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添付資料番号	試験番号	タイトル	著者	試験実施期間	試験実施場所	国内/海外	掲載誌	評価/参考	同一添付資料番号
4.2.2 薬物動態試験									
4.2.2.1 分析法及びバリデーション報告書									
4.2.2.1-1	[redacted]	Pharmacokinetics of LDP-02 following intravenous and subcutaneous administration to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-3
4.2.2.1-2	[redacted]	Determination of saturation binding and circulating antibody levels in a single dose study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-4
4.2.2.1-3	[redacted]	Serum LDP-02 Concentrations, Leukocyte Alpha4Beta7 Saturation and Free Alpha4Beta7 Sites, and Serum Anti-LDP-02 Antibody Titers in Cynomolgus Monkeys Receiving A Single IV or SC Dose of LDP-02	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-5
4.2.2.1-4	[redacted]	Fourteen-day repeated dose toxicity study of LDP-02 administered via intravenous infusion to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-9 4.2.3.2-2
4.2.2.1-5	[redacted]	Determination of saturation binding and circulating antibody levels in a multiple dose toxicology study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-10 4.2.3.2-2
4.2.2.1-6	[redacted]	Serum LDP-02 concentrations and leukocyte alpha4beta7 saturation and free alpha4beta7 sites in cynomolgus monkeys receiving 14 repeated IV doses of LDP-02, and results of clinical pathology and laboratory assays in cynomolgus monkeys receiving 14 repeated IV doses of LDP-02	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-11 4.2.3.2-2
4.2.2.1-7	[redacted]	Three-month pharmacokinetic and safety study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-14 4.2.3.2-4 4.2.3.7.1-5
4.2.2.1-8	[redacted]	Development and qualification of a test method for the quantitation of natalizumab in rhesus and cynomolgus macaque serum by ELISA assay	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	---
4.2.2.1-9	[redacted]	Development and qualification of an enzyme-linked immunosorbent assay for the detection of anti-human antibodies to natalizumab in rhesus and cynomolgus macaque serum	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	---
4.2.2.1-10	[redacted]	Validation of a flow cytometry method for the beckman coulter FC500 flow cytometer using CD4/CD45RA/CD8/CD3 in cynomolgus monkey whole blood	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-11	[redacted]	Rabbit serum validation study: determination of MLN0002 in rabbit serum by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-12	[redacted]	Rabbit serum validation study: determination of MLN0002 in rabbit serum by ELISA addendum 1	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---

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4.2.2.1-13	[redacted]	Monkey serum validation study: determination of MLN0002 in monkey serum by ELISA (amendment #1)	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-14	[redacted]	Monkey serum validation study: determination of MLN0002 in monkey serum by ELISA addendum 1	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-15	[redacted]	Monkey serum validation study: determination of MLN0002 in monkey serum by ELISA addendum 2	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-16	[redacted]	Determination of MLN0002 in monkey breast milk by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-17	[redacted]	Determination of MLN0002 in monkey breast milk by ELISA addendum 1	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-18	[redacted]	Rabbit serum validation study: detection of rabbit anti-human (MLN0002) antibodies in rabbit serum by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-19	[redacted]	Monkey serum validation study: detection of primate anti-human antibodies to MLN0002 in cynomolgus monkey serum by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	---
4.2.2.1-20	[redacted]	Validation of an assay to measure a4b7 free sites on leukocytes from whole blood of new zealand white rabbits by flow cytometry in the presence of MLN0002	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	---
4.2.2.1-21	[redacted]	Validation of a flow cytometric assay to measure MLN0002 free sites on CD4+/CD45RA- and CD4+/CD45RA+ T-cells and CD20+ B-cells from whole blood of cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	---
4.2.2.1-22	[redacted]	Validation of a Flow Cytometric Assay for Monitoring Saturation of a Humanized IgG1 Monoclonal Antibody [MLN0002] (Bound drug) on CD4+ Lymphocytes in the Peripheral Blood of New Zealand White Rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	---
4.2.2.1-23	[redacted]	Validation of a flow cytometric assay for monitoring bound humanized IgG1 monoclonal antibody [MLN0002] on CD4+/CD45RA- and CD4+/CD45RA+ lymphocytes in the peripheral blood of cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	---
4.2.2.1-24	[redacted]	Development of a test method for the quantitation of MLN02 in cynomolgus monkey serum using anti-1D9 idiotypic antibody-coated plates	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	---
4.2.2.1-25	[redacted]	Development and qualification of an enzyme-linked immunosorbent assay for the quantitation of MLN0002 in rhesus macaque serum	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	---
4.2.2.1-26	[redacted]	An intravenous infusion dose range-finding study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-1 4.2.3.5.2-1 4.2.3.7.1-8
4.2.2.1-27	[redacted]	A single dose pharmacokinetic, pharmacodynamic, and immunogenicity study of MLN0002 administered intravenously to cynomolgus monkeys	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	4.2.2.3-1 4.2.2.7-6
4.2.2.1-28	[redacted]	A multiple dose pharmacokinetic/pharmacodynamic study of MLN02 administered intravenously in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.7-13 4.2.3.2-3 4.2.3.7.1-4

