1.1.4.2.4 治験薬との因果関係が否定できない有害事象

本治験の治療期間（増量期間+維持期間）に認められた治験薬との因果関係別の有害事象を表 1.1-46（全集団）及び表 1.1-47（日本人集団）に示した。

全集団では、治療期間に治験薬との因果関係が否定できない有害事象がプラセボ群で 42 例（34.7%）及びラコサミド群で 56 例（46.3%）に認められ、ラコサミド群の発現率が高かった。治療期間で最も多く認められた治験薬との因果関係が否定できない有害事象は、プラセボ群では傾眠（11.6%）で、次いでアスパラギン酸アミノトランスフェラーゼ増加及び浮動性めまい（各 3.3%）、並びにアラニンアミノトランスフェラーゼ増加、疲労及び悪心（各 2.5%）であった。ラコサミド群では浮動性めまい（17.4%）で、次いで傾眠（13.2%）及び悪心（7.4%）であった。

日本人集団では、治療期間に治験薬との因果関係が否定できない有害事象がプラセボ群で 6 例（31.6%）及びラコサミド群で 7 例（63.6%）に認められた。治療期間で最も多く認められた治験薬との因果関係が否定できない有害事象は、プラセボ群では傾眠（21.1%）で、次いで便秘（10.5%）であり、その他の事象はいずれも 1 例以下の発現であった。ラコサミド群では傾眠（45.5%）で、その他の事象はいずれも 1 例以下の発現であった。

