)	1 (2.7)
耳および迷路障害	23 (9.0)	0	0	0	0
回転性めまい	23 (9.0)	0	0	0	0
眼障害	16 (6.3)	0	0	0	0
複視	9 (3.5)	0	0	0	0
霧視	7 (2.7)	0	0	0	0
胃腸障害	49 (19.2)	5 (6.2)	0	0	0
悪心	24 (9.4)	1 (1.2)	0	0	0
嘔吐	18 (7.1)	1 (1.2)	0	0	0
下痢	14 (5.5)	2 (2.5)	0	0	0
腹痛	7 (2.7)	2 (2.5)	0	0	0
一般・全身障害および投与部位の状態	30 (11.8)	0	0	2 (4.3)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	All Subjects	n (%)	n (%)
Number evaluated	255	12	3
Any TEAE	192 (75.3)	1 (8.3)	1 (33.3)
耳および迷路障害	23 (9.0)	0	0
回転性めまい	23 (9.0)	0	0
眼障害	16 (6.3)	0	0
複視	9 (3.5)	0	0
霧視	7 (2.7)	0	0
胃腸障害	49 (19.2)	0	0
悪心	24 (9.4)	0	0
嘔吐	18 (7.1)	0	0
下痢	14 (5.5)	0	0
腹痛	7 (2.7)	0	0
一般・全身障害および投与部位の状態	30 (11.8)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	16	(6.3)	10	(3.9)	1	(0.5)	1	(0.5)	0	
発熱	10	(3.9)	3	(1.2)	3	(1.4)	0		1	(0.6)
易刺激性	6	(2.4)	4	(1.6)	0		1	(0.5)	1	(0.6)
感染症および寄生虫症	74	(29.0)	27	(10.6)	13	(6.0)	14	(7.0)	15	(9.1)
鼻咽頭炎	43	(16.9)	15	(5.9)	8	(3.7)	8	(4.0)	7	(4.3)
上気道感染	17	(6.7)	8	(3.1)	1	(0.5)	4	(2.0)	2	(1.2)
インフルエンザ	11	(4.3)	3	(1.2)	2	(0.9)	1	(0.5)	4	(2.4)
尿路感染	8	(3.1)	2	(0.8)	1	(0.5)	1	(0.5)	0	
胃腸炎	7	(2.7)	2	(0.8)	2	(0.9)	1	(0.5)	2	(1.2)
傷害、中毒および処置合併症	37	(14.5)	11	(4.3)	9	(4.1)	9	(4.5)	2	(1.2)
挫傷	17	(6.7)	5	(2.0)	5	(2.3)	3	(1.5)	1	(0.6)
頭部損傷	10	(3.9)	4	(1.6)	0		3	(1.5)	1	(0.6)
裂傷	7	(2.7)	0		2	(0.9)	1	(0.5)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	16	(6.3)	2	(1.4)	2	(1.6)	0		0	
発熱	10	(3.9)	1	(0.7)	0		0		0	
易刺激性	6	(2.4)	0		0		0		0	
感染症および寄生虫症	74	(29.0)	5	(3.4)	2	(1.6)	1	(0.9)	0	
鼻咽頭炎	43	(16.9)	1	(0.7)	1	(0.8)	0		0	
上気道感染	17	(6.7)	2	(1.4)	0		0		0	
インフルエンザ	11	(4.3)	0		1	(0.8)	0		0	
尿路感染	8	(3.1)	2	(1.4)	0		1	(0.9)	0	
胃腸炎	7	(2.7)	0		0		0		0	
傷害、中毒および処置合併症	37	(14.5)	2	(1.4)	1	(0.8)	2	(1.8)	2	(2.1)
挫傷	17	(6.7)	1	(0.7)	0		1	(0.9)	0	
頭部損傷	10	(3.9)	1	(0.7)	1	(0.8)	0		0	
裂傷	7	(2.7)	0		0		1	(0.9)	2	(2.1)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	16	(6.3)	0		0		0		0	
発熱	10	(3.9)	0		0		2	(4.3)	0	
易刺激性	6	(2.4)	0		0		0		0	
感染症および寄生虫症	74	(29.0)	0		1	(1.6)	2	(4.3)	0	
鼻咽頭炎	43	(16.9)	0		1	(1.6)	1	(2.2)	0	
上気道感染	17	(6.7)	0		0		0		0	
インフルエンザ	11	(4.3)	0		0		0		0	
尿路感染	8	(3.1)	0		0		1	(2.2)	0	
胃腸炎	7	(2.7)	0		0		0		0	
傷害、中毒および処置合併症	37	(14.5)	1	(1.2)	2	(3.1)	0		0	
挫傷	17	(6.7)	0		1	(1.6)	0		0	
頭部損傷	10	(3.9)	0		0		0		0	
裂傷	7	(2.7)	0		1	(1.6)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	All Subjects		n	(%)	n	(%)
一般・全身障害および投与部位の状態						
疲労	16	(6.3)	0		0	
発熱	10	(3.9)	0		0	
易刺激性	6	(2.4)	0		0	
感染症および寄生虫症	74	(29.0)	0		1	(33.3)
鼻咽頭炎	43	(16.9)	0		1	(33.3)
上気道感染	17	(6.7)	0		0	
インフルエンザ	11	(4.3)	0		0	
尿路感染	8	(3.1)	0		0	
胃腸炎	7	(2.7)	0		0	
傷害、中毒および処置合併症	37	(14.5)	0		0	
挫傷	17	(6.7)	0		0	
頭部損傷	10	(3.9)	0		0	
裂傷	7	(2.7)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
転倒	6	(2.4)	2	(0.8)	2	(0.9)	1	(0.5)	0	
靭帯捻挫	6	(2.4)	3	(1.2)	0		2	(1.0)	0	
臨床検査	7	(2.7)	2	(0.8)	2	(0.9)	1	(0.5)	0	
アラニンアミノトランスフェラーゼ増加	7	(2.7)	2	(0.8)	2	(0.9)	1	(0.5)	0	
筋骨格系および結合組織障害	16	(6.3)	5	(2.0)	3	(1.4)	3	(1.5)	1	(0.6)
背部痛	10	(3.9)	2	(0.8)	3	(1.4)	2	(1.0)	1	(0.6)
関節痛	6	(2.4)	3	(1.2)	0		1	(0.5)	0	
神経系障害	137	(53.7)	101	(39.6)	21	(9.6)	18	(9.0)	10	(6.1)
浮動性めまい	64	(25.1)	47	(18.4)	5	(2.3)	4	(2.0)	4	(2.4)
頭痛	52	(20.4)	26	(10.2)	10	(4.6)	5	(2.5)	6	(3.7)
傾眠	45	(17.6)	33	(12.9)	4	(1.8)	3	(1.5)	2	(1.2)
大発作痙攣	13	(5.1)	6	(2.4)	1	(0.5)	1	(0.5)	0	
片頭痛	10	(3.9)	5	(2.0)	2	(0.9)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
転倒	6	(2.4)	1	(0.7)	0		0		0	
靭帯捻挫	6	(2.4)	0		0		0		0	
臨床検査	7	(2.7)	0		2	(1.6)	0		0	
アラニンアミノトランスフェラーゼ増加	7	(2.7)	0		2	(1.6)	0		0	
筋骨格系および結合組織障害	16	(6.3)	1	(0.7)	0		0		0	
背部痛	10	(3.9)	0		0		0		0	
関節痛	6	(2.4)	1	(0.7)	0		0		0	
神経系障害	137	(53.7)	7	(4.8)	7	(5.5)	3	(2.6)	3	(3.1)
浮動性めまい	64	(25.1)	2	(1.4)	0		0		0	
頭痛	52	(20.4)	3	(2.0)	0		1	(0.9)	1	(1.0)
傾眠	45	(17.6)	0		2	(1.6)	0		1	(1.0)
大発作痙攣	13	(5.1)	1	(0.7)	3	(2.3)	1	(0.9)	0	
片頭痛	10	(3.9)	1	(0.7)	1	(0.8)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
転倒	6	(2.4)	0		0		0		0	
靭帯捻挫	6	(2.4)	1	(1.2)	0		0		0	
臨床検査	7	(2.7)	0		0		0		0	
アラニンアミノトランスフェラーゼ増加	7	(2.7)	0		0		0		0	
筋骨格系および結合組織障害	16	(6.3)	0		2	(3.1)	1	(2.2)	0	
背部痛	10	(3.9)	0		2	(3.1)	0		0	
関節痛	6	(2.4)	0		0		1	(2.2)	0	
神経系障害	137	(53.7)	1	(1.2)	0		2	(4.3)	1	(2.7)
浮動性めまい	64	(25.1)	0		0		0		1	(2.7)
頭痛	52	(20.4)	0		0		0		0	
傾眠	45	(17.6)	0		0		0		0	
大発作痙攣	13	(5.1)	0		0		0		0	
片頭痛	10	(3.9)	1	(1.2)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	All Subjects		n	(%)	n	(%)
傷害、中毒および処置合併症						
転倒	6	(2.4)	0		0	
靭帯捻挫	6	(2.4)	0		0	
臨床検査	7	(2.7)	0		0	
アラニンアミノトランスフェラーゼ増加	7	(2.7)	0		0	
筋骨格系および結合組織障害	16	(6.3)	0		0	
背部痛	10	(3.9)	0		0	
関節痛	6	(2.4)	0		0	
神経系障害	137	(53.7)	1	(8.3)	0	
浮動性めまい	64	(25.1)	1	(8.3)	0	
頭痛	52	(20.4)	0		0	
傾眠	45	(17.6)	0		0	
大発作痙攣	13	(5.1)	0		0	
片頭痛	10	(3.9)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
ミオクローヌス性てんかん	8	(3.1)	5	(2.0)	0		0		0	
錯感覚	8	(3.1)	5	(2.0)	0		3	(1.5)	0	
振戦	8	(3.1)	5	(2.0)	0		0		0	
平衡障害	7	(2.7)	5	(2.0)	0		2	(1.0)	0	
健忘	6	(2.4)	6	(2.4)	0		0		0	
運動失調	6	(2.4)	5	(2.0)	0		0		0	
注意力障害	6	(2.4)	5	(2.0)	0		0		0	
精神障害	14	(5.5)	9	(3.5)	3	(1.4)	0		0	
不安	7	(2.7)	6	(2.4)	1	(0.5)	0		0	
不眠症	7	(2.7)	3	(1.2)	2	(0.9)	0		0	
呼吸器、胸郭および縦隔障害	7	(2.7)	4	(1.6)	1	(0.5)	1	(0.5)	1	(0.6)
口腔咽頭痛	7	(2.7)	4	(1.6)	1	(0.5)	1	(0.5)	1	(0.6)
血管障害	7	(2.7)	2	(0.8)	2	(0.9)	2	(1.0)	0	
高血圧	7	(2.7)	2	(0.8)	2	(0.9)	2	(1.0)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
神経系障害					
ミオクローヌス性てんかん	8 (3.1)	0	1 (0.8)	1 (0.9)	0
錯感覚	8 (3.1)	0	0	0	0
振戦	8 (3.1)	1 (0.7)	1 (0.8)	0	0
平衡障害	7 (2.7)	0	0	0	0
健忘	6 (2.4)	0	0	0	0
運動失調	6 (2.4)	0	0	0	1 (1.0)
注意力障害	6 (2.4)	0	0	0	0
精神障害	14 (5.5)	0	0	0	0
不安	7 (2.7)	0	0	0	0
不眠症	7 (2.7)	0	0	0	0
呼吸器、胸郭および縦隔障害	7 (2.7)	0	0	0	0
口腔咽頭痛	7 (2.7)	0	0	0	0
血管障害	7 (2.7)	0	0	0	0
高血圧	7 (2.7)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
神経系障害					
ミオクローヌス性てんかん	8 (3.1)	0	0	1 (2.2)	0
錯感覚	8 (3.1)	0	0	0	0
振戦	8 (3.1)	0	0	1 (2.2)	0
平衡障害	7 (2.7)	0	0	0	0
健忘	6 (2.4)	0	0	0	0
運動失調	6 (2.4)	0	0	0	0
注意力障害	6 (2.4)	0	0	0	0
精神障害	14 (5.5)	2 (2.5)	0	0	0
不安	7 (2.7)	0	0	0	0
不眠症	7 (2.7)	2 (2.5)	0	0	0
呼吸器、胸郭および縦隔障害	7 (2.7)	0	0	0	0
口腔咽頭痛	7 (2.7)	0	0	0	0
血管障害	7 (2.7)	0	1 (1.6)	0	0
