第5部（モジュール5）

5.2　全臨床試験一覧表

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.2	全臨床試験一覧表	---	---	---	---	---

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

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.3.1.1-1	Study P00042 - Study Report SCH 66336: A Pilot Study to Determine the Intrasubject Variability in SCH 66336 Pharmacokinetics: a Two-Way Crossover Study	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無

5.3.1.1-2	Study EIG-LNF-017 A Phase 1, Single-Center, Open-Label, Single-Sequence, Drug-Drug Interaction Study to Evaluate the Effects of Multiple-Dose Lonafarnib on the Pharmacokinetics of Single-Dose Omeprazole, a Sensitive CYP2C19 Substrate, and in Parallel, a Single-Sequence, Three-Period Crossover, Pivotal Food-Effect Evaluation with Single-Dose Lonafarnib and a Single-Sequence, Two-Period Crossover Pivotal Food-Effect Evaluation with Single-Dose Lonafarnib and Ritonavir in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.1.1-3	Study EIG-LNF-019 A Phase 1, Single-Center, Single-Sequence, 3-Period Crossover, Relative Bioavailability Study with Single-Dose Lonafarnib Suspension Formulation, Single-Dose Lonafarnib Mixed with Applesauce, and Single-Dose Lonafarnib Intact Capsule Formulation in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.1.1-4	Study EIG-LNF-020 A Phase 1, Single-Center, Single-Sequence, 6-Period Crossover, Relative Bioavailability Study with Single-Dose Lonafarnib Mixed with 5 Different Soft Foods and Single-Dose Lonafarnib Intact Capsule Formulation in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有

5.3.1.2　比較BA試験及び生物学的同等性（BE）試験報告書
該当資料なし

5.3.1.3　In Vitro - In Vivoの関連を検討した試験報告書
該当資料なし

5.3.1.4　生物学的及び理化学的分析法検討報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.3.1.4-1	Study 09-06-0298 (ProLon2) - Bioanalytical Report - Interference Evaluation Interference Evaluation of Pravastatin and Zoledronic Acid in a High Performance Liquid Chromatographic Method Using Tandem Mass Spectrometry Detection for the Determination of MK-6336 (5 to 5000 ng/mL) in Human Sodium Heparinized Plasma (135138AJUO)	---	海外	Eiger社内資料 （海外）	評価	有
5.3.1.4-1	Study 09-06-0298 (ProLon2) - Bioanalytical Report - Validation Validation of a High Performance Liquid Chromatographic Method Using Tandem Mass Spectrometry Detection for the Determination of MK-6336 (5 to 5000 ng/mL) in Human Sodium Heparinized Plasma (135138AJIV)	---	海外	Eiger社内資料 （海外）	評価	有
5.3.1.4-2	Study EIG-LNF-003 - Bioanalytical Report Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (EGE-P6-451)	---	海外	Eiger社内資料 （海外）	参考	有

5.3.1.4-3	Study EIG-LNF-006 - Bioanalytical Report - LNI Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (RRI-P7-131(LNI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-3	Study EIG-LNF-006 - Bioanalytical Report - RTI Study for the Determination of Ritonavir in Human Plasma Using HPLC with MS/MS Detection (RRI-P7-131(RTI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-4	Study EIG-LNF-007 - Bioanalytical Report - LNI Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection EGE-P7-411(LNI)	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-4	Study EIG-LNF-007 - Bioanalytical Report - RTI Study for the Determination of Ritonavir in Human Plasma Using HPLC with MS/MS Detection EGE-P7-411(RTI)	---	海外	Eiger社内資料 （海外）	参考	有

5.3.1.4-5	Study EIG-LNF-008 - Bioanalytical Report Analysis of Fexofenadine and Rosuvastatin in Human Plasma Using High Performance Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS) (A18.0747)	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-6	Study EIG-LNF-009 - Bioanalytical Report - LNI Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection RRI-P0-010(LNI)	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-6	Study EIG-LNF-009 - Bioanalytical Report - RTI Study for the Determination of Ritonavir in Human Plasma Using HPLC with MS/MS Detection RRI-P0-010(RTI)	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-6	Study EIG-LNF-009 - Bioanalytical Report - Midazolam and Pitavastatin Analysis of Midazolam and Pitavastatin in Human Plasma Using High Performance Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS) (A18.0748)	---	海外	Eiger社内資料 （海外）	参考	有