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
Any TEAE	Any	79 (65.3) [231]	96 (79.3) [320]
	Related	42 (34.7) [72]	56 (46.3) [133]
	Not Related	65 (53.7) [159]	75 (62.0) [187]
血液およびリンパ系障害	Any	1 (0.8) [1]	2 (1.7) [2]
	Related	1 (0.8) [1]	0
	Not Related	0	2 (1.7) [2]
好酸球増加症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
血液およびリンパ系障害			
鉄欠乏性貧血	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
白血球減少症	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
心臓障害	Any	3 (2.5) [4]	4 (3.3) [4]
	Related	0	1 (0.8) [1]
	Not Related	3 (2.5) [4]	3 (2.5) [3]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
心臓障害			
右脚ブロック	Any	0	2 (1.7) [2]
	Related	0	0
	Not Related	0	2 (1.7) [2]
不整脈	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
第一度房室ブロック	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
心臓障害			
洞性徐脈	Any	2 (1.7) [3]	0
	Related	0	0
	Not Related	2 (1.7) [3]	0
頻脈	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
耳および迷路障害	Any	2 (1.7) [3]	9 (7.4) [9]
	Related	2 (1.7) [3]	8 (6.6) [8]
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
耳および迷路障害			
回転性めまい	Any	2 (1.7) [2]	8 (6.6) [8]
	Related	2 (1.7) [2]	7 (5.8) [7]
	Not Related	0	1 (0.8) [1]
耳鳴	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
聴覚過敏	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
内分泌障害	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
自己免疫性甲状腺炎	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
眼障害	Any	3 (2.5) [3]	9 (7.4) [11]
	Related	1 (0.8) [1]	6 (5.0) [7]
	Not Related	2 (1.7) [2]	4 (3.3) [4]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
眼障害			
霧視	Any	1 (0.8) [1]	4 (3.3) [6]
	Related	1 (0.8) [1]	3 (2.5) [4]
	Not Related	0	2 (1.7) [2]
複視	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
眼刺激	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
眼障害			
流涙増加	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
光視症	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
視力低下	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
眼障害			
結膜炎	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
眼部腫脹	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
胃腸障害	Any	19 (15.7) [28]	25 (20.7) [47]
	Related	7 (5.8) [7]	14 (11.6) [29]
	Not Related	14 (11.6) [21]	13 (10.7) [18]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
悪心	Any	7 (5.8) [7]	12 (9.9) [13]
	Related	3 (2.5) [3]	9 (7.4) [10]
	Not Related	4 (3.3) [4]	3 (2.5) [3]
嘔吐	Any	1 (0.8) [3]	7 (5.8) [11]
	Related	0	6 (5.0) [8]
	Not Related	1 (0.8) [3]	2 (1.7) [3]
下痢	Any	2 (1.7) [2]	4 (3.3) [5]
	Related	0	3 (2.5) [4]
	Not Related	2 (1.7) [2]	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
腹痛	Any	2 (1.7) [2]	3 (2.5) [3]
	Related	0	1 (0.8) [1]
	Not Related	2 (1.7) [2]	2 (1.7) [2]
上腹部痛	Any	2 (1.7) [2]	2 (1.7) [3]
	Related	1 (0.8) [1]	1 (0.8) [2]
	Not Related	1 (0.8) [1]	1 (0.8) [1]
齲歯	Any	0	2 (1.7) [2]
	Related	0	0
	Not Related	0	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
胃炎	Any	1 (0.8) [5]	2 (1.7) [2]
	Related	0	0
	Not Related	1 (0.8) [5]	2 (1.7) [2]
腹部不快感	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
下腹部痛	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
便秘	Any	2 (1.7) [2]	1 (0.8) [1]
	Related	2 (1.7) [2]	1 (0.8) [1]
	Not Related	0	0
口内乾燥	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	0	0
鼓腸	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
口の感覚鈍麻	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
レッチング	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
舌障害	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
根尖肉芽腫	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
消化不良	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
食中毒	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
胃腸障害			
胃食道逆流性疾患	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
一般・全身障害および投与部位の状態	Any	14 (11.6) [15]	15 (12.4) [18]
	Related	6 (5.0) [7]	9 (7.4) [10]
	Not Related	8 (6.6) [8]	7 (5.8) [8]
疲労	Any	6 (5.0) [6]	8 (6.6) [8]
	Related	3 (2.5) [3]	6 (5.0) [6]
	Not Related	3 (2.5) [3]	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
一般・全身障害および投与部位の状態			
易刺激性	Any	2 (1.7) [3]	2 (1.7) [2]
	Related	2 (1.7) [3]	2 (1.7) [2]
	Not Related	0	0
発熱	Any	0	2 (1.7) [3]
	Related	0	0
	Not Related	0	2 (1.7) [3]
無力症	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