高血圧	7 (2.7)	0	1 (1.6)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	All Subjects		n	(%)	n	(%)
神経系障害						
ミオクローヌス性てんかん	8	(3.1)	0		0	
錯感覚	8	(3.1)	0		0	
振戦	8	(3.1)	0		0	
平衡障害	7	(2.7)	0		0	
健忘	6	(2.4)	0		0	
運動失調	6	(2.4)	0		0	
注意力障害	6	(2.4)	1	(8.3)	0	
精神障害	14	(5.5)	0		0	
不安	7	(2.7)	0		0	
不眠症	7	(2.7)	0		0	
呼吸器、胸郭および縦隔障害	7	(2.7)	0		0	
口腔咽頭痛	7	(2.7)	0		0	
血管障害	7	(2.7)	0		0	
高血圧	7	(2.7)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	50	48	43	32
Any TEAE	37 (74.0)	27 (54.0)	12 (25.0)	11 (25.6)	6 (18.8)
耳および迷路障害	2 (4.0)	1 (2.0)	0	1 (2.3)	0
回転性めまい	2 (4.0)	1 (2.0)	0	1 (2.3)	0
眼障害	1 (2.0)	1 (2.0)	0	0	0
複視	1 (2.0)	1 (2.0)	0	0	0
胃腸障害	14 (28.0)	7 (14.0)	2 (4.2)	1 (2.3)	1 (3.1)
悪心	6 (12.0)	5 (10.0)	0	0	1 (3.1)
嘔吐	5 (10.0)	2 (4.0)	1 (2.1)	1 (2.3)	0
下痢	3 (6.0)	0	0	0	0
腹痛	1 (2.0)	0	1 (2.1)	0	0
一般・全身障害および投与部位の状態	7 (14.0)	3 (6.0)	2 (4.2)	0	1 (3.1)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	28	24	21	19
Any TEAE	37 (74.0)	3 (10.7)	4 (16.7)	1 (4.8)	1 (5.3)
耳および迷路障害	2 (4.0)	0	0	0	0
回転性めまい	2 (4.0)	0	0	0	0
眼障害	1 (2.0)	0	0	0	0
複視	1 (2.0)	0	0	0	0
胃腸障害	14 (28.0)	1 (3.6)	0	1 (4.8)	1 (5.3)
悪心	6 (12.0)	0	0	0	0
嘔吐	5 (10.0)	0	0	1 (4.8)	0
下痢	3 (6.0)	1 (3.6)	0	0	1 (5.3)
腹痛	1 (2.0)	0	0	0	0
一般・全身障害および投与部位の状態	7 (14.0)	0	1 (4.2)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
Number evaluated	50		16		12		9		7	
Any TEAE	37	(74.0)	1	(6.3)	0		0		0	
耳および迷路障害	2	(4.0)	0		0		0		0	
回転性めまい	2	(4.0)	0		0		0		0	
眼障害	1	(2.0)	0		0		0		0	
複視	1	(2.0)	0		0		0		0	
胃腸障害	14	(28.0)	1	(6.3)	0		0		0	
悪心	6	(12.0)	0		0		0		0	
嘔吐	5	(10.0)	0		0		0		0	
下痢	3	(6.0)	1	(6.3)	0		0		0	
腹痛	1	(2.0)	0		0		0		0	
一般・全身障害および投与部位の状態	7	(14.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
Number evaluated	50		3	0
Any TEAE	37	(74.0)	0	0
耳および迷路障害	2	(4.0)	0	0
回転性めまい	2	(4.0)	0	0
眼障害	1	(2.0)	0	0
複視	1	(2.0)	0	0
胃腸障害	14	(28.0)	0	0
悪心	6	(12.0)	0	0
嘔吐	5	(10.0)	0	0
下痢	3	(6.0)	0	0
腹痛	1	(2.0)	0	0
一般・全身障害および投与部位の状態	7	(14.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	3	(6.0)	1	(2.0)	1	(2.1)	0		0	
発熱	3	(6.0)	1	(2.0)	1	(2.1)	0		1	(3.1)
易刺激性	1	(2.0)	1	(2.0)	0		0		0	
感染症および寄生虫症	23	(46.0)	10	(20.0)	4	(8.3)	6	(14.0)	3	(9.4)
鼻咽頭炎	14	(28.0)	4	(8.0)	3	(6.3)	4	(9.3)	2	(6.3)
上気道感染	5	(10.0)	2	(4.0)	0		2	(4.7)	1	(3.1)
インフルエンザ	4	(8.0)	2	(4.0)	1	(2.1)	0		0	
尿路感染	2	(4.0)	1	(2.0)	0		0		0	
胃腸炎	1	(2.0)	1	(2.0)	0		0		0	
傷害、中毒および処置合併症	8	(16.0)	3	(6.0)	4	(8.3)	2	(4.7)	0	
挫傷	6	(12.0)	1	(2.0)	3	(6.3)	1	(2.3)	0	
頭部損傷	3	(6.0)	2	(4.0)	0		0		0	
転倒	2	(4.0)	0		1	(2.1)	1	(2.3)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
疲労	3	(6.0)	0		1	(4.2)	0		0	
発熱	3	(6.0)	0		0		0		0	
易刺激性	1	(2.0)	0		0		0		0	
感染症および寄生虫症	23	(46.0)	1	(3.6)	1	(4.2)	1	(4.8)	0	
鼻咽頭炎	14	(28.0)	1	(3.6)	0		0		0	
上気道感染	5	(10.0)	0		0		0		0	
インフルエンザ	4	(8.0)	0		1	(4.2)	0		0	
尿路感染	2	(4.0)	0		0		1	(4.8)	0	
胃腸炎	1	(2.0)	0		0		0		0	
傷害、中毒および処置合併症	8	(16.0)	1	(3.6)	0		0		0	
挫傷	6	(12.0)	1	(3.6)	0		0		0	
頭部損傷	3	(6.0)	1	(3.6)	0		0		0	
転倒	2	(4.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態						
疲労	3	(6.0)	0	0	0	0
発熱	3	(6.0)	0	0	0	0
易刺激性	1	(2.0)	0	0	0	0
感染症および寄生虫症	23	(46.0)	0	0	0	0
鼻咽頭炎	14	(28.0)	0	0	0	0
上気道感染	5	(10.0)	0	0	0	0
インフルエンザ	4	(8.0)	0	0	0	0
尿路感染	2	(4.0)	0	0	0	0
胃腸炎	1	(2.0)	0	0	0	0
傷害、中毒および処置合併症	8	(16.0)	0	0	0	0
挫傷	6	(12.0)	0	0	0	0
頭部損傷	3	(6.0)	0	0	0	0
転倒	2	(4.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
一般・全身障害および投与部位の状態				
疲労	3	(6.0)	0	0
発熱	3	(6.0)	0	0
易刺激性	1	(2.0)	0	0
感染症および寄生虫症	23	(46.0)	0	0
鼻咽頭炎	14	(28.0)	0	0
上気道感染	5	(10.0)	0	0
インフルエンザ	4	(8.0)	0	0
尿路感染	2	(4.0)	0	0
胃腸炎	1	(2.0)	0	0
傷害、中毒および処置合併症	8	(16.0)	0	0
挫傷	6	(12.0)	0	0
頭部損傷	3	(6.0)	0	0
転倒	2	(4.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症					
裂傷	1 (2.0)	0	0	1 (2.3)	0
臨床検査	2 (4.0)	0	1 (2.1)	0	0
アラニンアミノトランスフェラーゼ増加	2 (4.0)	0	1 (2.1)	0	0
神経系障害	23 (46.0)	17 (34.0)	5 (10.4)	1 (2.3)	3 (9.4)
傾眠	13 (26.0)	8 (16.0)	3 (6.3)	1 (2.3)	1 (3.1)
浮動性めまい	11 (22.0)	9 (18.0)	1 (2.1)	0	1 (3.1)
頭痛	9 (18.0)	5 (10.0)	1 (2.1)	0	2 (6.3)
大発作痙攣	2 (4.0)	1 (2.0)	0	0	0
運動失調	1 (2.0)	1 (2.0)	0	0	0
平衡障害	1 (2.0)	1 (2.0)	0	0	0
精神障害	2 (4.0)	1 (2.0)	1 (2.1)	0	0
不安	1 (2.0)	1 (2.0)	0	0	0
不眠症	1 (2.0)	0	1 (2.1)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Pediatrics		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
裂傷	1	(2.0)	0		0		0		0	
臨床検査	2	(4.0)	0		1	(4.2)	0		0	
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0		1	(4.2)	0		0	
神経系障害	23	(46.0)	0		1	(4.2)	1	(4.8)	0	
傾眠	13	(26.0)	0		0		0		0	
浮動性めまい	11	(22.0)	0		0		0		0	
頭痛	9	(18.0)	0		0		1	(4.8)	0	
大発作痙攣	2	(4.0)	0		1	(4.2)	0		0	
運動失調	1	(2.0)	0		0		0		0	
平衡障害	1	(2.0)	0		0		0		0	
精神障害	2	(4.0)	0		0		0		0	
不安	1	(2.0)	0		0		0		0	
不眠症	1	(2.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症						
裂傷	1	(2.0)	0	0	0	0
臨床検査	2	(4.0)	0	0	0	0
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0	0	0	0
神経系障害	23	(46.0)	0	0	0	0
傾眠	13	(26.0)	0	0	0	0
浮動性めまい	11	(22.0)	0	0	0	0
頭痛	9	(18.0)	0	0	0	0
大発作痙攣	2	(4.0)	0	0	0	0
運動失調	1	(2.0)	0	0	0	0
平衡障害	1	(2.0)	0	0	0	0
精神障害	2	(4.0)	0	0	0	0
不安	1	(2.0)	0	0	0	0
不眠症	1	(2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
傷害、中毒および処置合併症				
裂傷	1	(2.0)	0	0
臨床検査	2	(4.0)	0	0
アラニンアミノトランスフェラーゼ増加	2	(4.0)	0	0
神経系障害	23	(46.0)	0	0
傾眠	13	(26.0)	0	0
浮動性めまい	11	(22.0)	0	0
頭痛	9	(18.0)	0	0
大発作痙攣	2	(4.0)	0	0
運動失調	1	(2.0)	0	0
平衡障害	1	(2.0)	0	0
精神障害	2	(4.0)	0	0
不安	1	(2.0)	0	0
不眠症	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	205	170	158	132
Any TEAE	155 (75.6)	120 (58.5)	37 (21.8)	40 (25.3)	23 (17.4)
耳および迷路障害	21 (10.2)	13 (6.3)	1 (0.6)	3 (1.9)	2 (1.5)
回転性めまい	21 (10.2)	13 (6.3)	1 (0.6)	3 (1.9)	2 (1.5)
眼障害	15 (7.3)	11 (5.4)	1 (0.6)	1 (0.6)	1 (0.8)
複視	8 (3.9)	4 (2.0)	1 (0.6)	1 (0.6)	1 (0.8)
霧視	7 (3.4)	7 (3.4)	0	0	0
胃腸障害	35 (17.1)	18 (8.8)	2 (1.2)	6 (3.8)	3 (2.3)
悪心	18 (8.8)	11 (5.4)	0	5 (3.2)	0
嘔吐	13 (6.3)	7 (3.4)	2 (1.2)	2 (1.3)	1 (0.8)
下痢	11 (5.4)	4 (2.0)	0	1 (0.6)	2 (1.5)
腹痛	6 (2.9)	3 (1.5)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	119	104	93	78
Any TEAE	155 (75.6)	15 (12.6)	10 (9.6)	6 (6.5)	6 (7.7)
耳および迷路障害	21 (10.2)	0	0	2 (2.2)	0