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4.2.2.1-29	[redacted]	Development of a test method for the qualitative determination of primate anti-human (MLN02) antibodies (PAHA) in cynomolgus monkey serum using an enzyme-linked immunosorbent assay	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	---
4.2.2.1-30	[redacted]	Development and qualification of an enzyme-linked immunosorbent assay for the detection of primate antihuman antibodies to MLN0002 in rhesus macaque serum	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	---
4.2.2.2 吸収									
該当なし									
4.2.2.3 分布									
4.2.2.3-1	[redacted]	A single dose pharmacokinetic, pharmacodynamic, and immunogenicity study of MLN0002 administered intravenously to cynomolgus monkeys	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	4.2.2.1-27 4.2.2.7-6
4.2.2.3-2	[redacted]	MLN0002: Intravenous infusion study for effects on pre- and postnatal development in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.5-1 4.2.2.7-17 4.2.3.5.3-1 4.2.3.7.1-10
4.2.2.4 代謝									
該当なし									
4.2.2.5 排泄									
4.2.2.5-1	[redacted]	MLN0002: Intravenous infusion study for effects on pre- and postnatal development in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.3-2 4.2.2.7-17 4.2.3.5.3-1 4.2.3.7.1-10
4.2.2.6 薬物動態学的薬物相互作用(非臨床)									
該当なし									
4.2.2.7 その他の薬物動態試験									
4.2.2.7-1	[redacted]	An intravenous infusion dose range-finding study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-26 4.2.3.5.2-1 4.2.3.7.1-8
4.2.2.7-2	[redacted]	An intravenous infusion study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.3.5.2-2 4.2.3.7.1-9
4.2.2.7-3	[redacted]	Pharmacokinetics of LDP-02 following intravenous and subcutaneous administration to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-1
4.2.2.7-4	[redacted]	Determination of saturation binding and circulating antibody levels in a single dose study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-2
4.2.2.7-5	[redacted]	Serum LDP-02 Concentrations, Leukocyte Alpha4Beta7 Saturation and Free Alpha4Beta7 Sites, and Serum Anti-LDP-02 Antibody Titers in Cynomolgus Monkeys Receiving A Single IV or SC Dose of LDP-02	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-3
4.2.2.7-6	[redacted]	A single dose pharmacokinetic, pharmacodynamic, and immunogenicity study of MLN0002 administered intravenously to cynomolgus monkeys	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc.	海外	社内資料	参考	4.2.2.1-27 4.2.2.3-1

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4.2.2.7-7	[redacted]	An acute intravenous infusion toxicology study of MLN0002 manufactured using process B and process C in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.3.1-2 4.2.3.7.1-2
4.2.2.7-8	[redacted]	A 3-month intravenous infusion toxicity and toxicokinetics study of MLN0002 with a 4-week recovery period in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.3.2-1 4.2.3.7.1-3
4.2.2.7-9	[redacted]	Fourteen-day repeated dose toxicity study of LDP-02 administered via intravenous infusion to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-4 4.2.3.2-2
4.2.2.7-10	[redacted]	Determination of saturation binding and circulating antibody levels in a multiple dose toxicology study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-5 4.2.3.2-2
4.2.2.7-11	[redacted]	Serum LDP-02 concentrations and leukocyte alpha4beta7 saturation and free alpha4beta7 sites in cynomolgus monkeys receiving 14 repeated IV doses of LDP-02, and results of clinical pathology and laboratory assays in cynomolgus monkeys receiving 14 repeated IV doses of LDP-02	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-6 4.2.3.2-2
4.2.2.7-12	[redacted]	Pharmacokinetic modeling of LDP-02	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	---
4.2.2.7-13	[redacted]	A multiple dose pharmacokinetic/pharmacodynamic study of MLN02 administered intravenously in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-28 4.2.3.2-3 4.2.3.7.1-4
4.2.2.7-14	[redacted]	Three-month pharmacokinetic and safety study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-7 4.2.3.2-4 4.2.3.7.1-5
4.2.2.7-15	[redacted]	A 13-week intravenous injection toxicity study of MLN0002 in the cynomolgus monkey (with a 12-week recovery period)	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.3.2-5 4.2.3.7.1-6 4.2.3.7.2-1
4.2.2.7-16	[redacted]	A 26-week toxicity study of MLN0002 administered by intravenous infusion to cynomolgus monkeys, with a 12-week recovery period	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.3.2-6 4.2.3.7.1-7

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4.2.2.7-17	[redacted]	MLN0002: Intravenous infusion study for effects on pre- and postnatal development in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.3-2 4.2.2.5-1 4.2.3.5.3-1 4.2.3.7.1-10
4.2.2.7-18	[redacted]	A 3-week comparative immunotoxicity study of natalizumab (Tysabri®) and vedolizumab (MLN0002) administered by intravenous infusion to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.3.7.1-11 4.2.3.7.2-2
4.2.3 毒性試験									
4.2.3.1 単回投与毒性試験									
4.2.3.1-1	[redacted]	A single dose pharmacokinetic/pharmacodynamic study of MLN02 administered intravenously to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.3.7.1-1
4.2.3.1-2	[redacted]	An acute intravenous infusion toxicology study of MLN0002 manufactured using Process B and Process C in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-7 4.2.3.7.1-2
4.2.3.2 反復投与毒性試験									
4.2.3.2-1	[redacted]	A 3-month intravenous infusion toxicity and toxicokinetics study of MLN0002 with a 4-week recovery period in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-8 4.2.3.7.1-3
4.2.3.2-2	[redacted]	Fourteen-day repeated dose toxicity study of LDP-02 administered via intravenous infusion to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.1-4 4.2.2.1-5 4.2.2.1-6 4.2.2.7-9 4.2.2.7-10 4.2.2.7-11
4.2.3.2-3	[redacted]	A multiple dose pharmacokinetic/pharmacodynamic study of MLN02 administrated intravenously in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-28 4.2.2.7-13 4.2.3.7.1-4
4.2.3.2-4	[redacted]	Three-month pharmacokinetic and safety study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.1-7 4.2.2.7-14 4.2.3.7.1-5
4.2.3.2-5	[redacted]	A 13-week intravenous injection toxicity study of MLN0002 in the cynomolgus monkey (with a 12-week recovery period)	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-15 4.2.3.7.1-6 4.2.3.7.2-1
4.2.3.2-6	[redacted]	A 26-week toxicity study of MLN0002 administered by intravenous infusion to cynomolgus monkeys, with a 12-week recovery period	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-16 4.2.3.7.1-7