一般・全身障害および投与部位の状態			
活力増進	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
酩酊感	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
熱感	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
一般・全身障害および投与部位の状態			
評価不能の事象	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
胸痛	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
インフルエンザ様疾患	Any	2 (1.7) [2]	0
	Related	0	0
	Not Related	2 (1.7) [2]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
一般・全身障害および投与部位の状態			
口渇	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
血管穿刺部位血腫	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
免疫系障害	Any	1 (0.8) [1]	2 (1.7) [2]
	Related	0	0
	Not Related	1 (0.8) [1]	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
免疫系障害			
過敏症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
季節性アレルギー	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]
感染症および寄生虫症	Any	23 (19.0) [32]	25 (20.7) [34]
	Related	0	0
	Not Related	23 (19.0) [32]	25 (20.7) [34]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
鼻咽頭炎	Any	4 (3.3) [4]	8 (6.6) [12]
	Related	0	0
	Not Related	4 (3.3) [4]	8 (6.6) [12]
インフルエンザ	Any	2 (1.7) [2]	3 (2.5) [3]
	Related	0	0
	Not Related	2 (1.7) [2]	3 (2.5) [3]
上気道感染	Any	6 (5.0) [9]	3 (2.5) [3]
	Related	0	0
	Not Related	6 (5.0) [9]	3 (2.5) [3]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
咽頭扁桃炎	Any	0	2 (1.7) [2]
	Related	0	0
	Not Related	0	2 (1.7) [2]
ウイルス性気道感染	Any	1 (0.8) [1]	2 (1.7) [2]
	Related	0	0
	Not Related	1 (0.8) [1]	2 (1.7) [2]
気管支炎	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
蜂巣炎	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
胃腸炎	Any	2 (1.7) [2]	1 (0.8) [1]
	Related	0	0
	Not Related	2 (1.7) [2]	1 (0.8) [1]
ウイルス性胃腸炎	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
膿痂疹	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
ライム病	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
爪囲炎	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
咽頭炎	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
鼻炎	Any	3 (2.5) [4]	1 (0.8) [1]
	Related	0	0
	Not Related	3 (2.5) [4]	1 (0.8) [1]
副鼻腔炎	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
尿路感染	Any	2 (1.7) [2]	1 (0.8) [1]
	Related	0	0
	Not Related	2 (1.7) [2]	1 (0.8) [1]
創傷感染	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
膀胱炎	Any	2 (1.7) [2]	0
	Related	0	0
	Not Related	2 (1.7) [2]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
耳感染	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
口腔カンジダ症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
ウイルス性上気道感染	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
感染症および寄生虫症			
外陰部腟カンジダ症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
傷害、中毒および処置合併症	Any	16 (13.2) [21]	11 (9.1) [18]
	Related	1 (0.8) [1]	0
	Not Related	15 (12.4) [20]	11 (9.1) [18]
挫傷	Any	5 (4.1) [6]	4 (3.3) [5]
	Related	0	0
	Not Related	5 (4.1) [6]	4 (3.3) [5]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
傷害、中毒および処置合併症			
上腕骨骨折	Any	0	2 (1.7) [3]
	Related	0	0
	Not Related	0	2 (1.7) [3]
靭帯捻挫	Any	1 (0.8) [1]	2 (1.7) [3]
	Related	0	0
	Not Related	1 (0.8) [1]	2 (1.7) [3]
眼挫傷	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
傷害、中毒および処置合併症			
顔面骨骨折	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
転倒	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]
頭部損傷	Any	2 (1.7) [2]	1 (0.8) [1]
	Related	0	0
	Not Related	2 (1.7) [2]	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
傷害、中毒および処置合併症			
筋断裂	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
熱傷	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]
歯牙破折	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
傷害、中毒および処置合併症			
外耳道損傷	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
擦過傷	Any	3 (2.5) [3]	0
	Related	0	0
	Not Related	3 (2.5) [3]	0
顔面損傷	Any	2 (1.7) [2]	0
	Related	0	0
	Not Related	2 (1.7) [2]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
傷害、中毒および処置合併症			
大腿骨骨折	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
手骨折	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
交通事故	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
傷害、中毒および処置合併症			
軟部組織損傷	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
臨床検査	Any	11 (9.1) [21]	9 (7.4) [12]
	Related	8 (6.6) [13]	2 (1.7) [2]
	Not Related	4 (3.3) [8]	7 (5.8) [10]
アラニンアミノトランスフェラーゼ増加	Any	4 (3.3) [4]	4 (3.3) [4]