5.3.1.4-7	Study EIG-LNF-010 - Bioanalytical Report - LNI Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (RRI-P2-452(LNI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-7	Study EIG-LNF-010 - Bioanalytical Report - MXI Study for the Determination of Moxifloxacin in Human Plasma Using HPLC with MS/MS Detection (RRI-P2-452(MXI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-7	Study EIG-LNF-010 - Bioanalytical Report - RTI Study for the Determination of Ritonavir in Human Plasma Using HPLC with MS/MS Detection (RRI-P2-452(RTI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-8	Study EIG-LNF-015 - Bioanalytical Report - LNI Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (RRI-P9-923(LNI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-8	Study EIG-LNF-015 - Bioanalytical Report - LPD Study for the Determination of Loperamide in Human Plasma Using HPLC with MS/MS Detection (RRI-P9-923(LPD))	---	海外	Eiger社内資料 （海外）	参考	有

5.3.1.4-9	Study EIG-LNF-016 - Bioanalytical Report - Midazolam and Fexofenadine Analysis of Midazolam and Fexofenadine in Human Plasma Using High Performance Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS) (A19.1009)	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-10	Study EIG-LNF-017 - Bioanalytical Report - LNI Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (RRI-P1-068(LNI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-10	Study EIG-LNF-017 - Bioanalytical Report - OEL Study for the Determination of Omeprazole in Human Plasma Using HPLC with MS/MS Detection (RRI-P1-068(OEL))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-11	Study EIG-LNF-019 - Bioanalytical Report Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (RRI-P9-693)	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-12	Study EIG-LNF-020 - Bioanalytical Report Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (EGE-P8-629)	---	海外	Eiger社内資料 （海外）	参考	有

5.3.1.4-13	Study P00394 - Analytical Report Determination of SCH 66336 Concentrations in Human Plasma Samples from Protocol No. P00394 Using a High Performance Liquid Chromatographic-Mass Spectrometric Method (1140.060300)	---	海外	Eiger社内資料 （海外）	参考	無
5.3.1.4-14	Study EIG-LNF-021 - Bioanalytical Report Study for the Determination of HM21 in Human Plasma Using HPLC with MS/MS Detection (EGE-P1-182(HM21))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-14	Study EIG-LNF-021 - Bioanalytical Report Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (EGE-P1-182(LNI))	---	海外	Eiger社内資料 （海外）	参考	有
5.3.1.4-15	Study P00042 - Study Report A Pilot Study to Determine the Intrasubject Variability in SCH 66336 Pharmacokinetics: A Two-Way Crossover Study	---	海外	Eiger社内資料 （海外）	参考	無

5.3.1.4-16	Study P00260 - Study Report THE Absorption, Metabolism and Excretion of ^{14}C-SCH 66336 following Oral Administration of ^{14}C-SCH 66336 in Healthy Volunteers Pre-Study Validation of the HPLC-Mass Spectrometric Method for the Determination of SCH 66336 in Human Plasma Pre-Study Validation of the HPLC-Mass Spectrometric Method for the Determination of SCH 66336 in Human Urine	---	海外	Eiger社内資料 （海外）	参考	無
5.3.1.4-17	Study P02673 - Study Report Determination of SCH 66336 Concentrations in Human Plasma Samples from Protocol No. P02673 Using a High Performance Liquid Chromatographic-Mass Spectrometric Method (2171.123002)	---	海外	Eiger社内資料 （海外）	参考	無
5.3.1.4-18	Study 07-01-0007 (ProLon1) - Study Report Abbreviated Pharmacokinetic Clinical Study Report for ProLon1 in Progeria Pediatric Patients	---	海外	Eiger社内資料 （海外）	評価	有
5.3.1.4-19	Study EIG-LNF-022 - Bioanalytical Report Study for the Determination of HM21 in Human Plasma Using HPLC with MS/MS Detection (EGE-P9-697(HM21))	---	海外	Eiger社内資料 （海外）	参考	無

5.3.1.4-19	Study EIG-LNF-022 - Bioanalytical Report Study for the Determination of Lonafarnib in Human Plasma Using HPLC with MS/MS Detection (EGE-P9-697(LNI))	---	海外	Eiger社内資料（海外）	参考	無
5.3.1.4-19	Study EIG-LNF-022 - Bioanalytical Report Study for the Determination of Moxifloxacin in Human Plasma Using HPLC with MS/MS Detection (EGE-P9-697(MXI))	---	海外	Eiger社内資料（海外）	参考	無