回転性めまい	21 (10.2)	0	0	2 (2.2)	0
眼障害	15 (7.3)	1 (0.8)	0	0	0
複視	8 (3.9)	1 (0.8)	0	0	0
霧視	7 (3.4)	0	0	0	0
胃腸障害	35 (17.1)	2 (1.7)	1 (1.0)	0	2 (2.6)
悪心	18 (8.8)	1 (0.8)	0	0	0
嘔吐	13 (6.3)	0	0	0	0
下痢	11 (5.4)	1 (0.8)	1 (1.0)	0	1 (1.3)
腹痛	6 (2.9)	0	0	0	1 (1.3)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	65	52	37	30
Any TEAE	155 (75.6)	6 (9.2)	6 (11.5)	6 (16.2)	1 (3.3)
耳および迷路障害	21 (10.2)	0	0	0	0
回転性めまい	21 (10.2)	0	0	0	0
眼障害	15 (7.3)	0	0	0	0
複視	8 (3.9)	0	0	0	0
霧視	7 (3.4)	0	0	0	0
胃腸障害	35 (17.1)	4 (6.2)	0	0	0
悪心	18 (8.8)	1 (1.5)	0	0	0
嘔吐	13 (6.3)	1 (1.5)	0	0	0
下痢	11 (5.4)	1 (1.5)	0	0	0
腹痛	6 (2.9)	2 (3.1)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	Adults	n (%)	n (%)
Number evaluated	205	9	3
Any TEAE	155 (75.6)	1 (11.1)	1 (33.3)
耳および迷路障害	21 (10.2)	0	0
回転性めまい	21 (10.2)	0	0
眼障害	15 (7.3)	0	0
複視	8 (3.9)	0	0
霧視	7 (3.4)	0	0
胃腸障害	35 (17.1)	0	0
悪心	18 (8.8)	0	0
嘔吐	13 (6.3)	0	0
下痢	11 (5.4)	0	0
腹痛	6 (2.9)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態	23	(11.2)	12	(5.9)	2	(1.2)	2	(1.3)	1	(0.8)
疲労	13	(6.3)	9	(4.4)	0		1	(0.6)	0	
発熱	7	(3.4)	2	(1.0)	2	(1.2)	0		0	
易刺激性	5	(2.4)	3	(1.5)	0		1	(0.6)	1	(0.8)
感染症および寄生虫症	51	(24.9)	17	(8.3)	9	(5.3)	8	(5.1)	12	(9.1)
鼻咽頭炎	29	(14.1)	11	(5.4)	5	(2.9)	4	(2.5)	5	(3.8)
上気道感染	12	(5.9)	6	(2.9)	1	(0.6)	2	(1.3)	1	(0.8)
インフルエンザ	7	(3.4)	1	(0.5)	1	(0.6)	1	(0.6)	4	(3.0)
胃腸炎	6	(2.9)	1	(0.5)	2	(1.2)	1	(0.6)	2	(1.5)
尿路感染	6	(2.9)	1	(0.5)	1	(0.6)	1	(0.6)	0	
傷害、中毒および処置合併症	29	(14.1)	8	(3.9)	5	(2.9)	7	(4.4)	2	(1.5)
挫傷	11	(5.4)	4	(2.0)	2	(1.2)	2	(1.3)	1	(0.8)
頭部損傷	7	(3.4)	2	(1.0)	0		3	(1.9)	1	(0.8)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態	23	(11.2)	3	(2.5)	1	(1.0)	0		0	
疲労	13	(6.3)	2	(1.7)	1	(1.0)	0		0	
発熱	7	(3.4)	1	(0.8)	0		0		0	
易刺激性	5	(2.4)	0		0		0		0	
感染症および寄生虫症	51	(24.9)	4	(3.4)	1	(1.0)	0		0	
鼻咽頭炎	29	(14.1)	0		1	(1.0)	0		0	
上気道感染	12	(5.9)	2	(1.7)	0		0		0	
インフルエンザ	7	(3.4)	0		0		0		0	
胃腸炎	6	(2.9)	0		0		0		0	
尿路感染	6	(2.9)	2	(1.7)	0		0		0	
傷害、中毒および処置合併症	29	(14.1)	1	(0.8)	1	(1.0)	2	(2.2)	2	(2.6)
挫傷	11	(5.4)	0		0		1	(1.1)	0	
頭部損傷	7	(3.4)	0		1	(1.0)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態	23	(11.2)	0		0		2	(5.4)	0	
疲労	13	(6.3)	0		0		0		0	
発熱	7	(3.4)	0		0		2	(5.4)	0	
易刺激性	5	(2.4)	0		0		0		0	
感染症および寄生虫症	51	(24.9)	0		1	(1.9)	2	(5.4)	0	
鼻咽頭炎	29	(14.1)	0		1	(1.9)	1	(2.7)	0	
上気道感染	12	(5.9)	0		0		0		0	
インフルエンザ	7	(3.4)	0		0		0		0	
胃腸炎	6	(2.9)	0		0		0		0	
尿路感染	6	(2.9)	0		0		1	(2.7)	0	
傷害、中毒および処置合併症	29	(14.1)	1	(1.5)	2	(3.8)	0		0	
挫傷	11	(5.4)	0		1	(1.9)	0		0	
頭部損傷	7	(3.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)		>39 - <=42 n (%)	
一般・全身障害および投与部位の状態	23	(11.2)	0		0	
疲労	13	(6.3)	0		0	
発熱	7	(3.4)	0		0	
易刺激性	5	(2.4)	0		0	
感染症および寄生虫症	51	(24.9)	0		1	(33.3)
鼻咽頭炎	29	(14.1)	0		1	(33.3)
上気道感染	12	(5.9)	0		0	
インフルエンザ	7	(3.4)	0		0	
胃腸炎	6	(2.9)	0		0	
尿路感染	6	(2.9)	0		0	
傷害、中毒および処置合併症	29	(14.1)	0		0	
挫傷	11	(5.4)	0		0	
頭部損傷	7	(3.4)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
裂傷	6	(2.9)	0		2	(1.2)	0		0	
靭帯捻挫	6	(2.9)	3	(1.5)	0		2	(1.3)	0	
転倒	4	(2.0)	2	(1.0)	1	(0.6)	0		0	
臨床検査	5	(2.4)	2	(1.0)	1	(0.6)	1	(0.6)	0	
アラニンアミノトランスフェラーゼ増加	5	(2.4)	2	(1.0)	1	(0.6)	1	(0.6)	0	
筋骨格系および結合組織障害	16	(7.8)	5	(2.4)	3	(1.8)	3	(1.9)	1	(0.8)
背部痛	10	(4.9)	2	(1.0)	3	(1.8)	2	(1.3)	1	(0.8)
関節痛	6	(2.9)	3	(1.5)	0		1	(0.6)	0	
神経系障害	114	(55.6)	84	(41.0)	16	(9.4)	17	(10.8)	7	(5.3)
浮動性めまい	53	(25.9)	38	(18.5)	4	(2.4)	4	(2.5)	3	(2.3)
頭痛	43	(21.0)	21	(10.2)	9	(5.3)	5	(3.2)	4	(3.0)
傾眠	32	(15.6)	25	(12.2)	1	(0.6)	2	(1.3)	1	(0.8)
大発作痙攣	11	(5.4)	5	(2.4)	1	(0.6)	1	(0.6)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
裂傷	6	(2.9)	0		0		1	(1.1)	2	(2.6)
靭帯捻挫	6	(2.9)	0		0		0		0	
転倒	4	(2.0)	1	(0.8)	0		0		0	
臨床検査	5	(2.4)	0		1	(1.0)	0		0	
アラニンアミノトランスフェラーゼ増加	5	(2.4)	0		1	(1.0)	0		0	
筋骨格系および結合組織障害	16	(7.8)	1	(0.8)	0		0		0	
背部痛	10	(4.9)	0		0		0		0	
関節痛	6	(2.9)	1	(0.8)	0		0		0	
神経系障害	114	(55.6)	7	(5.9)	6	(5.8)	2	(2.2)	3	(3.8)
浮動性めまい	53	(25.9)	2	(1.7)	0		0		0	
頭痛	43	(21.0)	3	(2.5)	0		0		1	(1.3)
傾眠	32	(15.6)	0		2	(1.9)	0		1	(1.3)
大発作痙攣	11	(5.4)	1	(0.8)	2	(1.9)	1	(1.1)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症										
裂傷	6	(2.9)	0		1	(1.9)	0		0	
靭帯捻挫	6	(2.9)	1	(1.5)	0		0		0	
転倒	4	(2.0)	0		0		0		0	
臨床検査	5	(2.4)	0		0		0		0	
アラニンアミノトランスフェラーゼ増加	5	(2.4)	0		0		0		0	
筋骨格系および結合組織障害	16	(7.8)	0		2	(3.8)	1	(2.7)	0	
背部痛	10	(4.9)	0		2	(3.8)	0		0	
関節痛	6	(2.9)	0		0		1	(2.7)	0	
神経系障害	114	(55.6)	1	(1.5)	0		2	(5.4)	1	(3.3)
浮動性めまい	53	(25.9)	0		0		0		1	(3.3)
頭痛	43	(21.0)	0		0		0		0	
傾眠	32	(15.6)	0		0		0		0	
大発作痙攣	11	(5.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	Adults		n	(%)	n	(%)
傷害、中毒および処置合併症						
裂傷	6	(2.9)	0		0	
靭帯捻挫	6	(2.9)	0		0	
転倒	4	(2.0)	0		0	
臨床検査	5	(2.4)	0		0	
アラニンアミノトランスフェラーゼ増加	5	(2.4)	0		0	
筋骨格系および結合組織障害	16	(7.8)	0		0	
背部痛	10	(4.9)	0		0	
関節痛	6	(2.9)	0		0	
神経系障害	114	(55.6)	1	(11.1)	0	
浮動性めまい	53	(25.9)	1	(11.1)	0	
頭痛	43	(21.0)	0		0	
傾眠	32	(15.6)	0		0	
大発作痙攣	11	(5.4)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
片頭痛	10	(4.9)	5	(2.4)	2	(1.2)	0		0	
ミオクローヌス性てんかん	8	(3.9)	5	(2.4)	0		0		0	
錯感覚	8	(3.9)	5	(2.4)	0		3	(1.9)	0	
振戦	8	(3.9)	5	(2.4)	0		0		0	
健忘	6	(2.9)	6	(2.9)	0		0		0	
平衡障害	6	(2.9)	4	(2.0)	0		2	(1.3)	0	
注意力障害	6	(2.9)	5	(2.4)	0		0		0	
運動失調	5	(2.4)	4	(2.0)	0		0		0	
精神障害	12	(5.9)	8	(3.9)	2	(1.2)	0		0	
不安	6	(2.9)	5	(2.4)	1	(0.6)	0		0	
不眠症	6	(2.9)	3	(1.5)	1	(0.6)	0		0	
呼吸器、胸郭および縦隔障害	7	(3.4)	4	(2.0)	1	(0.6)	1	(0.6)	1	(0.8)
口腔咽頭痛	7	(3.4)	4	(2.0)	1	(0.6)	1	(0.6)	1	(0.8)
血管障害	7	(3.4)	2	(1.0)	2	(1.2)	2	(1.3)	0	
高血圧	7	(3.4)	2	(1.0)	2	(1.2)	2	(1.3)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
片頭痛	10	(4.9)	1	(0.8)	1	(1.0)	0		0	
ミオクローヌス性てんかん	8	(3.9)	0		1	(1.0)	1	(1.1)	0	
錯感覚	8	(3.9)	0		0		0		0	
振戦	8	(3.9)	1	(0.8)	1	(1.0)	0		0	
健忘	6	(2.9)	0		0		0		0	
平衡障害	6	(2.9)	0		0		0		0	
注意力障害	6	(2.9)	0		0		0		0	
運動失調	5	(2.4)	0		0		0		1	(1.3)
精神障害	12	(5.9)	0		0		0		0	
不安	6	(2.9)	0		0		0		0	
不眠症	6	(2.9)	0		0		0		0	
呼吸器、胸郭および縦隔障害	7	(3.4)	0		0		0		0	
口腔咽頭痛	7	(3.4)	0		0		0		0	
血管障害	7	(3.4)	0		0		0		0	
高血圧	7	(3.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)

Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)		>27 - <=30 n (%)		>30 - <=33 n (%)		>33 - <=36 n (%)	
神経系障害										
片頭痛	10	(4.9)	1	(1.5)	0		0		0	
ミオクローヌス性てんかん	8	(3.9)	0		0		1	(2.7)	0	
錯感覚	8	(3.9)	0		0		0		0	
振戦	8	(3.9)	0		0		1	(2.7)	0	
健忘	6	(2.9)	0		0		0		0	
平衡障害	6	(2.9)	0		0		0		0	
注意力障害	6	(2.9)	0		0		0		0	
運動失調	5	(2.4)	0		0		0		0	
精神障害	12	(5.9)	2	(3.1)	0		0		0	
不安	6	(2.9)	0		0		0		0	
不眠症	6	(2.9)	2	(3.1)	0		0		0	
呼吸器、胸郭および縦隔障害	7	(3.4)	0		0		0		0	
口腔咽頭痛	7	(3.4)	0		0		0		0	
血管障害	7	(3.4)	0		1	(1.9)	0		0	
高血圧	7	(3.4)	0		1	(1.9)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-2　LCM 曝露期間に発現した発現率 2%以上の有害事象［Pool SGTC-1］（続き）

Table 5.1.2 Incidence of TEAEs by 3-Month LCM Exposure Period of TEAE Onset (>=2%)
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>36 - <=39		>39 - <=42	
Preferred Term	Adults		n	(%)	n	(%)
神経系障害						
片頭痛	10	(4.9)	0		0	
ミオクローヌス性てんかん	8	(3.9)	0		0	
錯感覚	8	(3.9)	0		0	
振戦	8	(3.9)	0		0	
健忘	6	(2.9)	0		0	
平衡障害	6	(2.9)	0		0	
注意力障害	6	(2.9)	1	(11.1)	0	
運動失調	5	(2.4)	0		0	
精神障害	12	(5.9)	0		0	
不安	6	(2.9)	0		0	
不眠症	6	(2.9)	0		0	
呼吸器、胸郭および縦隔障害	7	(3.4)	0		0	
口腔咽頭痛	7	(3.4)	0		0	
血管障害	7	(3.4)	0		0	
高血圧	7	(3.4)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
Number evaluated	255		255		218		201		164	
Any TEAE	41	(16.1)	13	(5.1)	5	(2.3)	7	(3.5)	4	(2.4)
胃腸障害	7	(2.7)	1	(0.4)	1	(0.5)	2	(1.0)	0	
嘔吐	3	(1.2)	1	(0.4)	0		1	(0.5)	0	
腹痛	2	(0.8)	0		1	(0.5)	0		0	
悪心	2	(0.8)	1	(0.4)	0		1	(0.5)	0	
セリアック病	1	(0.4)	0		0		0		0	
小腸穿孔	1	(0.4)	0		0		0		0	
一般・全身障害および投与部位の状態	2	(0.8)	1	(0.4)	0		0		0	
無力症	1	(0.4)	1	(0.4)	0		0		0	
非心臓性胸痛	1	(0.4)	0		0		0		0	
感染症および寄生虫症	3	(1.2)	1	(0.4)	1	(0.5)	0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
Number evaluated	255	147	128	114	97
Any TEAE	41 (16.1)	1 (0.7)	3 (2.3)	6 (5.3)	0
胃腸障害	7 (2.7)	0	0	1 (0.9)	0
嘔吐	3 (1.2)	0	0	1 (0.9)	0
腹痛	2 (0.8)	0	0	0	0
悪心	2 (0.8)	0	0	0	0
セリアック病	1 (0.4)	0	0	0	0
小腸穿孔	1 (0.4)	0	0	0	0
一般・全身障害および投与部位の状態	2 (0.8)	0	0	1 (0.9)	0
無力症	1 (0.4)	0	0	0	0
非心臓性胸痛	1 (0.4)	0	0	1 (0.9)	0
感染症および寄生虫症	3 (1.2)	0	0	1 (0.9)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
Number evaluated	255	81	64	46	37
Any TEAE	41 (16.1)	2 (2.5)	2 (3.1)	1 (2.2)	0
胃腸障害	7 (2.7)	2 (2.5)	0	0	0
嘔吐	3 (1.2)	0	0	0	0
腹痛	2 (0.8)	1 (1.2)	0	0	0
悪心	2 (0.8)	0	0	0	0
セリアック病	1 (0.4)	1 (1.2)	0	0	0
小腸穿孔	1 (0.4)	1 (1.2)	0	0	0
一般・全身障害および投与部位の状態	2 (0.8)	0	0	0	0
無力症	1 (0.4)	0	0	0	0
非心臓性胸痛	1 (0.4)	0	0	0	0
感染症および寄生虫症	3 (1.2)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	All Subjects	n (%)	n (%)
Number evaluated	255	12	3
Any TEAE	41 (16.1)	0	0
胃腸障害	7 (2.7)	0	0
嘔吐	3 (1.2)	0	0
腹痛	2 (0.8)	0	0
悪心	2 (0.8)	0	0
セリアック病	1 (0.4)	0	0
小腸穿孔	1 (0.4)	0	0
一般・全身障害および投与部位の状態	2 (0.8)	0	0
無力症	1 (0.4)	0	0
非心臓性胸痛	1 (0.4)	0	0
感染症および寄生虫症	3 (1.2)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
大腸菌性尿路感染	1	(0.4)	1	(0.4)	0		0		0	
尿路感染	1	(0.4)	0		0		0		0	
ウイルス性上気道感染	1	(0.4)	0		1	(0.5)	0		0	
傷害、中毒および処置合併症	7	(2.7)	2	(0.8)	0		1	(0.5)	0	
頭部損傷	2	(0.8)	1	(0.4)	0		1	(0.5)	0	
挫傷	1	(0.4)	1	(0.4)	0		0		0	
顔面骨骨折	1	(0.4)	0		0		0		0	
骨折	1	(0.4)	0		0		0		0	
手骨折	1	(0.4)	1	(0.4)	0		0		0	
刺創	1	(0.4)	0		0		0		0	
硬膜下血腫	1	(0.4)	0		0		0		0	
外傷性頭蓋内出血	1	(0.4)	0		0		0		0	
臨床検査	2	(0.8)	0		1	(0.5)	1	(0.5)	1	(0.6)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
		n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症					
大腸菌性尿路感染	1 (0.4)	0	0	0	0
尿路感染	1 (0.4)	0	0	1 (0.9)	0
ウイルス性上気道感染	1 (0.4)	0	0	0	0
傷害、中毒および処置合併症	7 (2.7)	0	1 (0.8)	1 (0.9)	0
頭部損傷	2 (0.8)	0	0	0	0
挫傷	1 (0.4)	0	0	0	0
顔面骨骨折	1 (0.4)	0	0	0	0
骨折	1 (0.4)	0	1 (0.8)	0	0
手骨折	1 (0.4)	0	0	0	0
刺創	1 (0.4)	0	0	1 (0.9)	0
硬膜下血腫	1 (0.4)	0	0	0	0
外傷性頭蓋内出血	1 (0.4)	0	0	0	0
臨床検査	2 (0.8)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
大腸菌性尿路感染	1	(0.4)	0		0		0		0	
尿路感染	1	(0.4)	0		0		0		0	
ウイルス性上気道感染	1	(0.4)	0		0		0		0	
傷害、中毒および処置合併症	7	(2.7)	0		2	(3.1)	0		0	
頭部損傷	2	(0.8)	0		0		0		0	
挫傷	1	(0.4)	0		0		0		0	
顔面骨骨折	1	(0.4)	0		1	(1.6)	0		0	
骨折	1	(0.4)	0		0		0		0	
手骨折	1	(0.4)	0		0		0		0	
刺創	1	(0.4)	0		0		0		0	
硬膜下血腫	1	(0.4)	0		1	(1.6)	0		0	
外傷性頭蓋内出血	1	(0.4)	0		1	(1.6)	0		0	
臨床検査	2	(0.8)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
感染症および寄生虫症				
大腸菌性尿路感染	1	(0.4)	0	0
尿路感染	1	(0.4)	0	0
ウイルス性上気道感染	1	(0.4)	0	0
傷害、中毒および処置合併症	7	(2.7)	0	0
頭部損傷	2	(0.8)	0	0
挫傷	1	(0.4)	0	0
顔面骨骨折	1	(0.4)	0	0
骨折	1	(0.4)	0	0
手骨折	1	(0.4)	0	0
刺創	1	(0.4)	0	0
硬膜下血腫	1	(0.4)	0	0
外傷性頭蓋内出血	1	(0.4)	0	0
臨床検査	2	(0.8)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
臨床検査										
薬物濃度増加	1	(0.4)	0		0		1	(0.5)	0	
トランスアミナーゼ上昇	1	(0.4)	0		1	(0.5)	0		0	
体重減少	1	(0.4)	0		0		0		1	(0.6)
代謝および栄養障害	2	(0.8)	0		0		0		2	(1.2)
脱水	1	(0.4)	0		0		0		1	(0.6)
糖尿病	1	(0.4)	0		0		0		1	(0.6)
筋骨格系および結合組織障害	1	(0.4)	1	(0.4)	0		0		0	
四肢痛	1	(0.4)	1	(0.4)	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	(0.4)	0		0		0		0	
膀胱癌	1	(0.4)	0		0		0		0	
神経系障害	25	(9.8)	10	(3.9)	2	(0.9)	3	(1.5)	2	(1.2)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
臨床検査										
薬物濃度増加	1	(0.4)	0		0		0		0	
トランスアミナーゼ上昇	1	(0.4)	0		0		0		0	
体重減少	1	(0.4)	0		0		0		0	
代謝および栄養障害	2	(0.8)	0		0		0		0	
脱水	1	(0.4)	0		0		0		0	
糖尿病	1	(0.4)	0		0		0		0	
筋骨格系および結合組織障害	1	(0.4)	0		0		0		0	
四肢痛	1	(0.4)	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	(0.4)	0		0		1	(0.9)	0	
膀胱癌	1	(0.4)	0		0		1	(0.9)	0	
神経系障害	25	(9.8)	1	(0.7)	3	(2.3)	4	(3.5)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
臨床検査						
薬物濃度増加	1	(0.4)	0	0	0	0
トランスアミナーゼ上昇	1	(0.4)	0	0	0	0
体重減少	1	(0.4)	0	0	0	0
代謝および栄養障害	2	(0.8)	0	0	0	0
脱水	1	(0.4)	0	0	0	0
糖尿病	1	(0.4)	0	0	0	0
筋骨格系および結合組織障害	1	(0.4)	0	0	0	0
四肢痛	1	(0.4)	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	(0.4)	0	0	0	0
膀胱癌	1	(0.4)	0	0	0	0
神経系障害	25	(9.8)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
臨床検査				
薬物濃度増加	1	(0.4)	0	0
トランスアミナーゼ上昇	1	(0.4)	0	0
体重減少	1	(0.4)	0	0
代謝および栄養障害	2	(0.8)	0	0
脱水	1	(0.4)	0	0
糖尿病	1	(0.4)	0	0
筋骨格系および結合組織障害	1	(0.4)	0	0
四肢痛	1	(0.4)	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	(0.4)	0	0
膀胱癌	1	(0.4)	0	0
神経系障害	25	(9.8)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
神経系障害										
大発作痙攣	9	(3.5)	4	(1.6)	0		1	(0.5)	0	
浮動性めまい	4	(1.6)	2	(0.8)	0		1	(0.5)	0	
てんかん重積状態	4	(1.6)	2	(0.8)	0		0		1	(0.6)
痙攣	2	(0.8)	1	(0.4)	0		0		1	(0.6)
傾眠	2	(0.8)	2	(0.8)	0		0		0	
良性頭蓋内圧亢進	1	(0.4)	0		0		1	(0.5)	0	
てんかん	1	(0.4)	0		1	(0.5)	0		0	
頭痛	1	(0.4)	1	(0.4)	0		0		0	
片頭痛	1	(0.4)	0		0		0		0	
ミオクローヌス性てんかん	1	(0.4)	0		0		0		0	
強直性痙攣	1	(0.4)	0		1	(0.5)	0		0	
精神障害	1	(0.4)	0		0		0		1	(0.6)
精神状態変化	1	(0.4)	0		0		0		1	(0.6)
呼吸器、胸郭および縦隔障害	2	(0.8)	0		0		1	(0.5)	0	
誤嚥性肺炎	2	(0.8)	0		0		1	(0.5)	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	All Subjects		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
大発作痙攣	9	(3.5)	0		3	(2.3)	1	(0.9)	0	
浮動性めまい	4	(1.6)	0		0		1	(0.9)	0	
てんかん重積状態	4	(1.6)	1	(0.7)	0		0		0	
痙攣	2	(0.8)	0		0		0		0	
傾眠	2	(0.8)	0		0		0		0	
良性頭蓋内圧亢進	1	(0.4)	0		0		0		0	
てんかん	1	(0.4)	0		0		0		0	
頭痛	1	(0.4)	0		0		0		0	
片頭痛	1	(0.4)	0		0		1	(0.9)	0	
ミオクローヌス性てんかん	1	(0.4)	0		0		1	(0.9)	0	
強直性痙攣	1	(0.4)	0		0		0		0	
精神障害	1	(0.4)	0		0		0		0	
精神状態変化	1	(0.4)	0		0		0		0	
呼吸器、胸郭および縦隔障害	2	(0.8)	1	(0.7)	0		0		0	
誤嚥性肺炎	2	(0.8)	1	(0.7)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
神経系障害						
大発作痙攣	9	(3.5)	0	0	0	0
浮動性めまい	4	(1.6)	0	0	0	0
てんかん重積状態	4	(1.6)	0	0	0	0
痙攣	2	(0.8)	0	0	0	0
傾眠	2	(0.8)	0	0	0	0
良性頭蓋内圧亢進	1	(0.4)	0	0	0	0
てんかん	1	(0.4)	0	0	0	0
頭痛	1	(0.4)	0	0	0	0
片頭痛	1	(0.4)	0	0	0	0
ミオクローヌス性てんかん	1	(0.4)	0	0	0	0
強直性痙攣	1	(0.4)	0	0	0	0
精神障害	1	(0.4)	0	0	0	0
精神状態変化	1	(0.4)	0	0	0	0
呼吸器、胸郭および縦隔障害	2	(0.8)	0	0	0	0
誤嚥性肺炎	2	(0.8)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
神経系障害				
大発作痙攣	9	(3.5)	0	0
浮動性めまい	4	(1.6)	0	0
てんかん重積状態	4	(1.6)	0	0
痙攣	2	(0.8)	0	0
傾眠	2	(0.8)	0	0
良性頭蓋内圧亢進	1	(0.4)	0	0
てんかん	1	(0.4)	0	0
頭痛	1	(0.4)	0	0
片頭痛	1	(0.4)	0	0
ミオクローヌス性てんかん	1	(0.4)	0	0
強直性痙攣	1	(0.4)	0	0
精神障害	1	(0.4)	0	0
精神状態変化	1	(0.4)	0	0
呼吸器、胸郭および縦隔障害	2	(0.8)	0	0
誤嚥性肺炎	2	(0.8)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害					
急性呼吸不全	1 (0.4)	0	0	0	0
外科および内科処置	1 (0.4)	0	0	1 (0.5)	0
人工流産	1 (0.4)	0	0	1 (0.5)	0
血管障害	1 (0.4)	0	0	0	0
末梢性虚血	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害					
急性呼吸不全	1 (0.4)	1 (0.7)	0	0	0
外科および内科処置	1 (0.4)	0	0	0	0
人工流産	1 (0.4)	0	0	0	0
血管障害	1 (0.4)	0	0	0	0
末梢性虚血	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害					
急性呼吸不全	1 (0.4)	0	0	0	0
外科および内科処置	1 (0.4)	0	0	0	0
人工流産	1 (0.4)	0	0	0	0
血管障害	1 (0.4)	0	0	1 (2.2)	0
末梢性虚血	1 (0.4)	0	0	1 (2.2)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	All Subjects	n (%)	n (%)
呼吸器、胸郭および縦隔障害			
急性呼吸不全	1 (0.4)	0	0
外科および内科処置	1 (0.4)	0	0
人工流産	1 (0.4)	0	0
血管障害	1 (0.4)	0	0
末梢性虚血	1 (0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	50	48	43	32