	Related	3 (2.5) [3]	0
	Not Related	1 (0.8) [1]	4 (3.3) [4]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 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	Any	5 (4.1) [5]	2 (1.7) [2]
	Related	4 (3.3) [4]	0
	Not Related	1 (0.8) [1]	2 (1.7) [2]
好酸球数増加	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]
γ－グルタミルトランスフェラーゼ増加	Any	3 (2.5) [3]	1 (0.8) [1]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	2 (1.7) [2]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
臨床検査			
肝機能検査異常	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]
尿中蛋白陽性	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
トランスアミナーゼ上昇	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
臨床検査			
体重減少	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	1 (0.8) [1]	0
	Not Related	0	1 (0.8) [1]
血中ビリルビン増加	Any	2 (1.7) [2]	0
	Related	1 (0.8) [1]	0
	Not Related	1 (0.8) [1]	0
体温上昇	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
臨床検査			
リンパ球数減少	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
体重増加	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
白血球数減少	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
代謝および栄養障害	Any	7 (5.8) [7]	3 (2.5) [3]
	Related	0	1 (0.8) [1]
	Not Related	7 (5.8) [7]	2 (1.7) [2]
食欲減退	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]
高尿酸血症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
代謝および栄養障害			
肥満	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
糖尿病	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
高クロール血症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
代謝および栄養障害			
高カリウム血症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
高脂血症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
高ナトリウム血症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
代謝および栄養障害			
２型糖尿病	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
筋骨格系および結合組織障害	Any	6 (5.0) [10]	6 (5.0) [9]
	Related	0	0
	Not Related	6 (5.0) [10]	6 (5.0) [9]
四肢痛	Any	0	2 (1.7) [2]
	Related	0	0
	Not Related	0	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
筋骨格系および結合組織障害			
関節痛	Any	3 (2.5) [3]	1 (0.8) [3]
	Related	0	0
	Not Related	3 (2.5) [3]	1 (0.8) [3]
背部痛	Any	2 (1.7) [2]	1 (0.8) [1]
	Related	0	0
	Not Related	2 (1.7) [2]	1 (0.8) [1]
筋骨格系胸痛	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
筋骨格系および結合組織障害			
ミオキミア	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
変形性関節症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
出血性関節症	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
筋骨格系および結合組織障害			
筋肉内出血	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
筋痙縮	Any	1 (0.8) [2]	0
	Related	0	0
	Not Related	1 (0.8) [2]	0
筋骨格痛	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 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）	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
脂肪腫	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
神経系障害	Any	36 (29.8) [51]	58 (47.9) [108]
	Related	22 (18.2) [27]	38 (31.4) [69]
	Not Related	19 (15.7) [24]	28 (23.1) [39]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
浮動性めまい	Any	7 (5.8) [7]	28 (23.1) [36]
	Related	4 (3.3) [4]	21 (17.4) [26]
	Not Related	3 (2.5) [3]	9 (7.4) [10]
傾眠	Any	17 (14.0) [17]	20 (16.5) [21]
	Related	14 (11.6) [14]	16 (13.2) [17]
	Not Related	3 (2.5) [3]	4 (3.3) [4]
頭痛	Any	12 (9.9) [13]	17 (14.0) [19]
	Related	2 (1.7) [2]	3 (2.5) [3]
	Not Related	10 (8.3) [11]	14 (11.6) [16]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
運動失調	Any	0	4 (3.3) [5]
	Related	0	4 (3.3) [5]
	Not Related	0	0
注意力障害	Any	0	4 (3.3) [5]
	Related	0	3 (2.5) [4]
	Not Related	0	1 (0.8) [1]
ミオクローヌス性てんかん	Any	0	3 (2.5) [3]
	Related	0	2 (1.7) [2]
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
健忘	Any	1 (0.8) [1]	2 (1.7) [2]
	Related	0	1 (0.8) [1]
	Not Related	1 (0.8) [1]	1 (0.8) [1]
平衡障害	Any	1 (0.8) [1]	2 (1.7) [2]
	Related	1 (0.8) [1]	2 (1.7) [2]
	Not Related	0	0
振戦	Any	0	2 (1.7) [2]
	Related	0	1 (0.8) [1]
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
よだれ	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
大発作痙攣	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	1 (0.8) [1]	0
	Not Related	0	1 (0.8) [1]
感覚鈍麻	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
嗜眠	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
意識消失	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