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

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌（国内／海外）	評価/参考の別	申請電子データの提出有無
5.3.2.1-1	Study CYP1838 R6 - Study Report Plasma Protein Binding of Lonafarnib HM21 Metabolite C	---	---	Eiger社内資料（海外）	参考	---
5.3.2.1-2	Study SN 98276 - Study Report SCH 66336: In Vitro Binding of ^{3}H-SCH 66336 to Purified Human Serum Proteins	---	---	Eiger社内資料（海外）	参考	---

5.3.2.2　肝代謝及び薬物相互作用試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.3.2.2-1	Study 14EIGEP1_Study 3 - Study Report Evaluation of the Potential for Inhibition of Cytochrome P450 Enzymes in Human Liver Microsomes by Lonafarnib	---	---	Eiger社内資料 （海外）	参考	---
5.3.2.2-2	Study 14EIGEP1_Study 4 - Study Report IC_{50} of Lonafarnib for Inhibition of Cytochrome P450 Enzymes in Human Liver Microsomes	---	---	Eiger社内資料 （海外）	参考	---
5.3.2.2-3	Study 14EIGEP1_Study 5 - Study Report Evaluation of the Potential for Time-dependent Inhibition of Cytochrome P450 Enzymes in Human Liver Microsomes by Lonafarnib	---	---	Eiger社内資料 （海外）	参考	---
5.3.2.2-4	Study 14EIGEP1_Study 6 - Study Report Evaluation of the Potential for Induction of CYP1A2, CYP2B6, and CYP3A in Human Hepatocytes by Lonafarnib	---	---	Eiger社内資料 （海外）	参考	---
5.3.2.2-5	Study 15EIGEP1 - Study Report Cytochrome P450 Reaction Phenotyping of Lonafarnib	---	---	Eiger社内資料 （海外）	参考	---
5.3.2.2-6	Study CYP1838 R3 - Study Report Reversible and Time Dependent Inhibition of Cytochrome P450 Enzymes by Lonafarnib API	---	---	Eiger社内資料 （海外）	参考	---

5.3.2.2-7	Study CYP1838 R4 - Study Report Reversible and Time Dependent Inhibition of Cytochrome P450 Enzymes by Lonafarnib HM21 Metabolite C	---	---	Eiger社内資料（海外）	参考	---
5.3.2.2-8	Study CYP1838 R5 - Study Report Cytochrome P450 Reaction Phenotyping (Recombinant Enzymes and Chemical Inhibitors) of Lonafarnib HM21 Metabolite C	---	---	Eiger社内資料（海外）	参考	---
5.3.2.2-9	Study XT203090 - Study Report Lonafarnib: Cytochrome P450 Induction in Cultured Human Hepatocytes	---	---	Eiger社内資料（海外）	参考	---

5.3.2.3　他のヒト生体試料を用いた試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌（国内／海外）	評価/参考の別	申請電子データの提出有無
5.3.2.3-1	Study 14EIGEP1 - Study Report Absorption Systems Study Number: 14eigep1 In Vitro Drug-Drug Interactions Studies of the Sponsor's Test Article, Lonafarnib	---	---	Eiger社内資料（海外）	参考	---
5.3.2.3-2	Study CYP1838 R1 - Study Report Study to Investigate Whether Compound Lonafarnib is an Inhibitor of the Human SLC Transporters MATE1 and MATE2-K in Transiently Transfected HEK293 Cells	---	---	Eiger社内資料（海外）	参考	---

5.3.2.3-3	Study CYP1838 R2 - HEK293 Cells - Study Report Study to Investigate Whether Compound Lonafarnib is a Substrate of the Human SLC Transporter OCT1 in Transiently Transfected HEK293 Cells	---	---	Eiger社内資料 （海外）	参考	---
5.3.2.3-4	Study CYP1838 R2 - Study Report Study to Investigate Whether Compound Lonafarnib is an Inhibitor of the Human Transporters OCT1 and BSEP in Various In Vitro Test Systems	---	---	Eiger社内資料 （海外）	参考	---