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4.2.3.3 遺伝毒性試験									
4.2.3.3.1 In vitro試験									
該当なし									
4.2.3.3.2 In vivo試験									
該当なし									
4.2.3.4 がん原性試験									
4.2.3.4.1 長期がん原性試験									
該当なし									
4.2.3.4.2 短期又は中期がん原性試験									
該当なし									
4.2.3.4.3 その他の試験									
4.2.3.4.3-1	[redacted]	A study of binding specificity of ACT-1 in malignant human tumors	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	-
4.2.3.4.3-2	[redacted]	Effect of ACT-1 antibody on the growth of the alpha 4 beta 7-expressing RPMI 8866 human B-cell lymphoma cell line	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc	海外	社内資料	参考	-
4.2.3.5 生殖発生毒性試験									
4.2.3.5.1 受胎能及び着床までの初期胚発生に関する試験									
該当なし									
4.2.3.5.2 胚・胎児発生に関する試験									
4.2.3.5.2-1	[redacted]	An intravenous infusion dose range-finding study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-26 4.2.2.7-1 4.2.3.7.1-8
4.2.3.5.2-2	[redacted]	An intravenous infusion study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-2 4.2.3.7.1-9
4.2.3.5.3 出生前及び出生後の発生並びに母体の機能に関する試験									
4.2.3.5.3-1	[redacted]	MLN0002: Intravenous infusion study for effects on pre- and postnatal development in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.3-2 4.2.2.5-1 4.2.2.7-17 4.2.3.7.1-10
4.2.3.5.4 新生児を用いた試験									
4.2.3.5.4-1	[redacted]	MLN0002: A 13-week intravenous infusion toxicity study in juvenile cynomolgus monkeys with a 12-week recovery period	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	-
4.2.3.6 局所刺激性試験									
4.2.3.6-1	[redacted]	A single-dose local toxicity study of MLN0002 administered either subcutaneously or intramuscularly to male New Zealand white rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	-
4.2.3.7 その他の毒性試験									
4.2.3.7.1 抗原性試験									
4.2.3.7.1-1	[redacted]	A single dose pharmacokinetic/pharmacodynamic study of MLN02 administered intravenously to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.3.1-1
4.2.3.7.1-2	[redacted]	An acute intravenous infusion toxicology study of MLN0002 manufactured using Process B and Process C in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-7 4.2.3.1-2

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4.2.3.7.1-3	[redacted]	A 3-month intravenous infusion toxicity and toxicokinetics study of MLN0002 with a 4-week recovery period in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-8 4.2.3.2-1
4.2.3.7.1-4	[redacted]	A multiple dose pharmacokinetic/pharmacodynamic study of MLN02 administrated intravenously in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-28 4.2.2.7-13 4.2.3.2-3
4.2.3.7.1-5	[redacted]	Three-month pharmacokinetic and safety study of LDP-02 in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-7 4.2.2.7-14 4.2.3.2-4
4.2.3.7.1-6	[redacted]	A 13-week intravenous injection toxicity study of MLN0002 in the cynomolgus monkey (with a 12-week recovery period)	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-15 4.2.3.2-5 4.2.3.7.2-1
4.2.3.7.1-7	[redacted]	A 26-week toxicity study of MLN0002 administered by intravenous infusion to cynomolgus monkeys, with a 12-week recovery period	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-16 4.2.3.2-6
4.2.3.7.1-8	[redacted]	An intravenous infusion dose range-finding study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.2.1-26 4.2.2.7-1 4.2.3.5.2-1
4.2.3.7.1-9	[redacted]	An intravenous infusion study of the effects of MLN0002 on embryo/fetal development in rabbits	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-2 4.2.3.5.2-2
4.2.3.7.1-10	[redacted]	MLN0002: Intravenous infusion study for effects on pre- and postnatal development in cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.3-2 4.2.2.5-1 4.2.2.7-17 4.2.3.5.3-1
4.2.3.7.1-11	[redacted]	A 3-week comparative immunotoxicity study of natalizumab (Tysabri®) and vedolizumab (MLN0002) administered by intravenous infusion to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-18 4.2.3.7.2-2
4.2.3.7.2 免疫毒性試験									
4.2.3.7.2-1	[redacted]	A 13-week intravenous injection toxicity study of MLN0002 in the cynomolgus monkey (with a 12-week recovery period)	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-15 4.2.3.2-5 4.2.3.7.1-6
4.2.3.7.2-2	[redacted]	A 3-week comparative immunotoxicity study of natalizumab (Tysabri®) and vedolizumab (MLN0002) administered by intravenous infusion to cynomolgus monkeys	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.2.7-18 4.2.3.7.1-11
4.2.3.7.2-3	[redacted]	Delayed-type hypersensitivity responses, anti-tetanus antibody titers, and laboratory assay results in Act-1 treated rhesus monkeys	[redacted]	[redacted]	Millennium Pharmaceuticals, Inc	海外	社内資料	参考	-

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4.2.3.7.3 毒性発現の機序に関する試験									
該当なし									
4.2.3.7.4 依存性試験									
該当なし									
4.2.3.7.5 代謝物の毒性試験									
該当なし									
4.2.3.7.6 不純物の毒性試験									
該当なし									
4.2.3.7.7 その他の試験									
4.2.3.7.7-1	[redacted]	Preliminary studies of cross reactivity of a humanized monoclonal antibody LDP-02	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	4.2.1.1-9
4.2.3.7.7-2	[redacted]	A cross-reactivity study of MLN0002 with normal cynomolgus monkey tissues	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.1.1-10
4.2.3.7.7-3	[redacted]	Cross reactivity of mouse monoclonal antibody ACT-1 with normal human tissues	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.1.1-11
4.2.3.7.7-4	[redacted]	Cross reactivity of humanized monoclonal IgG1 LDP-02/3A9-8E3.C1 antibody with normal human tissues	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.1.1-12
4.2.3.7.7-5	[redacted]	Cross-reactivity study of MLN0002 with normal human tissues	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	4.2.1.1-13
4.3 参考文献									
4.3-1	—	Treatment of ulcerative colitis with a humanized antibody to the alpha4beta7 integrin.	Feagan BG, et al.	—	—	—	The New England Journal of Medicine. 2005;352(24):2499-507.	参考	
4.3-2	—	Treatment of active Crohn's disease with MLN0002, a humanized antibody to the alpha4beta7 integrin.	Feagan BG, et al.	—	—	—	Clinical Gastroenterology and Hepatology. 2008;6(12):1370-7.	参考	
4.3-3	—	Lymphocyte activation antigens. I. A monoclonal antibody, anti-Act I, defines a new late lymphocyte activation antigen.	Lazarovits AI, et al.	—	—	—	The Journal of Immunology. 1984;133(4):1857-62.	参考	
4.3-4	—	Selective expression of integrin alpha 4 beta 7 on a subset of human CD4+ memory T cells with hallmarks of gut-trophism.	Schweighoffer T, et al	—	—	—	The Journal of Immunology. 1993;151(2):717-29.	参考	
4.3-5	—	Vedolizumab for the treatment of active ulcerative colitis: A randomized controlled phase 2 dose-ranging study.	Parikh A, et al.	—	—	—	Inflammatory Bowel Disease. 2012;18(8):1470-9.	参考	
4.3-6	—	Vedolizumab does not affect the suppressive activity of gut-homing T regulatory cells.	Fedyk ER, et al	—	—	—	Inflammatory Bowel Disease. 2012;18(S1):S86-7.	参考	