記憶障害	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
片頭痛	Any	2 (1.7) [2]	1 (0.8) [1]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	1 (0.8) [1]	0
錯感覚	Any	2 (1.7) [4]	1 (0.8) [1]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	2 (1.7) [3]	0
姿勢時振戦	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
鎮静	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
単純部分発作	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
会話障害	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
てんかん重積状態	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
脳血腫	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
体位性めまい	Any	2 (1.7) [2]	0
	Related	1 (0.8) [1]	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
神経系障害			
ミオクローヌス	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
精神障害	Any	10 (8.3) [14]	12 (9.9) [14]
	Related	4 (3.3) [6]	3 (2.5) [3]
	Not Related	7 (5.8) [8]	9 (7.4) [11]
不眠症	Any	3 (2.5) [3]	3 (2.5) [3]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	2 (1.7) [2]	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
精神障害			
不安	Any	3 (2.5) [3]	2 (1.7) [2]
	Related	1 (0.8) [1]	1 (0.8) [1]
	Not Related	2 (1.7) [2]	1 (0.8) [1]
自殺念慮	Any	0	2 (1.7) [2]
	Related	0	0
	Not Related	0	2 (1.7) [2]
怒り	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
精神障害			
抑うつ気分	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
ディスフェミア	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
心因性発作	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
精神障害			
睡眠障害	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
早朝覚醒型不眠症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
思考異常	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
精神障害			
攻撃性	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
身体醜形障害	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
うつ病	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
精神障害			
気分変化	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
神経過敏	Any	1 (0.8) [4]	0
	Related	1 (0.8) [3]	0
	Not Related	1 (0.8) [1]	0
腎および尿路障害	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
腎および尿路障害			
尿失禁	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
生殖系および乳房障害	Any	1 (0.8) [1]	3 (2.5) [3]
	Related	0	1 (0.8) [1]
	Not Related	1 (0.8) [1]	2 (1.7) [2]
月経困難症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
生殖系および乳房障害			
卵巣嚢胞	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
子宮出血	Any	0	1 (0.8) [1]
	Related	0	1 (0.8) [1]
	Not Related	0	0
不正子宮出血	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
呼吸器、胸郭および縦隔障害	Any	4 (3.3) [4]	8 (6.6) [11]
	Related	0	0
	Not Related	4 (3.3) [4]	8 (6.6) [11]
咳嗽	Any	1 (0.8) [1]	4 (3.3) [4]
	Related	0	0
	Not Related	1 (0.8) [1]	4 (3.3) [4]
鼻出血	Any	1 (0.8) [1]	2 (1.7) [2]
	Related	0	0
	Not Related	1 (0.8) [1]	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
呼吸器、胸郭および縦隔障害			
口腔咽頭痛	Any	0	2 (1.7) [3]
	Related	0	0
	Not Related	0	2 (1.7) [3]
鼻閉	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
鼻漏	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	0	0
	Not Related	1 (0.8) [1]	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
呼吸器、胸郭および縦隔障害			
呼吸障害	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
皮膚および皮下組織障害	Any	8 (6.6) [9]	8 (6.6) [10]
	Related	6 (5.0) [6]	2 (1.7) [2]
	Not Related	3 (2.5) [3]	6 (5.0) [8]
発疹	Any	2 (1.7) [2]	3 (2.5) [3]
	Related	2 (1.7) [2]	1 (0.8) [1]
	Not Related	0	2 (1.7) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
皮膚および皮下組織障害			
そう痒症	Any	0	2 (1.7) [2]
	Related	0	1 (0.8) [1]
	Not Related	0	1 (0.8) [1]
脱毛症	Any	1 (0.8) [1]	1 (0.8) [1]
	Related	1 (0.8) [1]	0
	Not Related	0	1 (0.8) [1]
異汗性湿疹	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
皮膚および皮下組織障害			
紅斑	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
多汗症	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
顔面腫脹	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
皮膚および皮下組織障害			
ざ瘡	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
アトピー性皮膚炎	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
光線過敏性反応	Any	1 (0.8) [2]	0
	Related	1 (0.8) [1]	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
皮膚および皮下組織障害			
斑状皮疹	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
蕁麻疹	Any	1 (0.8) [1]	0
	Related	1 (0.8) [1]	0
	Not Related	0	0
社会環境	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1