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

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子データの提出有無
5.3.3.1-1	Study P00260 - Study Report SCH 66336: The Absorption, Metabolism and Excretion of ^{14}C-SCH 66336 Following Oral Administration of ^{14}C-SCH 66336 in Healthy Volunteers	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	---	Eiger社内資料 （海外）	参考	無
5.3.3.1-2	Study P00042 - Study Report SCH 66336: A Pilot Study to Determine the Intrasubject Variability in SCH 66336 Pharmacokinetics: a Two-Way Crossover Study	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	---	Eiger社内資料 （海外）	参考	無

5.3.3.2　患者におけるPK及び初期忍容性試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所 （国内／海外）	社内資料/公表論文	評価/参考 の別	申請電子 データの 提出有無
5.3.3.2-1	Study I97-211 - Study Report Phase I Study To Determine The Safety Of SCH 66336 In Patients With A Solid Tumor On Twice Daily Oral Schedule For 28 Days (Protocol No. I97-211).	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無
5.3.3.2-2	Study C97-258 - Study Report SCH 66336: A Phase I Study Of Cyclic One-Week Oral Administration Of SCH 66336 In Patients With Advanced Cancer	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無
5.3.3.2-3	Study C97-262 - Study Report SCH 66336: A Phase I Study Of Cyclic Two-week Oral Administration Of SCH 66336 In Patients With Advanced Cancer (Protocol No. C97-262)	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無
5.3.3.2-4	Study P00394 Phase 1 Study to Determine the Safety, Tolerance and Pharmacokinetics of Lonafarnib (SCH 66336) Administered in Fasting Patients With a Solid Tumor on Twice Daily Oral Schedule for 28 Days (Protocol No. P00394)	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無

5.3.3.3　内因性要因を検討したPK試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.3.3.3-1	Study EIG-LNF-003 A Phase 1, Nonrandomized, Multicenter, Open-Label, Parallel-Group Study to Investigate the Effect of Hepatic Impairment (Mild and Moderate) on the Single-Dose Pharmacokinetics of Lonafarnib Plus Ritonavir in Hepatically Impaired vs. Healthy Male and Female Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.3-2	Study EIG-LNF-006 A Phase 1, Nonrandomized, Single-Center, Open-Label, Parallel-Group Study to Investigate the Effect of Severe and Moderate Renal Impairment on the Single-Dose Pharmacokinetics of Lonafarnib + Ritonavir in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.3-3	Study P02673 - Study Report SCH 66336: Effects of Age and Gender on the Pharmacokinetics of SCH 66336 (Lonafarnib)	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無

5.3.3.4　外因性要因を検討したPK試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.3.3.4-1	Study P00393 - Study Report SCH 66336: The Effect of Ketoconazole on the Pharmacokinetics of SCH 66336. An Open-Label, Two-Way Crossover Study (Protocol No. P00393)	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無
5.3.3.4-2	Study P00394 Phase 1 Study to Determine the Safety, Tolerance and Pharmacokinetics of Lonafarnib (SCH 66336) Administered in Fasting Patients With a Solid Tumor on Twice Daily Oral Schedule for 28 Days (Protocol No. P00394)	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無
5.3.3.4-3	Study EIG-LNF-007 A Phase 1, Single-Center, Open-Label, Single-Sequence, Crossover CYP3A Induction Drug-Drug Interaction Evaluation and Single-Sequence Crossover, Food-Effect Evaluation on the Single-Dose Pharmacokinetics of Lonafarnib + Ritonavir in Healthy Male and Female Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有

5.3.3.4-4	Study EIG-LNF-008 A Phase 1, Open-Label, Single-Center, Two-Period, Single-Sequence, Multi-Drug-Drug Interaction Study to Evaluate the Effects of Multiple-Dose Lonafarnib + Ritonavir on the Pharmacokinetics of Single-Dose Fexofenadine, a Sensitive P-Glycoprotein Substrate, and in Parallel, Single-Dose Rosuvastatin, a Sensitive BCRP Substrate, in Healthy Male and Female Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.4-5	Study EIG-LNF-009 A Phase 1, Open-Label, Single-Center, Two-Period, Single-Sequence, Multi-Drug-Drug Interaction Study to Evaluate the Effects of Multiple-Dose Lonafarnib + Ritonavir on the Pharmacokinetics of Single-Dose Midazolam, a Sensitive Cytochrome P450-3A4 Substrate and in Parallel, Single-Dose Pitavastatin, a Sensitive OATP1B1 Substrate, in Healthy Male and Female Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.4-6	Study EIG-LNF-015 A Phase 1, Open-Label, Single-Center, Two Period, Single-Sequence, Multi-Drug-Drug Interaction Study to Evaluate the Effects of Multiple-Dose Lonafarnib + Ritonavir or Multiple-Dose Lonafarnib on the Pharmacokinetics of Single-Dose Loperamide in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有