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4.3-7	—	Alpha4 integrins as therapeutic targets in autoimmune disease.	von Andrian U H, et al.	—	—	—	The New England Journal of Medicine. 2003;348(1):68-72.	参考	
4.3-8	—	The ins and outs of T-lymphocyte trafficking to the CNS: anatomical sites and molecular mechanisms.	Engelhardt B, et al.	—	—	—	Trends Immunology. 2005;26(9):485-95.	参考	
4.3-9	—	Regional and mucosal memory T cells.	Sheridan BS, et al	—	—	—	Nature Immunology. 2011;12(6):485-91.	参考	
4.3-10	—	Expression and function of the MAdCAM-1 receptor, integrin alpha 4 beta 7, on human leukocytes.	Erle DJ, et al.	—	—	—	The Journal of Immunology. 1994;153(2):517-28.	参考	
4.3-11	—	A fundamental subdivision of circulating lymphocytes defined by adhesion to mucosal addressin cell adhesion molecule-1. Comparison with vascular cell adhesion molecule-1 and correlation with beta 7 integrins and memory differentiation.	Rott LS, et al.	—	—	—	The Journal of Immunology. 1996;156(10):3727-36.	参考	
4.3-12	—	The development of experimental autoimmune encephalomyelitis in the mouse requires alpha4-integrin but not alpha4beta7-integrin.	Engelhardt B, et al.	—	—	—	Journal of Clinical Investigation. 1998;102(12):2096-105.	参考	
4.3-13	—	Surface expression of alpha 4 integrin by CD4 T cells is required for their entry into brain parenchyma.	Baron JL, et al	—	—	—	Journal Experimental Medicine. 1993;177(1):57-68.	参考	
4.3-14	—	A monoclonal antibody to alpha 4 integrin suppresses and reverses active experimental allergic encephalomyelitis.	Kent SJ, et al.	—	—	—	Journal of Neuroimmunology. 1995;58(1):1-10.	参考	
4.3-15	—	Evidence for a prolonged role of alpha 4 integrin throughout active experimental allergic encephalomyelitis.	Keszthelyi E, et al.	—	—	—	Neurology. 1996;47(4):1053-9.	参考	
4.3-16	—	Suppression of acute experimental allergic encephalomyelitis with a small molecule inhibitor of alpha4 integrin.	Piraino PS, et al.	—	—	—	Multiple Sclerosis. 2005;11(6):683-90.	参考	
4.3-17	—	Prevention of experimental autoimmune encephalomyelitis by antibodies against alpha 4 beta 1 integrin.	Yednock TA, et al.	—	—	—	Nature. 1992;356(6364):63-6.	参考	
4.3-18	—	Natalizumab induction and maintenance therapy for Crohn's disease.	Sandborn WJ, et al.	—	—	—	The New England Journal of Medicine. 2005;353(18):1912-25.	参考	
4.3-19	—	A randomized, placebo-controlled trial of natalizumab for relapsing multiple sclerosis.	Polman CH, et al.	—	—	—	The New England Journal of Medicine. 2006;354(9):899-910.	参考	
4.3-20	—	Progressive multifocal leukoencephalopathy in patients on immunomodulatory therapies.	Major EO.	—	—	—	Annual Review of Medicine. 2010;61:35-47.	参考	
4.3-21	—	Natalizumab and progressive multifocal leucoencephalopathy.	Berger JR.	—	—	—	Annuals of Rheumatic Diseases. 2006;65 Suppl 3:iii48-53.	参考	
4.3-22	—	Progressive multifocal leukoencephalopathy and other disorders caused by JC virus: clinical features and pathogenesis.	Tan CS, et al.	—	—	—	Lancet Neurology. 2010;9(4):425-37.	参考	