Any TEAE	11 (22.0)	2 (4.0)	4 (8.3)	2 (4.7)	2 (6.3)
胃腸障害	3 (6.0)	0	1 (2.1)	1 (2.3)	0
嘔吐	2 (4.0)	0	0	1 (2.3)	0
腹痛	1 (2.0)	0	1 (2.1)	0	0
一般・全身障害および投与部位の状態	1 (2.0)	0	0	0	0
非心臓性胸痛	1 (2.0)	0	0	0	0
感染症および寄生虫症	2 (4.0)	0	1 (2.1)	0	0
尿路感染	1 (2.0)	0	0	0	0
ウイルス性上気道感染	1 (2.0)	0	1 (2.1)	0	0
臨床検査	1 (2.0)	0	1 (2.1)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	28	24	21	19
Any TEAE	11 (22.0)	0	1 (4.2)	1 (4.8)	0
胃腸障害	3 (6.0)	0	0	1 (4.8)	0
嘔吐	2 (4.0)	0	0	1 (4.8)	0
腹痛	1 (2.0)	0	0	0	0
一般・全身障害および投与部位の状態	1 (2.0)	0	0	1 (4.8)	0
非心臓性胸痛	1 (2.0)	0	0	1 (4.8)	0
感染症および寄生虫症	2 (4.0)	0	0	1 (4.8)	0
尿路感染	1 (2.0)	0	0	1 (4.8)	0
ウイルス性上気道感染	1 (2.0)	0	0	0	0
臨床検査	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	16	12	9	7
Any TEAE	11 (22.0)	0	0	0	0
胃腸障害	3 (6.0)	0	0	0	0
嘔吐	2 (4.0)	0	0	0	0
腹痛	1 (2.0)	0	0	0	0
一般・全身障害および投与部位の状態	1 (2.0)	0	0	0	0
非心臓性胸痛	1 (2.0)	0	0	0	0
感染症および寄生虫症	2 (4.0)	0	0	0	0
尿路感染	1 (2.0)	0	0	0	0
ウイルス性上気道感染	1 (2.0)	0	0	0	0
臨床検査	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Pediatrics		n (%)	n (%)
Number evaluated	50		3	0
Any TEAE	11	(22.0)	0	0
胃腸障害	3	(6.0)	0	0
嘔吐	2	(4.0)	0	0
腹痛	1	(2.0)	0	0
一般・全身障害および投与部位の状態	1	(2.0)	0	0
非心臓性胸痛	1	(2.0)	0	0
感染症および寄生虫症	2	(4.0)	0	0
尿路感染	1	(2.0)	0	0
ウイルス性上気道感染	1	(2.0)	0	0
臨床検査	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
臨床検査					
トランスアミナーゼ上昇	1 (2.0)	0	1 (2.1)	0	0
神経系障害	7 (14.0)	2 (4.0)	1 (2.1)	0	2 (6.3)
痙攣	2 (4.0)	1 (2.0)	0	0	1 (3.1)
大発作痙攣	2 (4.0)	1 (2.0)	0	0	0
浮動性めまい	1 (2.0)	0	0	0	0
てんかん重積状態	1 (2.0)	0	0	0	1 (3.1)
強直性痙攣	1 (2.0)	0	1 (2.1)	0	0
外科および内科処置	1 (2.0)	0	0	1 (2.3)	0
人工流産	1 (2.0)	0	0	1 (2.3)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Pediatrics	Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)	>15 - <=18 n (%)	>18 - <=21 n (%)	>21 - <=24 n (%)
臨床検査					
トランスアミナーゼ上昇	1 (2.0)	0	0	0	0
神経系障害	7 (14.0)	0	1 (4.2)	1 (4.8)	0
痙攣	2 (4.0)	0	0	0	0
大発作痙攣	2 (4.0)	0	1 (4.2)	0	0
浮動性めまい	1 (2.0)	0	0	1 (4.8)	0
てんかん重積状態	1 (2.0)	0	0	0	0
強直性痙攣	1 (2.0)	0	0	0	0
外科および内科処置	1 (2.0)	0	0	0	0
人工流産	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics		n (%)	n (%)	n (%)	n (%)
臨床検査						
トランスアミナーゼ上昇	1	(2.0)	0	0	0	0
神経系障害	7	(14.0)	0	0	0	0
痙攣	2	(4.0)	0	0	0	0
大発作痙攣	2	(4.0)	0	0	0	0
浮動性めまい	1	(2.0)	0	0	0	0
てんかん重積状態	1	(2.0)	0	0	0	0
強直性痙攣	1	(2.0)	0	0	0	0
外科および内科処置	1	(2.0)	0	0	0	0
人工流産	1	(2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Pediatrics		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
臨床検査				
トランスアミナーゼ上昇	1	(2.0)	0	0
神経系障害	7	(14.0)	0	0
痙攣	2	(4.0)	0	0
大発作痙攣	2	(4.0)	0	0
浮動性めまい	1	(2.0)	0	0
てんかん重積状態	1	(2.0)	0	0
強直性痙攣	1	(2.0)	0	0
外科および内科処置	1	(2.0)	0	0
人工流産	1	(2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
Number evaluated	205		205		170		158		132	
Any TEAE	30	(14.6)	11	(5.4)	1	(0.6)	5	(3.2)	2	(1.5)
胃腸障害	4	(2.0)	1	(0.5)	0		1	(0.6)	0	
悪心	2	(1.0)	1	(0.5)	0		1	(0.6)	0	
腹痛	1	(0.5)	0		0		0		0	
セリアック病	1	(0.5)	0		0		0		0	
小腸穿孔	1	(0.5)	0		0		0		0	
嘔吐	1	(0.5)	1	(0.5)	0		0		0	
一般・全身障害および投与部位の状態	1	(0.5)	1	(0.5)	0		0		0	
無力症	1	(0.5)	1	(0.5)	0		0		0	
感染症および寄生虫症	1	(0.5)	1	(0.5)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	119	104	93	78
Any TEAE	30 (14.6)	1 (0.8)	2 (1.9)	5 (5.4)	0
胃腸障害	4 (2.0)	0	0	0	0
悪心	2 (1.0)	0	0	0	0
腹痛	1 (0.5)	0	0	0	0
セリアック病	1 (0.5)	0	0	0	0
小腸穿孔	1 (0.5)	0	0	0	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	1 (0.5)	0	0	0	0
無力症	1 (0.5)	0	0	0	0
感染症および寄生虫症	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	65	52	37	30
Any TEAE	30 (14.6)	2 (3.1)	2 (3.8)	1 (2.7)	0
胃腸障害	4 (2.0)	2 (3.1)	0	0	0
悪心	2 (1.0)	0	0	0	0
腹痛	1 (0.5)	1 (1.5)	0	0	0
セリアック病	1 (0.5)	1 (1.5)	0	0	0
小腸穿孔	1 (0.5)	1 (1.5)	0	0	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	1 (0.5)	0	0	0	0
無力症	1 (0.5)	0	0	0	0
感染症および寄生虫症	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
Number evaluated	205		9	3
Any TEAE	30	(14.6)	0	0
胃腸障害	4	(2.0)	0	0
悪心	2	(1.0)	0	0
腹痛	1	(0.5)	0	0
セリアック病	1	(0.5)	0	0
小腸穿孔	1	(0.5)	0	0
嘔吐	1	(0.5)	0	0
一般・全身障害および投与部位の状態	1	(0.5)	0	0
無力症	1	(0.5)	0	0
感染症および寄生虫症	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
大腸菌性尿路感染	1	(0.5)	1	(0.5)	0		0		0	
傷害、中毒および処置合併症	7	(3.4)	2	(1.0)	0		1	(0.6)	0	
頭部損傷	2	(1.0)	1	(0.5)	0		1	(0.6)	0	
挫傷	1	(0.5)	1	(0.5)	0		0		0	
顔面骨骨折	1	(0.5)	0		0		0		0	
骨折	1	(0.5)	0		0		0		0	
手骨折	1	(0.5)	1	(0.5)	0		0		0	
刺創	1	(0.5)	0		0		0		0	
硬膜下血腫	1	(0.5)	0		0		0		0	
外傷性頭蓋内出血	1	(0.5)	0		0		0		0	
臨床検査	1	(0.5)	0		0		1	(0.6)	1	(0.8)
薬物濃度増加	1	(0.5)	0		0		1	(0.6)	0	
体重減少	1	(0.5)	0		0		0		1	(0.8)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults		n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症						
大腸菌性尿路感染	1	(0.5)	0	0	0	0
傷害、中毒および処置合併症	7	(3.4)	0	1 (1.0)	1 (1.1)	0
頭部損傷	2	(1.0)	0	0	0	0
挫傷	1	(0.5)	0	0	0	0
顔面骨骨折	1	(0.5)	0	0	0	0
骨折	1	(0.5)	0	1 (1.0)	0	0
手骨折	1	(0.5)	0	0	0	0
刺創	1	(0.5)	0	0	1 (1.1)	0
硬膜下血腫	1	(0.5)	0	0	0	0
外傷性頭蓋内出血	1	(0.5)	0	0	0	0
臨床検査	1	(0.5)	0	0	0	0
薬物濃度増加	1	(0.5)	0	0	0	0
体重減少	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>24 - <=27		>27 - <=30		>30 - <=33		>33 - <=36	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症										
大腸菌性尿路感染	1	(0.5)	0		0		0		0	
傷害、中毒および処置合併症	7	(3.4)	0		2	(3.8)	0		0	
頭部損傷	2	(1.0)	0		0		0		0	
挫傷	1	(0.5)	0		0		0		0	
顔面骨骨折	1	(0.5)	0		1	(1.9)	0		0	
骨折	1	(0.5)	0		0		0		0	
手骨折	1	(0.5)	0		0		0		0	
刺創	1	(0.5)	0		0		0		0	
硬膜下血腫	1	(0.5)	0		1	(1.9)	0		0	
外傷性頭蓋内出血	1	(0.5)	0		1	(1.9)	0		0	
臨床検査	1	(0.5)	0		0		0		0	
薬物濃度増加	1	(0.5)	0		0		0		0	
体重減少	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
感染症および寄生虫症				
大腸菌性尿路感染	1	(0.5)	0	0
傷害、中毒および処置合併症	7	(3.4)	0	0
頭部損傷	2	(1.0)	0	0
挫傷	1	(0.5)	0	0
顔面骨骨折	1	(0.5)	0	0
骨折	1	(0.5)	0	0
手骨折	1	(0.5)	0	0
刺創	1	(0.5)	0	0
硬膜下血腫	1	(0.5)	0	0
外傷性頭蓋内出血	1	(0.5)	0	0
臨床検査	1	(0.5)	0	0
薬物濃度増加	1	(0.5)	0	0
体重減少	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
代謝および栄養障害	2	(1.0)	0		0		0		2	(1.5)
脱水	1	(0.5)	0		0		0		1	(0.8)
糖尿病	1	(0.5)	0		0		0		1	(0.8)
筋骨格系および結合組織障害	1	(0.5)	1	(0.5)	0		0		0	
四肢痛	1	(0.5)	1	(0.5)	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		0		0		0	
膀胱癌	1	(0.5)	0		0		0		0	
神経系障害	18	(8.8)	8	(3.9)	1	(0.6)	3	(1.9)	0	
大発作痙攣	7	(3.4)	3	(1.5)	0		1	(0.6)	0	
浮動性めまい	3	(1.5)	2	(1.0)	0		1	(0.6)	0	
てんかん重積状態	3	(1.5)	2	(1.0)	0		0		0	
傾眠	2	(1.0)	2	(1.0)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
代謝および栄養障害	2	(1.0)	0		0		0		0	
脱水	1	(0.5)	0		0		0		0	
糖尿病	1	(0.5)	0		0		0		0	
筋骨格系および結合組織障害	1	(0.5)	0		0		0		0	
四肢痛	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		0		1	(1.1)	0	
膀胱癌	1	(0.5)	0		0		1	(1.1)	0	
神経系障害	18	(8.8)	1	(0.8)	2	(1.9)	3	(3.2)	0	
大発作痙攣	7	(3.4)	0		2	(1.9)	1	(1.1)	0	
浮動性めまい	3	(1.5)	0		0		0		0	
てんかん重積状態	3	(1.5)	1	(0.8)	0		0		0	
傾眠	2	(1.0)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults		n (%)	n (%)	n (%)	n (%)
代謝および栄養障害	2	(1.0)	0	0	0	0
脱水	1	(0.5)	0	0	0	0
糖尿病	1	(0.5)	0	0	0	0
筋骨格系および結合組織障害	1	(0.5)	0	0	0	0
四肢痛	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	0	0	0
膀胱癌	1	(0.5)	0	0	0	0
神経系障害	18	(8.8)	0	0	0	0
大発作痙攣	7	(3.4)	0	0	0	0
浮動性めまい	3	(1.5)	0	0	0	0
てんかん重積状態	3	(1.5)	0	0	0	0
傾眠	2	(1.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
代謝および栄養障害	2	(1.0)	0	0
脱水	1	(0.5)	0	0
糖尿病	1	(0.5)	0	0
筋骨格系および結合組織障害	1	(0.5)	0	0
四肢痛	1	(0.5)	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	0
膀胱癌	1	(0.5)	0	0
神経系障害	18	(8.8)	0	0
大発作痙攣	7	(3.4)	0	0
浮動性めまい	3	(1.5)	0	0
てんかん重積状態	3	(1.5)	0	0
傾眠	2	(1.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>0 - <=3		>3 - <=6		>6 - <=9		>9 - <=12	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
神経系障害										
良性頭蓋内圧亢進	1	(0.5)	0		0		1	(0.6)	0	
てんかん	1	(0.5)	0		1	(0.6)	0		0	
頭痛	1	(0.5)	1	(0.5)	0		0		0	
片頭痛	1	(0.5)	0		0		0		0	
ミオクローヌス性てんかん	1	(0.5)	0		0		0		0	
精神障害	1	(0.5)	0		0		0		1	(0.8)
精神状態変化	1	(0.5)	0		0		0		1	(0.8)
呼吸器、胸郭および縦隔障害	2	(1.0)	0		0		1	(0.6)	0	
誤嚥性肺炎	2	(1.0)	0		0		1	(0.6)	0	
急性呼吸不全	1	(0.5)	0		0		0		0	
血管障害	1	(0.5)	0		0		0		0	
末梢性虚血	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
神経系障害										
良性頭蓋内圧亢進	1	(0.5)	0		0		0		0	
てんかん	1	(0.5)	0		0		0		0	
頭痛	1	(0.5)	0		0		0		0	
片頭痛	1	(0.5)	0		0		1	(1.1)	0	
ミオクローヌス性てんかん	1	(0.5)	0		0		1	(1.1)	0	
精神障害	1	(0.5)	0		0		0		0	
精神状態変化	1	(0.5)	0		0		0		0	
呼吸器、胸郭および縦隔障害	2	(1.0)	1	(0.8)	0		0		0	
誤嚥性肺炎	2	(1.0)	1	(0.8)	0		0		0	
急性呼吸不全	1	(0.5)	1	(0.8)	0		0		0	
血管障害	1	(0.5)	0		0		0		0	
末梢性虚血	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults		n (%)	n (%)	n (%)	n (%)
神経系障害						
良性頭蓋内圧亢進	1	(0.5)	0	0	0	0
てんかん	1	(0.5)	0	0	0	0
頭痛	1	(0.5)	0	0	0	0
片頭痛	1	(0.5)	0	0	0	0
ミオクローヌス性てんかん	1	(0.5)	0	0	0	0
精神障害	1	(0.5)	0	0	0	0
精神状態変化	1	(0.5)	0	0	0	0
呼吸器、胸郭および縦隔障害	2	(1.0)	0	0	0	0
誤嚥性肺炎	2	(1.0)	0	0	0	0
急性呼吸不全	1	(0.5)	0	0	0	0
血管障害	1	(0.5)	0	0	1 (2.7)	0
末梢性虚血	1	(0.5)	0	0	1 (2.7)	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-3　LCM 曝露期間に発現した重篤な有害事象［Pool SGTC-1］（続き）