5.3.3.4-7	Study EIG-LNF-016 A Phase 1, Open-Label, Single-Center, Two-Period, Single-Sequence, Multi-Drug-Drug Interaction Study to Evaluate the Effects of Multiple-Dose Lonafarnib on the Pharmacokinetics of Single-Dose Midazolam, a Sensitive Cytochrome P450-3A Substrate, and in Parallel, the Effects of Multiple-Dose Lonafarnib on the Pharmacokinetics of Single-Dose Fexofenadine, a Sensitive P-Glycoprotein Substrate, in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.4-8	Study EIG-LNF-017 A Phase 1, Single-Center, Open-Label, Single-Sequence, Drug-Drug Interaction Study to Evaluate the Effects of Multiple-Dose Lonafarnib on the Pharmacokinetics of Single-Dose Omeprazole, a Sensitive CYP2C19 Substrate, and in Parallel, a Single-Sequence, Three-Period Crossover, Pivotal Food-Effect Evaluation with Single-Dose Lonafarnib and a Single-Sequence, Two-Period Crossover Pivotal Food-Effect Evaluation with Single-Dose Lonafarnib and Ritonavir in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.4-9	Study P00042 - Study Report SCH 66336: A Pilot Study to Determine the Intrasubject Variability in SCH 66336 Pharmacokinetics: a Two-Way Crossover Study	19[redacted]年[redacted]月[redacted]日 ～ 19[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無

5.3.3.4-10	Study EIG-LNF-021 A Phase 1, Single-Center, 2 Period, Single-Sequence, Study to Assess the Effects of Lonafarnib Autoinhibition Following Multiple-Dose Lonafarnib and the Effects of a Nonspecific CYP2C9 Inhibitor on Multiple-Dose Lonafarnib Pharmacokinetics in Healthy Subjects	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	有
5.3.3.4-11	Inhibition Induction Simulation Report Clearance Inhibition and Induction Simulation Analysis to Investigate Metabolism-mediated DDIs on the Pharmacokinetics of Lonafarnib in Patients with Hutchinson-Gilford Progeria Syndrome (HGPS)	---	海外	Eiger社内資料 （海外）	参考	有

5.3.3.5　ポピュレーションPK試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子データの提出有無
5.3.3.5-1	Population PK Report - Modeling and Simulation Report for Lonafarnib Population PK Analysis in Patients with HGPS Modeling & Simulation Report for Lonafarnib Population PK analysis in Patients with HGPS	---	海外	Eiger社内資料 （海外）	参考	有

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

該当資料なし

5.3.4.2　患者におけるPD試験及びPK/PD試験報告書
該当資料なし

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
該当資料なし

5.3.5.2　非対照試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所	掲載誌 （国内／海外）	評価/参考 の別	申請電子 データの 提出有無
5.3.5.2-1	Study 07-01-0007 An Open Label Dose Adjusted Phase II Trial of the Oral Farnesyltransferase Inhibitor (FTI) Lonafarnib (SCH66336) for Patients with Hutchinson-Gilford Progeria Syndrome (HGPS) and Progeroid Laminopathies	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	評価	有
5.3.5.2-2	Study 09-06-0298 An Open Label Phase II Trial of Zoledronic Acid, Pravastatin, and Lonafarnib (SCH66336) for Patients with Hutchinson-Gilford Progeria Syndrome and Progeroid Laminopathies	20[redacted]年[redacted]月[redacted]日 ～継続中	海外	Eiger社内資料 （海外）	評価	有

5.3.5.3　複数の試験成績を併せて解析した報告書

添付資料番号	タイトル	試験実施期間	試験実施場所（国内／海外）	掲載誌	評価/参考の別	申請電子データの提出有無
5.3.5.3-1	Observational Cohort Survival Study Survival Analyses of Data from ProLon1 and ProLon2 Studies and Data from Natural History Untreated Patients with Hutchinson-Gilford Progeria Syndrome Phase 3	---	海外	Eiger社内資料（海外）	参考	有
5.3.5.3-2	Integrated Summary of Efficacy	---	海外	Eiger社内資料（海外）	参考	無
5.3.5.3-3	Integrated Summary of Safety	---	海外	Eiger社内資料（海外）	評価	有

