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第5部　臨床試験報告書

5.3.1　生物薬剤学試験報告書

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料	申請電子データ提出
1	5.3.1.4.1	Assay Validation Report: Determination of $DAB_{389}IL$-2 Bioactivity Levels in Preclinical and Clinical Serum Samples by Bioassay ([redacted]054)	[redacted]	19[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	参考資料	無
2	5.3.1.4.2	Measurement of $DAB_{389}IL$-2 Blood Levels ([redacted]113)	[redacted]	19[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	参考資料	無
3	5.3.1.4.3	Assay Development and Performance Report: Determination of $DAB_{389}IL$-2 Levels by ELISA with Anti-fragment B Capture and Chemiluminescent Detection ([redacted]021)	[redacted]	19[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	参考資料	無
4	5.3.1.4.4	Stability of $DAB_{389}IL$-2 in Human Serum and Rat Serum and Plasma ([redacted]014)	[redacted]	19[redacted]-19[redacted]	[redacted] (米国)	外国	社内報	参考資料	無
5	5.3.1.4.5	Assay Development and Performance Report: Determination of Neutralizing Anti-$DAB_{389}IL$-2 Antibody Levels ([redacted]098)	[redacted]	19[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	参考資料	無
6	5.3.1.4.6	Validation of an Electrochemiluminescent Method for the Determination of E7777 Concentration in Human Serum (AOW2)	[redacted]	20[redacted] Addendum 1: 20[redacted] Addendum 2: 20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
7	5.3.1.4.7	Validation of an Electrochemiluminescent Method for the Quantitation of E7777 in Human Serum (RCQG5)	[redacted]	20[redacted] Addendum 1: 20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
8	5.3.1.4.8	Validation of an Electrochemiluminescent Method for the Quantitation of E7777 in Human Serum -Evaluation of Selectivity/Specificity for E7777 in T-Cell Lymphoma and Normal Human Serum (RCQG7)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料	申請電子データ提出
9	5.3.1.4.9	Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-E7777 Antibodies in Human Serum (ZOW2)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
10	5.3.1.4.10	Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-IL-2 Antibodies in Human Serum (APW2)	[redacted]	20[redacted] Addendum 1: 20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
11	5.3.1.4.11	Validation of a Cell-Based Assay for the Detection of Anti-E7777 Neutralizing Antibodies in Human Serum (45-1102)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
12	5.3.1.4.12	Validation of a Cell-Based Assay for Detecting the Neutralizing Activity of Anti-E7777 Antibodies in Human Serum (P[redacted]-47104)	[redacted]	20[redacted] (報告書作成年月)	[redacted]	国内	社内報	評価資料	無
13	5.3.1.4.13	Bioanalysis of E7777 in Human Serum Samples from the Clinical Study of E7777-J081-101 by an Electrochemiluminescent Method (UDZ)	[redacted]	20[redacted] Amendment 1: 20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
14	5.3.1.4.14	Analysis of Samples Using an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-IL-2 Antibodies in Human Serum (E7777-J081-101) (ASX)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
15	5.3.1.4.15	Analysis of Samples Using an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-E7777 Antibodies in Human Serum (E7777-J081-101) (ZRX)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
16	5.3.1.4.16	Detection of Anti-E7777 Neutralizing Antibodies in Human Serum Samples by Cell-Based Neutralization Assay for Eisai Clinical Protocol E7777-J081-101 (45-1218)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
17	5.3.1.4.17	Electrochemiluminescent Analysis for the Quantitation of E7777 in Human Serum (E7777-J081-205) (RFPT)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
18	5.3.1.4.18	Detection of Anti-E7777 Antibodies in Human Serum Using an Electrochemiluminescent (ECL) Immunoassay (E7777-J081-205) (RFPU)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料	申請電子データ提出
19	5.3.1.4.19	Detection of Anti-IL-2 Antibodies in Human Serum by an Electrochemiluminescence Method (E7777-J081-205) (RFPV)	[redacted]	20[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	評価資料	無
20	5.3.1.4.20	Cell-Based Assay for Detecting the Neutralizing Activity of Anti-E7777 Antibodies in Human Serum - A Phase 2 Study of E7777 in Patients With Relapsed or Refractory Peripheral T Cell Lymphoma and Cutaneous T Cell Lymphoma (Clinical Study Protocol No. E7777-J081-205) (P[redacted]-47105)	[redacted]	20[redacted] (報告書作成年月)	[redacted]	国内	社内報	評価資料	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

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料	申請電子データ提出
1	5.3.2.1.1	Preclinical Study No. 2113-04,10-94 - Partition of [^{35}S] DAB_{389}IL-2 in Whole Rat and Human Blood ([redacted]165)	[redacted]	19[redacted] (報告書作成年月)	[redacted] (米国)	外国	社内報	参考資料	無
2	5.3.2.1.2	Investigation Into the Potential for Interaction of [^{35}S]DAB_{389}IL-2 With a High Molecular Weight Entity in Serum ([redacted]009)	[redacted]	19[redacted]-19[redacted]	[redacted] (米国)	外国	社内報	参考資料	無