Table 5.1.4 Incidence of Non-fatal SAEs by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	Adults		n (%)	n (%)
神経系障害				
良性頭蓋内圧亢進	1	(0.5)	0	0
てんかん	1	(0.5)	0	0
頭痛	1	(0.5)	0	0
片頭痛	1	(0.5)	0	0
ミオクローヌス性てんかん	1	(0.5)	0	0
精神障害	1	(0.5)	0	0
精神状態変化	1	(0.5)	0	0
呼吸器、胸郭および縦隔障害	2	(1.0)	0	0
誤嚥性肺炎	2	(1.0)	0	0
急性呼吸不全	1	(0.5)	0	0
血管障害	1	(0.5)	0	0
末梢性虚血	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
Number evaluated	255		255		218		201		164	
Any TEAE	17	(6.7)	14	(5.5)	1	(0.5)	0		0	
耳および迷路障害	1	(0.4)	1	(0.4)	0		0		0	
回転性めまい	1	(0.4)	1	(0.4)	0		0		0	
眼障害	2	(0.8)	2	(0.8)	0		0		0	
複視	1	(0.4)	1	(0.4)	0		0		0	
霧視	1	(0.4)	1	(0.4)	0		0		0	
一般・全身障害および投与部位の状態	2	(0.8)	2	(0.8)	0		0		0	
疲労	1	(0.4)	1	(0.4)	0		0		0	
易刺激性	1	(0.4)	1	(0.4)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects	Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)	>15 - <=18 n (%)	>18 - <=21 n (%)	>21 - <=24 n (%)
Number evaluated	255	147	128	114	97
Any TEAE	17 (6.7)	0	1 (0.8)	1 (0.9)	0
耳および迷路障害	1 (0.4)	0	0	0	0
回転性めまい	1 (0.4)	0	0	0	0
眼障害	2 (0.8)	0	0	0	0
複視	1 (0.4)	0	0	0	0
霧視	1 (0.4)	0	0	0	0
一般・全身障害および投与部位の状態	2 (0.8)	0	0	0	0
疲労	1 (0.4)	0	0	0	0
易刺激性	1 (0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
Number evaluated	255		81	64	46	37
Any TEAE	17	(6.7)	0	0	0	0
耳および迷路障害	1	(0.4)	0	0	0	0
回転性めまい	1	(0.4)	0	0	0	0
眼障害	2	(0.8)	0	0	0	0
複視	1	(0.4)	0	0	0	0
霧視	1	(0.4)	0	0	0	0
一般・全身障害および投与部位の状態	2	(0.8)	0	0	0	0
疲労	1	(0.4)	0	0	0	0
易刺激性	1	(0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset

Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
Number evaluated	255		12	3
Any TEAE	17	(6.7)	0	0
耳および迷路障害	1	(0.4)	0	0
回転性めまい	1	(0.4)	0	0
眼障害	2	(0.8)	0	0
複視	1	(0.4)	0	0
霧視	1	(0.4)	0	0
一般・全身障害および投与部位の状態	2	(0.8)	0	0
疲労	1	(0.4)	0	0
易刺激性	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)		>6 - <=9 n (%)		>9 - <=12 n (%)	
臨床検査	2	(0.8)	1	(0.4)	1	(0.5)	0		0	
アラニンアミノトランスフェラーゼ増加	1	(0.4)	1	(0.4)	0		0		0	
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.4)	1	(0.4)	0		0		0	
トランスアミナーゼ上昇	1	(0.4)	0		1	(0.5)	0		0	
神経系障害	9	(3.5)	7	(2.7)	0		0		0	
浮動性めまい	3	(1.2)	3	(1.2)	0		0		0	
ミオクローヌス性てんかん	3	(1.2)	1	(0.4)	0		0		0	
健忘	2	(0.8)	2	(0.8)	0		0		0	
失語症	1	(0.4)	1	(0.4)	0		0		0	
平衡障害	1	(0.4)	1	(0.4)	0		0		0	
痙攣	1	(0.4)	1	(0.4)	0		0		0	
頭痛	1	(0.4)	1	(0.4)	0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)		>15 - <=18 n (%)		>18 - <=21 n (%)		>21 - <=24 n (%)	
臨床検査	2	(0.8)	0		0		0		0	
アラニンアミノトランスフェラーゼ増加	1	(0.4)	0		0		0		0	
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.4)	0		0		0		0	
トランスアミナーゼ上昇	1	(0.4)	0		0		0		0	
神経系障害	9	(3.5)	0		1	(0.8)	1	(0.9)	0	
浮動性めまい	3	(1.2)	0		0		0		0	
ミオクローヌス性てんかん	3	(1.2)	0		1	(0.8)	1	(0.9)	0	
健忘	2	(0.8)	0		0		0		0	
失語症	1	(0.4)	0		0		0		0	
平衡障害	1	(0.4)	0		0		0		0	
痙攣	1	(0.4)	0		0		0		0	
頭痛	1	(0.4)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	All Subjects		n (%)	n (%)	n (%)	n (%)
臨床検査	2	(0.8)	0	0	0	0
アラニンアミノトランスフェラーゼ増加	1	(0.4)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.4)	0	0	0	0
トランスアミナーゼ上昇	1	(0.4)	0	0	0	0
神経系障害	9	(3.5)	0	0	0	0
浮動性めまい	3	(1.2)	0	0	0	0
ミオクローヌス性てんかん	3	(1.2)	0	0	0	0
健忘	2	(0.8)	0	0	0	0
失語症	1	(0.4)	0	0	0	0
平衡障害	1	(0.4)	0	0	0	0
痙攣	1	(0.4)	0	0	0	0
頭痛	1	(0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
臨床検査	2	(0.8)	0	0
アラニンアミノトランスフェラーゼ増加	1	(0.4)	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.4)	0	0
トランスアミナーゼ上昇	1	(0.4)	0	0
神経系障害	9	(3.5)	0	0
浮動性めまい	3	(1.2)	0	0
ミオクローヌス性てんかん	3	(1.2)	0	0
健忘	2	(0.8)	0	0
失語症	1	(0.4)	0	0
平衡障害	1	(0.4)	0	0
痙攣	1	(0.4)	0	0
頭痛	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)	>6 - <=9 n (%)	>9 - <=12 n (%)
神経系障害							
てんかん重積状態	1	(0.4)	1	(0.4)	0	0	0
精神障害	4	(1.6)	4	(1.6)	0	0	0
自殺念慮	3	(1.2)	3	(1.2)	0	0	0
うつ病	1	(0.4)	1	(0.4)	0	0	0
皮膚および皮下組織障害	1	(0.4)	1	(0.4)	0	0	0
発疹	1	(0.4)	1	(0.4)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	All Subjects		n (%)	n (%)	n (%)	n (%)
神経系障害						
てんかん重積状態	1	(0.4)	0	0	0	0
精神障害	4	(1.6)	0	0	0	0
自殺念慮	3	(1.2)	0	0	0	0
うつ病	1	(0.4)	0	0	0	0
皮膚および皮下組織障害	1	(0.4)	0	0	0	0
発疹	1	(0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	All Subjects		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
神経系障害						
てんかん重積状態	1	(0.4)	0	0	0	0
精神障害	4	(1.6)	0	0	0	0
自殺念慮	3	(1.2)	0	0	0	0
うつ病	1	(0.4)	0	0	0	0
皮膚および皮下組織障害	1	(0.4)	0	0	0	0
発疹	1	(0.4)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period.
SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class			>36 - <=39	>39 - <=42
Preferred Term	All Subjects		n (%)	n (%)
神経系障害				
てんかん重積状態	1	(0.4)	0	0
精神障害	4	(1.6)	0	0
自殺念慮	3	(1.2)	0	0
うつ病	1	(0.4)	0	0
皮膚および皮下組織障害	1	(0.4)	0	0
発疹	1	(0.4)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>0 - <=3	>3 - <=6	>6 - <=9	>9 - <=12
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	50	48	43	32
Any TEAE	2 (4.0)	1 (2.0)	1 (2.1)	0	0
臨床検査	1 (2.0)	0	1 (2.1)	0	0
トランスアミナーゼ上昇	1 (2.0)	0	1 (2.1)	0	0
神経系障害	1 (2.0)	1 (2.0)	0	0	0
痙攣	1 (2.0)	1 (2.0)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset

Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	28	24	21	19
Any TEAE	2 (4.0)	0	0	0	0
臨床検査	1 (2.0)	0	0	0	0
トランスアミナーゼ上昇	1 (2.0)	0	0	0	0
神経系障害	1 (2.0)	0	0	0	0
痙攣	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.

Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.

Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).

Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.

Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Pediatrics	n (%)	n (%)	n (%)	n (%)
Number evaluated	50	16	12	9	7
Any TEAE	2 (4.0)	0	0	0	0
臨床検査	1 (2.0)	0	0	0	0
トランスアミナーゼ上昇	1 (2.0)	0	0	0	0
神経系障害	1 (2.0)	0	0	0	0
痙攣	1 (2.0)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)	
System Organ Class		>36 - <=39	>39 - <=42
Preferred Term	Pediatrics	n (%)	n (%)
Number evaluated	50	3	0
Any TEAE	2 (4.0)	0	0
臨床検査	1 (2.0)	0	0
トランスアミナーゼ上昇	1 (2.0)	0	0
神経系障害	1 (2.0)	0	0
痙攣	1 (2.0)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)	>6 - <=9 n (%)	>9 - <=12 n (%)
Number evaluated	205		205		170	158	132
Any TEAE	15	(7.3)	13	(6.3)	0	0	0
耳および迷路障害	1	(0.5)	1	(0.5)	0	0	0
回転性めまい	1	(0.5)	1	(0.5)	0	0	0
眼障害	2	(1.0)	2	(1.0)	0	0	0
複視	1	(0.5)	1	(0.5)	0	0	0
霧視	1	(0.5)	1	(0.5)	0	0	0
一般・全身障害および投与部位の状態	2	(1.0)	2	(1.0)	0	0	0
疲労	1	(0.5)	1	(0.5)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1		Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class		>12 - <=15	>15 - <=18	>18 - <=21	>21 - <=24
Preferred Term	Adults	n (%)	n (%)	n (%)	n (%)
Number evaluated	205	119	104	93	78
Any TEAE	15 (7.3)	0	1 (1.0)	1 (1.1)	0
耳および迷路障害	1 (0.5)	0	0	0	0
回転性めまい	1 (0.5)	0	0	0	0
眼障害	2 (1.0)	0	0	0	0
複視	1 (0.5)	0	0	0	0
霧視	1 (0.5)	0	0	0	0
一般・全身障害および投与部位の状態	2 (1.0)	0	0	0	0
疲労	1 (0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
Number evaluated	205		65	52	37	30
Any TEAE	15	(7.3)	0	0	0	0
耳および迷路障害	1	(0.5)	0	0	0	0
回転性めまい	1	(0.5)	0	0	0	0
眼障害	2	(1.0)	0	0	0	0
複視	1	(0.5)	0	0	0	0
霧視	1	(0.5)	0	0	0	0
一般・全身障害および投与部位の状態	2	(1.0)	0	0	0	0
疲労	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset

Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
Number evaluated	205		9	3
Any TEAE	15	(7.3)	0	0
耳および迷路障害	1	(0.5)	0	0
回転性めまい	1	(0.5)	0	0
眼障害	2	(1.0)	0	0
複視	1	(0.5)	0	0
霧視	1	(0.5)	0	0
一般・全身障害および投与部位の状態	2	(1.0)	0	0
疲労	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)	>6 - <=9 n (%)	>9 - <=12 n (%)
一般・全身障害および投与部位の状態							
易刺激性	1	(0.5)	1	(0.5)	0	0	0
臨床検査	1	(0.5)	1	(0.5)	0	0	0
アラニンアミノトランスフェラーゼ増加	1	(0.5)	1	(0.5)	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.5)	1	(0.5)	0	0	0
神経系障害	8	(3.9)	6	(2.9)	0	0	0
浮動性めまい	3	(1.5)	3	(1.5)	0	0	0
ミオクローヌス性てんかん	3	(1.5)	1	(0.5)	0	0	0
健忘	2	(1.0)	2	(1.0)	0	0	0
失語症	1	(0.5)	1	(0.5)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)							
System Organ Class			>12 - <=15		>15 - <=18		>18 - <=21		>21 - <=24	
Preferred Term	Adults		n	(%)	n	(%)	n	(%)	n	(%)
一般・全身障害および投与部位の状態										
易刺激性	1	(0.5)	0		0		0		0	
臨床検査	1	(0.5)	0		0		0		0	
アラニンアミノトランスフェラーゼ増加	1	(0.5)	0		0		0		0	
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.5)	0		0		0		0	
神経系障害	8	(3.9)	0		1	(1.0)	1	(1.1)	0	
浮動性めまい	3	(1.5)	0		0		0		0	
ミオクローヌス性てんかん	3	(1.5)	0		1	(1.0)	1	(1.1)	0	
健忘	2	(1.0)	0		0		0		0	
失語症	1	(0.5)	0		0		0		0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1			Period of TEAE Onset within the LCM Exposure Interval (Months)			
System Organ Class			>24 - <=27	>27 - <=30	>30 - <=33	>33 - <=36
Preferred Term	Adults		n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態						
易刺激性	1	(0.5)	0	0	0	0
臨床検査	1	(0.5)	0	0	0	0
アラニンアミノトランスフェラーゼ増加	1	(0.5)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.5)	0	0	0	0
神経系障害	8	(3.9)	0	0	0	0
浮動性めまい	3	(1.5)	0	0	0	0
ミオクローヌス性てんかん	3	(1.5)	0	0	0	0
健忘	2	(1.0)	0	0	0	0
失語症	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
一般・全身障害および投与部位の状態				
易刺激性	1	(0.5)	0	0
臨床検査	1	(0.5)	0	0
アラニンアミノトランスフェラーゼ増加	1	(0.5)	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1	(0.5)	0	0
神経系障害	8	(3.9)	0	0
浮動性めまい	3	(1.5)	0	0
ミオクローヌス性てんかん	3	(1.5)	0	0
健忘	2	(1.0)	0	0
失語症	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >0 - <=3 n (%)		>3 - <=6 n (%)	>6 - <=9 n (%)	>9 - <=12 n (%)
神経系障害							
平衡障害	1	(0.5)	1	(0.5)	0	0	0
頭痛	1	(0.5)	1	(0.5)	0	0	0
てんかん重積状態	1	(0.5)	1	(0.5)	0	0	0
精神障害	4	(2.0)	4	(2.0)	0	0	0
自殺念慮	3	(1.5)	3	(1.5)	0	0	0
うつ病	1	(0.5)	1	(0.5)	0	0	0
皮膚および皮下組織障害	1	(0.5)	1	(0.5)	0	0	0
発疹	1	(0.5)	1	(0.5)	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >12 - <=15 n (%)	>15 - <=18 n (%)	>18 - <=21 n (%)	>21 - <=24 n (%)
神経系障害						
平衡障害	1	(0.5)	0	0	0	0
頭痛	1	(0.5)	0	0	0	0
てんかん重積状態	1	(0.5)	0	0	0	0
精神障害	4	(2.0)	0	0	0	0
自殺念慮	3	(1.5)	0	0	0	0
うつ病	1	(0.5)	0	0	0	0
皮膚および皮下組織障害	1	(0.5)	0	0	0	0
発疹	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >24 - <=27 n (%)	>27 - <=30 n (%)	>30 - <=33 n (%)	>33 - <=36 n (%)
神経系障害						
平衡障害	1	(0.5)	0	0	0	0
頭痛	1	(0.5)	0	0	0	0
てんかん重積状態	1	(0.5)	0	0	0	0
精神障害	4	(2.0)	0	0	0	0
自殺念慮	3	(1.5)	0	0	0	0
うつ病	1	(0.5)	0	0	0	0
皮膚および皮下組織障害	1	(0.5)	0	0	0	0
発疹	1	(0.5)	0	0	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

表 7-4　LCM 曝露期間に発現した治験薬の投与中止に至った有害事象［Pool SGTC-1］（続き）

Table 5.1.5 Incidence of TEAEs leading to Discontinuation by 3-Month LCM Exposure Period of TEAE Onset
Analysis Set: Pool SGTC-1

MedDRA v.16.1 System Organ Class / Preferred Term	Adults		Period of TEAE Onset within the LCM Exposure Interval (Months) >36 - <=39 n (%)	>39 - <=42 n (%)
神経系障害				
平衡障害	1	(0.5)	0	0
頭痛	1	(0.5)	0	0
てんかん重積状態	1	(0.5)	0	0
精神障害	4	(2.0)	0	0
自殺念慮	3	(1.5)	0	0
うつ病	1	(0.5)	0	0
皮膚および皮下組織障害	1	(0.5)	0	0
発疹	1	(0.5)	0	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=treatment-emergent adverse event.
Note: Subjects can be counted in more than one time interval if the first occurrence of their SOC/PTs are in different time intervals.
Note: Percentages are based on the number of subjects evaluated which is the number of subjects in Pool SGTC-1 with LCM exposure during each TEAE onset interval (ie, number of subjects at risk in each interval).
Note: A month is defined as 28 days. Each 3-month LCM exposure interval represents an 84 day period.
Note: There are three additional subjects reported in this table compared to Table 1.2. SP0982-[redacted] is ongoing on EP0012 at the time of the datacut [redacted], but a TEAE leading to discontinuation was also reported. SP0982-[redacted] completed study SP0982 with '>=2 PGTCS' during the treatment period and experienced a TEAE leading to discontinuation during the transition period. SP0982-[redacted] completed SP0982 with the Occurrence of the 125th Event after which the subject had the TEAE leading to discontinuation.

(1) 2.7.1 項 参考文献

参考文献なし。

(2) 2.7.2 項 参考文献

参考文献なし。

(3) 2.7.3 項 参考文献

参考文献なし。

(4) 2.7.4 項 参考文献

参考文献なし。