Incidence of TEAEs During the Treatment Period by Relationship

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
社会環境			
閉経	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
血管障害	Any	3 (2.5) [3]	4 (3.3) [4]
	Related	0	0
	Not Related	3 (2.5) [3]	4 (3.3) [4]
高血圧	Any	1 (0.8) [1]	3 (2.5) [3]
	Related	0	0
	Not Related	1 (0.8) [1]	3 (2.5) [3]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-46　全集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]
血管障害			
潮紅	Any	0	1 (0.8) [1]
	Related	0	0
	Not Related	0	1 (0.8) [1]
血腫	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0
腹腔内血腫	Any	1 (0.8) [1]	0
	Related	0	0
	Not Related	1 (0.8) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.
Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
Any TEAE	Any	13 (68.4) [32]	11 (100) [34]
	Related	6 (31.6) [8]	7 (63.6) [13]
	Not Related	11 (57.9) [24]	11 (100) [21]
心臓障害	Any	2 (10.5) [3]	0
	Related	0	0
	Not Related	2 (10.5) [3]	0
洞性徐脈	Any	2 (10.5) [3]	0
	Related	0	0
	Not Related	2 (10.5) [3]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
耳および迷路障害	Any	0	2 (18.2) [2]
	Related	0	2 (18.2) [2]
	Not Related	0	0
耳鳴	Any	0	1 (9.1) [1]
	Related	0	1 (9.1) [1]
	Not Related	0	0
回転性めまい	Any	0	1 (9.1) [1]
	Related	0	1 (9.1) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
眼障害	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
結膜炎	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
胃腸障害	Any	3 (15.8) [4]	4 (36.4) [8]
	Related	2 (10.5) [2]	1 (9.1) [5]
	Not Related	2 (10.5) [2]	3 (27.3) [3]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
胃腸障害			
腹痛	Any	1 (5.3) [1]	2 (18.2) [2]
	Related	0	1 (9.1) [1]
	Not Related	1 (5.3) [1]	1 (9.1) [1]
悪心	Any	0	2 (18.2) [2]
	Related	0	1 (9.1) [1]
	Not Related	0	1 (9.1) [1]
腹部不快感	Any	0	1 (9.1) [1]
	Related	0	1 (9.1) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
胃腸障害			
便秘	Any	2 (10.5) [2]	1 (9.1) [1]
	Related	2 (10.5) [2]	1 (9.1) [1]
	Not Related	0	0
下痢	Any	1 (5.3) [1]	1 (9.1) [1]
	Related	0	1 (9.1) [1]
	Not Related	1 (5.3) [1]	0
胃炎	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
一般・全身障害および投与部位の状態	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
発熱	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
免疫系障害	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
免疫系障害			
季節性アレルギー	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
感染症および寄生虫症	Any	2 (10.5) [2]	3 (27.3) [6]
	Related	0	0
	Not Related	2 (10.5) [2]	3 (27.3) [6]
鼻咽頭炎	Any	1 (5.3) [1]	3 (27.3) [6]
	Related	0	0
	Not Related	1 (5.3) [1]	3 (27.3) [6]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
感染症および寄生虫症			
インフルエンザ	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
傷害、中毒および処置合併症	Any	5 (26.3) [8]	1 (9.1) [1]
	Related	0	0
	Not Related	5 (26.3) [8]	1 (9.1) [1]
挫傷	Any	3 (15.8) [4]	1 (9.1) [1]
	Related	0	0
	Not Related	3 (15.8) [4]	1 (9.1) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
傷害、中毒および処置合併症			
外耳道損傷	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
擦過傷	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
靭帯捻挫	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
傷害、中毒および処置合併症			
熱傷	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
臨床検査	Any	1 (5.3) [1]	1 (9.1) [1]
	Related	1 (5.3) [1]	0
	Not Related	0	1 (9.1) [1]
尿中蛋白陽性	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 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	Any	1 (5.3) [1]	0
	Related	1 (5.3) [1]	0
	Not Related	0	0
代謝および栄養障害	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
高尿酸血症	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
筋骨格系および結合組織障害	Any	2 (10.5) [3]	1 (9.1) [1]
	Related	0	0
	Not Related	2 (10.5) [3]	1 (9.1) [1]
背部痛	Any	2 (10.5) [2]	1 (9.1) [1]
	Related	0	0
	Not Related	2 (10.5) [2]	1 (9.1) [1]
関節痛	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
神経系障害	Any	5 (26.3) [7]	6 (54.5) [7]
	Related	4 (21.1) [5]	6 (54.5) [6]
	Not Related	2 (10.5) [2]	1 (9.1) [1]
傾眠	Any	4 (21.1) [4]	5 (45.5) [5]
	Related	4 (21.1) [4]	5 (45.5) [5]
	Not Related	0	0
浮動性めまい	Any	0	1 (9.1) [1]
	Related	0	1 (9.1) [1]
	Not Related	0	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
神経系障害			
頭痛	Any	1 (5.3) [1]	1 (9.1) [1]
	Related	0	0
	Not Related	1 (5.3) [1]	1 (9.1) [1]
体位性めまい	Any	2 (10.5) [2]	0
	Related	1 (5.3) [1]	0
	Not Related	1 (5.3) [1]	0
精神障害	Any	0	2 (18.2) [2]
	Related	0	0
	Not Related	0	2 (18.2) [2]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
精神障害			
不安	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
早朝覚醒型不眠症	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
腎および尿路障害	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
腎および尿路障害			
尿失禁	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0
生殖系および乳房障害	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
月経困難症	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
呼吸器、胸郭および縦隔障害	Any	0	2 (18.2) [2]
	Related	0	0
	Not Related	0	2 (18.2) [2]
鼻出血	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
口腔咽頭痛	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 1.1-47　日本人集団の治験薬との因果関係別の有害事象（治療期間）：SS（続き）

Table 11.4.1.1
Incidence of TEAEs During the Treatment Period by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]
皮膚および皮下組織障害	Any	1 (5.3) [1]	1 (9.1) [1]
	Related	0	0
	Not Related	1 (5.3) [1]	1 (9.1) [1]
発疹	Any	0	1 (9.1) [1]
	Related	0	0
	Not Related	0	1 (9.1) [1]
ざ瘡	Any	1 (5.3) [1]	0
	Related	0	0
	Not Related	1 (5.3) [1]	0

AE=Adverse Event, LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: [#] is the number of individual occurrences of the TEAE.
Note: A subject may be counted more than once according to the relationship of the TEAEs.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