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4.3-23	—	Signals of progressive multifocal leukoencephalopathy for immunosuppressants: a disproportionality analysis of spontaneous reports within the US Adverse Event Reporting System (AERS).	Schmedt N, et al.	—	—	—	Pharmacoepidemiology and Drug Safty. 2012; 21(11): 1216-20	参考	
4.3-24	—	Functional relevance of T helper 17 (Th17) cells and the IL-17 cytokine family in inflammatory bowel disease.	Hundorfean G, et al	—	—	—	Inflammatory Bowel Diseases. 2012;18(1):180-6.	参考	
4.3-25	—	Regulatory lymphocytes and intestinal inflammation.	Izcue A, et al.	—	—	—	Annual Review of Immunology. 2009;27:313-38.	参考	
4.3-26	—	Tysabri (natalizumab) injection, for intravenous use [package insert].	Cambridge (MA, USA): Biogen Idec Inc; 2012.	—	—	—	FDA	参考	
4.3-27	—	Tysabri 300 mg concentrate for solution for infusion [summary of product characteristics].	Maidenhead (Berkshire, United Kingdom): Biogen Idec Ltd; 2011.	—	—	—	EPAR	参考	
4.3-28	—	A humanized monoclonal antibody targeting the β7 integrin selectively blocks intestinal homing of T lymphocytes.	Stefanich EG, et al.	—	—	—	British Journal of Pharmacology. 2011; 162(8): 1855-70	参考	
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4.3-30	—	Immunotoxicity profile of natalizumab.	Wehner NG, et al.	—	—	—	Journal of Immunotoxicology. 2009;6:115-29.	参考	
4.3-31	—	Critical role for beta7 integrins in formation of the gut-associated lymphoid tissue.	Wagner N, et al.	—	—	—	Nature. 1996;382(6589):366-70.	参考	
4.3-32	—	Lymphocyte trafficking and regional immunity.	Butcher EC, et al.	—	—	—	Advances in Immunology. 1999;72:209-53.	参考	
4.3-33	—	MAdCAM-1 has homology to immunoglobulin and mucin-like adhesion receptors and to IgA1.	Briskin MJ, et al.	—	—	—	Nature. 1993;363(6428):461-4.	参考	
4.3-34	—	Integrins as therapeutic targets: lessons and opportunities.	Cox D, et al.	—	—	—	Nature Reviews Drug Discovery. 2010;9(10):804-20.	参考	
4.3-35	—	Control of alpha4beta7 integrin expression and CD4 T cell homing by the beta1 integrin subunit.	DeNucci CC, et al.	—	—	—	The Journal of Immunology. 2010;184(5):2458-67.	参考	
4.3-36	—	TET inducible expression of the α4β7-integrin ligand MAdCAM-1 on the blood-brain barrier does not influence the immunopathogenesis of experimental autoimmune encephalomyelitis.	Döring A, et al.	—	—	—	European Journal of Immunology. 2011;41(3):813-21.	参考	
4.3-37	—	Trafficking of immune cells in the central nervous system.	Wilson EH, et al.	—	—	—	Journal of Clinical Investigation. 2010;120(5):1368-79.	参考	
4.3-38	—	Structural specializations of alpha4beta7, an integrin that mediates rolling adhesion.	Yu Y, et al.	—	—	—	The Journal of Cell Biology. 2012;196(1):131-46.	参考	

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4.3-39	—	Ten years of Orthoclone OKT3 (muromonab-CD3): a review.	Smith SL.	—	—	—	Journal of Transplant Coordination. 1996;6(3):109-19.	参考	
4.3-40	—	Rituxan® (rituximab) injection for intravenous use [package insert].	South San Francisco (CA, USA): Genentech, Inc; 2012.	—	—	—	FDA	参考	
4.3-41	—	Structure-function analysis of the integrin beta 7 subunit: identification of domains involved in adhesion to MAdCAM-1.	Tidswell M, et al.	—	—	—	The Journal of Immunology. 1997;159(3):1497-505.	参考	
4.3-42	—	Regional specialization in the mucosal immune system: primed cells do not always home along the same track.	Brandtzaeg P, et al.	—	—	—	Immunology Today. 1999;20(6):267-77.	参考	
4.3-43	—	Expression of alpha4beta7 and E-selectin ligand by circulating memory B cells: implications for targeted trafficking to mucosal and systemic sites.	Rott LS, et al.	—	—	—	Journal of Leukocyte Biology. 2000;68(6):807-14.	参考	
4.3-44	—	Alpha 4 beta 7 integrin mediates B cell binding to fibronectin and vascular cell adhesion molecule-1. Expression and function of alpha 4 integrins on human B lymphocytes.	Postigo AA, et al.	—	—	—	The Journal of Immunology. 1993;151(5):2471-83.	参考	
4.3-45	—	Exclusive antagonism of the α4β7 integrin by vedolizumab confirms the gut-selectivity of this pathway in primates.	Fedyk ER, et al.	—	—	—	Inflammatory Bowel Disease. 2012;18:2107-19.	参考	
4.3-46	—	Fluids and barriers of the CNS establish immune privilege by confining immune surveillance to a two-walled castle moat surrounding the CNS castle.	Engelhardt B, et al.	—	—	—	Fluids and Barriers of the CNS. 2011;8(1):4.	参考	
4.3-47	—	Non-human primate models of experimental autoimmune encephalomyelitis: Variations on a theme.	t Hart BA, et al.	—	—	—	Journal of Neuroimmunology. 2005;168:1-12.	参考	
4.3-48	—	Preliminary in vivo efficacy studies of a recombinant rhesus anti-alpha(4)beta(7) monoclonal antibody.	Pereira LE, et al.	—	—	—	Cellular Immunology. 2009;259(2):165-76.	参考	
4.3-49	—	Cutting edge: Natalizumab blocks adhesion but not initial contact of human T cells to the blood-brain barrier in vivo in an animal model of multiple sclerosis.	Coisne C, et al.	—	—	—	The Journal of Immunology. 2009;182(10):5909-13.	参考	
4.3-50	—	MRI outcomes in a placebo-controlled trial of natalizumab in relapsing MS.	Miller DH, et al.	—	—	—	Neurology. 2007;68(17):1390-401.	参考	
4.3-51	—	Decrease in the numbers of dendritic cells and CD4+ T cells in cerebral perivascular spaces due to natalizumab.	del Pilar Martin M, et al.	—	—	—	Archieves of Neurology. 2008;65(12):1596-603.	参考	
4.3-52	—	Kinetics of serum amyloid protein A in casein-induced murine amyloidosis.	Benson MD, et al.	—	—	—	The Journal of Clinical Investigation. 1977;59(3):412-7.	参考	
4.3-53	—	The binding specificity and selective antagonism of vedolizumab, an anti-alpha4beta7 integrin therapeutic antibody in development for inflammatory bowel diseases.	Soler D, et al.	—	—	—	The Journal of Pharmacology and Experimental Therrapeutics. 2009;330(3):864-75.	参考	
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4.3-55	－	Risk of natalizumab-associated progressive multifocal leukoencephalopathy.	Bloomgren G, et al.	－	－	－	The New England Journal of Medicine. 2012;366(20):1870-80.	参考	
4.3-56	－	Homing commitment of lymphocytes activated in the human gastric and intestingal mucosa.	Quiding-Järbrink M, et al.	－	－	－	Gut. 2001;49(4):519-25.	参考	
4.3-57	－	Rapid resolution of chronic colitis in the cotton-top tamarin with an antibody to a gut-homing integrin alpha4beta7.	Hesterberg PE, et al.	－	－	－	Gastroenterology. 1996;111(5):1373-80.	参考	