5.3.3　臨床薬物動態（PK）試験報告書

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料	申請電子データ提出
1	5.3.3.2.1	A Phase 1/1b Study of E7777 in Patients with Peripheral T-cell Lymphoma (Protocol Number: E7777-J081-101)	エーザイ株式会社	2011.6-2015.8	4施設 (日本)	国内	社内報	評価資料	無
2	5.3.3.2.2	A Clinical Study to Demonstrate Safety and Efficacy of E7777 in Persistent or Recurrent Cutaneous T-Cell Lymphoma (Lead-In Part) (Protocol Number: E7777-G000-302)	Eisai Inc.	2013.5-20[redacted]	6施設 (米国及び豪州)	外国	社内報	参考資料	無
3	5.3.3.2.3	A Clinical Study to Demonstrate Safety and Efficacy of E7777 in Persistent or Recurrent Cutaneous T-Cell Lymphoma (Lead-In Part) (Protocol Number: E7777-G000-302) Clinical Study Report Addendum	Eisai Inc.	2013.5-20[redacted]	6施設 (米国及び豪州)	外国	社内報	参考資料	無

5.3.5　有効性及び安全性試験報告書

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料	申請電子データ提出
1	5.3.5.2.1	A Phase 2 study of E7777 in patients with relapsed or refractory peripheral T-cell lymphoma and cutaneous T-cell lymphoma（Protocol Number: E7777-J081-205）	エーザイ株式会社	2016.3-2019.4	20施設（日本）	国内	社内報	評価資料	無
2	5.3.5.4.1	A multicenter Phase III blinded, randomized study to evaluate the safety, efficacy and pharmacokinetics of two levels of DAB_{389}IL-2 (9 and 18 μg/kg/day) in cutaneous T-cell lymphoma (CTCL) patients with Ib-III disease who, ≥4 previous therapies or stage IVa disease patients following ≥1 previous therapy, have recurrent or persistent disease.（Protocol Number: 93-04-10）	Seragen, Inc.	19[redacted]-19[redacted]	20施設（米国）	外国	社内報	参考資料	無
3	5.3.5.4.2	A multicenter phase III randomized double-blind placebo-controlled study to evaluate the efficacy of two dose levels of DAB389IL-2 (9 and 18 μg/kg/day) in cutaneous T-cell lymphoma (CTCL) patients with Stage IA-III disease who, following ≤3 previous therapies, have recurrent or persistent disease that has been biopsy-documented to express CD25.（Protocol Number: L4389-11）	エーザイ株式会社	1995.5-2006.3	42施設（米国他）	外国	社内報	参考資料	無
4	5.3.5.4.3	A multicenter open-label study to evaluate the safety and efficacy of DAB389IL-2 in cutaneous T-cell lymphoma (CTCL) patients following Protocol 93-04-10, Protocol 93-04-11, or Protocol 92-04-01 or who meet the requirements for Protocol 93-04-11 except have biopsy-documented CTCL that does not express CD25.（Protocol Number: L4389-14）	エーザイ株式会社	1995.9-2006.10	35施設（米国他）	外国	社内報	参考資料	無

5.3.7　患者データ一覧表及び症例記録

番号	添付資料番号	タイトル	著者	試験実施期間	試験実施場所	報種類	掲載誌	評価資料・参考資料
1	5.3.7.1	症例一覧表 （国内101試験）	エーザイ株式会社	2011.6-2015.8	4施設（日本）	国内	社内報	評価資料
2	5.3.7.2	症例一覧表 （国内205試験）	エーザイ株式会社	2016.3-2019.4	20施設（日本）	国内	社内報	評価資料
3	5.3.7.3	有害事象一覧表 （国内101試験）	エーザイ株式会社	2011.6-2015.8	4施設（日本）	国内	社内報	評価資料
4	5.3.7.4	有害事象一覧表 （国内205試験）	エーザイ株式会社	2016.3-2019.4	20施設（日本）	国内	社内報	評価資料
5	5.3.7.5	重篤な有害事象一覧表 （国内101試験）	エーザイ株式会社	2011.6-2015.8	4施設（日本）	国内	社内報	評価資料
6	5.3.7.6	重篤な有害事象一覧表 （国内205試験）	エーザイ株式会社	2016.3-2019.4	20施設（日本）	国内	社内報	評価資料

7	5.3.7.7	臨床検査異常値一覧表 （国内101試験）	エーザイ株式会社	2011.6-2015.8	4施設 （日本）	国内	社内報	評価資料
8	5.3.7.8	臨床検査異常値一覧表 （国内205試験）	エーザイ株式会社	2016.3-2019.4	20施設 （日本）	国内	社内報	評価資料
9	5.3.7.9	臨床検査値推移図 （Box-Plot） （国内205試験）	エーザイ株式会社	2016.3-2019.4	20施設 （日本）	国内	社内報	評価資料

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第3部　品質に関する文書

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