5.3.5.4　その他の試験報告書

添付資料番号	タイトル	試験実施期間	試験実施場所（国内／海外）	掲載誌	評価/参考の別	申請電子データの提出有無
5.3.5.4-1	Study EIG-LNF-010 A Phase 1, Double-Blind, Randomized, Placebo- and Active-Control, Parallel-Group, High-Precision QTc Study Evaluating the Effects of Multiple-Dose Lonafarnib and Ritonavir on Cardiac Repolarization in Healthy Male and Female Volunteers	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料（海外）	参考	有

5.3.5.4-2.1	[redacted] Report Efficacy of the Farnesyltransferase Inhibitor (FTI) Lonafarnib to Improve Nuclear Morphology in Fibroblasts from Patients with Processing-Deficient Progeroid Laminopathies	---	海外	Eiger社内資料 （海外）	参考	---
5.3.5.4-2.2	White Paper: Progeroid Laminopathies	---	海外	Eiger社内資料 （海外）	参考	---
5.3.5.4-2.3	[redacted] in vitro Report Analyses of Nuclear Morphology and Lamin A Localization in Normal and RD/Progeria Patient-Derived Fibroblasts Following Lonafarnib Treatment	---	海外	Eiger社内資料 （海外）	参考	---
5.3.5.4-3	Study EIG-LNF-022 A Phase 1, double-blind, randomized, placebo- and active-control, parallel-group, high-precision QTc study evaluating the effects of multiple-dose lonafarnib on cardiac repolarization in healthy male and female volunteers	20[redacted]年[redacted]月[redacted]日 ～ 20[redacted]年[redacted]月[redacted]日	海外	Eiger社内資料 （海外）	参考	無

5.3.6　市販後の使用経験に関する報告書
該当資料なし

5.3.7　患者データ一覧表及び症例記録

添付資料番号	タイトル	評価/参考の別
5.3.7.1	該当なし	参考
5.3.7.2	副作用発現症例一覧表	参考
5.3.7.3	重篤な有害事象発現症例一覧表	参考
5.3.7.4	臨床検査値異常変動症例一覧表	参考
5.3.7.5	該当なし	参考

5.4　参考文献（評価/参考の別：参考）

添付資料番号	タイトル	著者	掲載誌 （国内／海外）
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5.4	Severe mandibuloacral dysplasia-associated lipodystrophy and progeria in a young girl with a novel homozygous Arg527Cys LMNA mutation.	Agarwal AK, Kazachkova I, Ten S, et al.	J Clin Endocrinol Metab. 2008;93:4617-4623.（海外）
5.4	Allegra Allergy [package label]. 2017	Chattanooga, TN: Chattem, Inc, a Sanofi Company	---
5.4	Eltrombopag increases plasma rosuvastatin exposure in healthy volunteers.	Allred AJ, Bowen CJ, Park JW, et al.	Br J Clin Pharmacol. 2011;72(2):321-9.（海外）
5.4	Children versus adults: pharmacokinetic and adverse-effect differences.	Anderson GD.	Epilepsia. 2002;43 Suppl 3:53-9（海外）
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5.4	Avelox [package insert]. 2019	Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.	---
5.4	Avelox [package insert]. 2020	Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.	---
5.4	Cardiovascular abnormalities in progeria. Case report and review of the literature.	Baker PB, Baba N, Boesel CP.	Arch of Path & Lab Med. 1981;105:384-386.（海外）

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5.4	Resveratrol Enhances the Bioavailability of Fexofenadine in Healthy Human Male Volunteers: Involvement of P-Glycoprotein Inhibition	Bedada SK, Yakkanti SA and Neerati P.	J Bioequiv Availab 2014, Volume 6(5): 158-163. (海外)
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5.4	Life at the edge: the nuclear envelope and human disease.	Burke B, Stewart CL.	Nat Rev Mol Cell Biol. 2002;3:575-585.（海外）
5.4	Diverse lamin-dependent mechanisms interact to control chromatin dynamics. Focus on laminopathies.	Camozzi D, Capanni C, Cenni V, et al	Nucleus. 2014;5:427-440.（海外）
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