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5.2 臨床試験一覧表									
5.2	—	全臨床試験一覧	—	—	—	—	—	—	—
5.3 臨床試験報告書									
5.3.1 生物薬剤学試験報告書									
5.3.1.1 バイオアベイラビリティ(BA)試験報告書									
該当なし									
5.3.1.2 比較BA試験及び生物学的同等性(BE)試験報告書									
該当なし									
5.3.1.3 In vitro－In vivoの関連を検討した試験報告書									
該当なし									
5.3.1.4 生物学的及び理化学的分析法検討報告書									
5.3.1.4-1	[redacted]	Human Serum Validation Study: Detection of Human Anti-MLN0002 Antibodies in Human Serum by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-2	[redacted]	Human Serum Validation Study: Detection of Human Anti-MLN0002 Antibodies in Human Serum by ELISA (Addendum 1)	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-3	[redacted]	Human Serum Validation Study: Detection of Human Anti-MLN0002 Antibodies in Human Serum by ELISA (Addendum 2)	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-4	[redacted]	Human Serum Validation Study: Detection of Human Anti-MLN0002 Antibodies in Human Serum by ELISA (Addendum 3)	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-5	[redacted]	Evaluation of ulcerative colitis patient serum for detection of human anti-MLN0002 antibodies by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-6	[redacted]	Determination of Human anti-MLN0002 Antibodies in Human Serum By ELISA (Cross Validation from QPS Study #96-0623)	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	
5.3.1.4-7	[redacted]	Human Serum Validation Study: Confirmatory and Specificity Assessment for the Detection of Anti-MLN0002 Antibodies in Human Serum by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-8	[redacted]	The Detection of Anti-MLN0002 Antibodies in Human Serum by ECL Assay	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-9	[redacted]	Validation of a neutralizing human anti-human antibody (HAHA) response using the cell line RPMI8866 and detection by flow cytometry.	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—
5.3.1.4-10	[redacted]	Partial validation of a neutralizing human anti-human antibody (HAHA) response using the cell line RPMI8866 and detection by flow cytometry.	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	—

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5.3.1.4-11	[redacted]	Validation of an ECL Assay for the Detection of Anti-MLN0002 Neutralizing Antibodies in Human Serum	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	－
5.3.2 ヒト生体試料を用いた薬物動態関連の試験報告書									
5.3.2.1 血漿蛋白結合試験報告書									
該当なし									
5.3.2.2 肝代謝及び薬物相互作用試験報告書									
該当なし									
5.3.2.3 他のヒト生体試料を用いた試験報告書									
5.3.2.3-1	[redacted]	Human Serum Validation Study: Determination of MLN0002 in Human Serum samples by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.2.3-2	[redacted]	Human Serum Validation Study: Determination of MLN0002 in Human Serum by ELISA (Addendum 1)	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.2.3-3	[redacted]	Evaluation of Ulcerative Colitis Patient Serum for Quantitation of MLN0002 by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.2.3-4	[redacted]	Determination of MLN0002 in Human Serum by ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.2.3-5	[redacted]	Determination of MLN0002 in Human Cerebrospinal Fluid (CSF) By ELISA	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.3 臨床薬物動態（PK）試験報告書									
5.3.3.1 健康被験者におけるPK及び初期忍容性試験報告書									
5.3.3.1-1	C13009	A Phase 1 Single Dose Study to Determine the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of a Lyophilized Formulation (Process C Drug Product) of MLN0002 in Healthy Subjects	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.3.1-2	C13001	A Phase 1, Single Ascending Dose, Randomized, Placebo-Controlled, Double-Blind Study to Determine the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of MLN0002 in Healthy Subjects	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	－
5.3.3.1-3	C13005	A Phase 1, Single Dose, Open-Label Study to Determine the Pharmacokinetics, Safety, and Tolerability of MLN0002 in Healthy Subjects Across a Range of Low and High Body Weights	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	－
5.3.3.2 患者におけるPK及び初期忍容性試験報告書									
5.3.3.2-1	CPH-001	Phase I, Multiple-dose Study of MLN0002 in Patients with Ulcerative Colitis	Takeda Pharmaceutical Company Ltd.	[redacted]	Japan	国内	社内資料	評価	－

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5.3.3.2-2	M200-022	A Phase II, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Multicenter Study to Determine the Safety, Pharmacokinetics, and Effectiveness of LDP-02 in Patients with Mildly to Moderately Active Ulcerative Colitis	[redacted]	[redacted]	Canada	海外	社内資料	参考	－
5.3.3.2-3	C13002	A Phase 2, Randomized, Placebo-Controlled, Double-Blind Study to Determine the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of MLN0002 Following Multiple Intravenous Doses in Patients with Ulcerative Colitis	[redacted]	[redacted]	Canada and Russia	海外	社内資料	参考	－
5.3.3.3 内因性要因を検討したPK試験報告書									
該当なし									
5.3.3.4 外因性要因を検討したPK試験報告書									
該当なし									
5.3.3.5 ポピュレーションPK試験報告書									
5.3.3.5-1	－	Population Pharmacokinetics of Vedolizumab: Japan Ulcerative Colitis	[redacted]	[redacted]	[redacted]	国内/海外	社内資料	評価	－
5.3.3.5-2	－	Population Pharmacokinetic and Pharmacodynamic Modeling of Vedolizumab in Subjects with Crohn's Disease and Ulcerative Colitis for Studies C13002, C13006, C13007, C13009, and C13011	[redacted]	[redacted]	[redacted]	海外	社内資料	参考	－
5.3.4 臨床薬力学（PD）試験報告書									
5.3.4.1 健康被験者におけるPD試験及びPK/PD試験報告書									
5.3.4.1-1	C13012	A Phase 1 Single-Arm Study to Evaluate the Effects of a Single Intravenous Dose of Vedolizumab (MLN0002) on the $CD4^+$:$CD8^+$ Lymphocyte Ratio in the Cerebrospinal Fluid of Healthy Subjects	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.4.1-2	C13013	A Phase 1, Randomized, Double-Blinded, Placebo-Controlled, Single Dose Study in Healthy Subjects to Determine the Immune Response to Systemic and Mucosal Antigenic Challenge in the Presence of Vedolizumab	[redacted]	[redacted]	[redacted]	海外	社内資料	評価	－
5.3.4.2 患者におけるPD試験及びPK/PD試験報告書									
該当なし									

添付資料番号	試験番号	タイトル	著者	試験実施期間	試験実施場所	国内/海外	掲載誌	評価/参考	電子データ提出
5.3.5 有効性及び安全性試験報告書									
5.3.5.1 申請する適応症に関する比較対照試験報告書									
5.3.5.1-1	CCT-101	Phase III, multicenter, randomized, double-blinded, placebo-controlled, parallel-group study to examine the efficacy, safety, and pharmacokinetics of intravenous MLN0002 (300 mg) infusion in induction and maintenance therapy in Japanese patients with moderate or severe ulcerative colitis	Takeda Pharmaceutical Company Ltd.	[redacted]～実施中	Japan	国内	社内資料	評価	あり
5.3.5.1-2	C13006	A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by Vedolizumab (MLN0002) in Patients with Moderate to Severe Ulcerative Colitis	Millennium Pharmaceuticals, Inc.	[redacted]	US, Canada, Europe, Asia, Australia, etc.	海外	社内資料	評価	－
5.3.5.2 非対照試験報告書									
5.3.5.2-1	C13008	A Phase 3, Open-label Study to Determine the Long-term Safety and Efficacy of Vedolizumab (MLN0002) in Patients With Ulcerative Colitis and Crohn's Disease	[redacted]	[redacted]～実施中	US, Canada, Europe, Asia, Australia, etc.	海外	社内資料	参考	－
5.3.5.3 複数の試験成績を併せて解析した報告書									
5.3.5.3-1	MLN0002/NDA-101	Integrated Summary of Safety (Analysis for RAMP Algorithm and PML Checklist)	Takeda Pharmaceutical Company Ltd.	－	－	海外	社内資料	参考	－
5.3.5.3-2	Clin-Pharm	Analysis Results of MLN0002 for EU CTD	[redacted]	－	－	海外	社内資料	参考	－
5.3.5.3-3	MLN0002/NDA001	Analysis Results of MLN0002 for CTD	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-4	MLN0002/NDA-101	MLN0002 NDA Phase I Multiple Administration Study of MLN0002 in Ulcerative Colitis (UC) Patients <MedDRA version up>	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-5	MLN0002/NDA-101	CTD用解析結果 3	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-6	MLN0002/NDA-101	CTD用解析結果 4	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-7	MLN0002/NDA-101	CTD用解析結果 5	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-8	MLN0002/NDA-101	CTD用解析結果 6	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-9	MLN0002/NDA-101	Integrated Summary of Safety (Analysis for Anti-Vedolizumab Antibody in C13006)	Takeda Pharmaceutical Company Ltd.	－	－	海外	社内資料	評価	－

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5.3.5.3-10	MLN0002/NDA-101	CTD用解析結果 7	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.3-11	MLN0002/NDA-101	CTD用解析結果 8	Takeda Pharmaceutical Company Ltd.	－	－	国内	社内資料	評価	－
5.3.5.4 その他の試験報告書									
該当なし									
5.3.6　市販後の使用経験に関する報告書									
5.3.6-1	－	PERIODIC SAFETY UPDATE REPORT for VEDOLIZUMAB	Takeda Pharmaceutical Company Limited	－	－	国内/海外	社内資料	参考	－
5.3.7　患者データ一覧表及び症例記録									
5.3.7.1 症例一覧表									
5.3.7.1-1	C13009	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	[redacted]	海外	社内資料	評価	－
5.3.7.1-2	C13001	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	[redacted]	海外	社内資料	参考	－
5.3.7.1-3	C13005	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	[redacted]	海外	社内資料	参考	－
5.3.7.1-4	CPH-001	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	Japan	国内	社内資料	評価	－
5.3.7.1-5	M200-022	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	Canada	海外	社内資料	参考	－
5.3.7.1-6	C13002	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	Canada and Russia	海外	社内資料	参考	－
5.3.7.1-7	C13012	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	[redacted]	海外	社内資料	評価	－
5.3.7.1-8	C13013	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	[redacted]	海外	社内資料	評価	－
5.3.7.1-9	CCT-101	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	Japan	国内	社内資料	評価	－
5.3.7.1-10	C13006	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	US, Canada, Europe, Asia, Australia, etc.	海外	社内資料	評価	－
5.3.7.1-11	C13008	症例一覧表	Takeda Pharmaceutical Company Ltd.	－	US, Canada, Europe, Asia, Australia, etc.	海外	社内資料	参考	－
5.3.7.2 臨床検査値変動図									

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5.3.7.2-1	CPH-001	臨床検査値変動図	Takeda Pharmaceutical Company Ltd.	－	Japan	国内	社内資料	評価	－
5.3.7.2-2	CCT-101	臨床検査値変動図	Takeda Pharmaceutical Company Ltd.	－	Japan	国内	社内資料	評価	－
5.4 参考文献									
5.4-1	－	Clinical pharmacokinetics of therapeutic monoclonal antibodies.	Keizer RJ, Huitema AD, Schellens JH, Beijnen JH.	－	－	－	Clin Pharmacokinet. 2010;49(8):493-507.	参考	－
5.4-2	－	Lymphocyte phenotype and subset distribution in normal cerebrospinal fluid.	Svenningsson A, Andersen O, Edsbagge M, Stemme S.	－	－	－	J Neuroimmunol. 1995;63(1):39-46.	参考	－
5.4-3	－	CYP-mediated therapeutic protein-drug interactions: clinical findings, proposed mechanisms and regulatory implications.	Lee JI, Zhang L, Men AY, Kenna LA, Huang SM.	－	－	－	Clin Pharmacokinet. 2010;49(5):295-310.	参考	－
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5.4-5	－	AAPS Workshop Report: Strategies to Address Therapeutic Protein–Drug Interactions during Clinical Development.	Girish S, Martin SW, Peterson MC, Zhang LK, Zhao H, Balthasar J, et al.	－	－	－	AAPS J. 2011;13(3):405-16.	参考	－
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5.4-7	－	Anti-TNF monoclonal antibodies in inflammatory bowel disease: pharmacokinetics-based dosing paradigms.	Ordás I, Mould DR, Feagan BG, Sandborn WJ.	－	－	－	Clin Pharmacol Ther. 2012;91(4):635-46.	参考	－
5.4-8	－	Infliximab pharmacokinetics in inflammatory bowel disease patients.	Ternant D, Aubourg A, Magdelaine-Beuzelin C, Degenne D, Watier H, Picon L, et al.	－	－	－	Ther Drug Monit. 2008;30(4):523-9.	参考	－
5.4-9	－	Electrocardiographic assessment for therapeutic proteins--scientific discussion.	Rodriguez I, Erdman A, Padhi D, Garnett CE, Zhao H, Targum SL, et al.	－	－	－	Am Heart J. 2010;160(4):627-34.	参考	－

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5.4-10	－	潰瘍性大腸炎診断基準(2010年2月改訂)	「難治性炎症性腸管障害に関する調査研究」班(鈴木班).	－	－	－	厚生労働科学研究費補助金 難治性疾患等克服研究事業 難治性炎症性腸管障害に関する調査研究 平成27年度 分担研究報告書 別冊. 2016. p.1-3.	参考	－
5.4-11	－	潰瘍性大腸炎治療指針(2016年1月改訂).	「難治性炎症性腸管障害に関する調査研究」班(鈴木班).	－	－	－	厚生労働科学研究費補助金 難治性疾患等政策研究事業 難治性炎症性腸管障害に関する調査研究 平成27年度 分担研究報告書 別冊. 2016. p.4-11.	参考	－
5.4-12	－	Infliximab for induction and maintenance therapy for ulcerative colitis.	Rutgeerts P, Sandborn WJ, Feagan BG, Reinisch W, Olson A, Johanns J, et al.	－	－	－	N Engl J Med. 2005;353:2462-76.	参考	－
5.4-13	－	Outpatient Ulcerative Colitis Primary Anti-TNF Responders Receiving Adalimumab or Infliximab Maintenance Therapy Have Similar Rates of Secondary Loss of Response.	Ma C, Huang V, Fedorak DK, Kroeker KI, Dieleman LA, Halloran BP, et al.	－	－	－	J Clin Gastroenterol. 2015;49(8):675-82.	参考	－
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5.4-16	－	Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease.	Long MD, Martin CF, Pipkin CA, Herfarth HH, Sandler RS, Kappelman MD.	－	－	－	Gastroenterology. 2012;143(2):390-9.	参考	－
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5.4-18	－	Colorectal cancer risk and mortality in patients with ulcerative colitis.	Langholz E, Munkholm P, Davidsen M, Binder V.	－	－	－	Gastroenterology. 1992;103(5):1444-51.	参考	－
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5.4-20	—	The effect of restorative proctocolectomy on sexual function, urinary function, fertility, pregnancy and delivery: a systematic review.	Cornish JA, Tan E, Teare J, Teoh TG, Rai R, Darzi AW, et al.	—	—	—	Dis Colon Rectum. 2007;50(8):1128-38.	参考	—
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5.4-22	—	Postoperative complications and mortality following colectomy for ulcerative colitis.	de Silva S, Ma C, Proulx MC, Crespin M, Kaplan BS, Hubbard J, et al.	—	—	—	Clin Gastroenterol Hepatol. 2011;9(11):972-80.	参考	—
5.4-23	—	Thirty-day mortality after elective and emergency total colectomy in Danish patients with inflammatory bowel disease: a population-based nationwide cohort study.	Tøttrup A, Erichsen R, Sværke C, Laurberg S, Srensen HT.	—	—	—	BMJ Open. 2012;2(2):e000823.	参考	—
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5.4-38	—	潰瘍性大腸炎と粘膜治癒.	藤谷幹浩、高後裕.	—	—	—	日本消化器病学会雑誌. 2013;110(11):1900-8.	参考	—
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5.4-42	—	Quality of life of patients with ulcerative colitis: past, present, and future	Irvine EJ.	—	—	—	Inflamm Bowel Dis. 2008;14(4):554-65.	参考	—
5.4-43	—	Mucosal healing restores normal health and quality of life in patients with inflammatory bowel disease.	Casellas F, Barreiro de Acosta M, Iglesias M, Robles V, Nos P, Aguas M, et al.	—	—	—	Eur J Gastroenterol Hepatol. 2012;24(7):762-9.	参考	—
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5.4-45	—	Vedolizumab, a monoclonal antibody to the gut homing α4β7 integrin, does not affect cerebrospinal fluid T-lymphocyte immunophenotype.	Milch C, Wyant T, Xu J, Parikh A, Kent W, Fox I, et al.	—	—	—	J Neuroimmunol. 2013;264(1-2):123-6.	参考	—
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5.4-47	—	Vedolizumab Levels in Breast Milk of Nursing Mothers With Inflammatory Bowel Disease	Lahat A, Shitrit AB, Naftali T, Milgrom Y Elyakim R, Goldin E, et al.	—	—	—	J Crohns Colitis. 2018; 12(1):120-3.	参考	—
5.4-48	—	Vedolizumab Concentrations in the Breast Milk of Nursing Mothers With Inflammatory Bowel Disease	Julsgaard M, Kjeldsen J, Bibby BM, Brock B, Baumgart DC.	—	—	—	Gastroenterology. 2018; 154(3):752-4	参考	—