1.1.4.2.5 死亡

本治験では、死亡は認められなかった。

1.1.4.2.6 重篤な有害事象

本治験の治療期間（増量期間+維持期間）に認められた重篤な有害事象を表 1.1-48（全集団）に示した。また、ラコサミド群の重篤な有害事象の詳細を本まとめ（その他の重篤な有害事象）に示し、すべての重篤な有害事象の詳細を SP0982 試験総括報告書（5.3.5.1.1）13 項に示した。

全集団では、治療期間に認められた重篤な有害事象の発現率は 5.0%と低く、投与群別ではプラセボ群 3.3%及びラコサミド群 6.6%であった。

日本人集団では、治療期間に重篤な有害事象は認められなかった。

表 1.1-48　全集団の重篤な有害事象（治療期間）：SS

Table 11.6.1
Incidence of Serious TEAEs During the Treatment Period
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All Subjects N=242 n (%) [#]
Any Serious TEAE	4 (3.3) [4]	8 (6.6) [14]	12 (5.0) [18]
胃腸障害	0	2 (1.7) [3]	2 (0.8) [3]
腹痛	0	1 (0.8) [1]	1 (0.4) [1]
悪心	0	1 (0.8) [1]	1 (0.4) [1]
嘔吐	0	1 (0.8) [1]	1 (0.4) [1]
一般・全身障害および投与部位の状態	0	1 (0.8) [1]	1 (0.4) [1]
無力症	0	1 (0.8) [1]	1 (0.4) [1]
感染症および寄生虫症	1 (0.8) [1]	0	1 (0.4) [1]
上気道感染	1 (0.8) [1]	0	1 (0.4) [1]
傷害、中毒および処置合併症	2 (1.7) [2]	1 (0.8) [1]	3 (1.2) [3]
挫傷	0	1 (0.8) [1]	1 (0.4) [1]
大腿骨骨折	1 (0.8) [1]	0	1 (0.4) [1]
交通事故	1 (0.8) [1]	0	1 (0.4) [1]

LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.
Reference: Listing 7.3

表 1.1-48　全集団の重篤な有害事象（治療期間）：SS（続き）

Table 11.6.1
Incidence of Serious TEAEs During the Treatment Period
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All Subjects N=242 n (%) [#]
臨床検査	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]
肝機能検査異常	1 (0.8) [1]	0	1 (0.4) [1]
筋骨格系および結合組織障害	0	1 (0.8) [1]	1 (0.4) [1]
四肢痛	0	1 (0.8) [1]	1 (0.4) [1]
神経系障害	0	5 (4.1) [7]	5 (2.1) [7]
浮動性めまい	0	2 (1.7) [2]	2 (0.8) [2]
傾眠	0	2 (1.7) [2]	2 (0.8) [2]
大発作痙攣	0	1 (0.8) [1]	1 (0.4) [1]
頭痛	0	1 (0.8) [1]	1 (0.4) [1]
てんかん重積状態	0	1 (0.8) [1]	1 (0.4) [1]

LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.
Reference: Listing 7.3

1.1.4.2.7 治験薬の投与中止に至った有害事象

本治験の治療期間（増量期間+維持期間）に認められた治験薬の投与中止に至った有害事象を表1.1-49（全集団）に示した。

全集団では、治療期間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6.6%と低く、投与群別ではプラセボ群4.1%及びラコサミド群9.1%であった。治験薬の投与中止に至った有害事象は、増量期間中に多く認められ、全被験者で14/19件であった。投与群別ではプラセボ群3/6件及びラコサミド群11/13件であった。

日本人集団では、治療期間に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。

表 1.1-49　全集団の治験薬の投与中止に至った有害事象（治療期間）：SS

Table 11.7.1
Incidence of TEAEs Leading to Discontinuation During the Treatment Period
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All Subjects N=242 n (%) [#]
Any TEAE	5 (4.1) [6]	11 (9.1) [13]	16 (6.6) [19]
耳および迷路障害	0	1 (0.8) [1]	1 (0.4) [1]
回転性めまい	0	1 (0.8) [1]	1 (0.4) [1]
眼障害	0	1 (0.8) [1]	1 (0.4) [1]
複視	0	1 (0.8) [1]	1 (0.4) [1]
一般・全身障害および投与部位の状態	0	1 (0.8) [1]	1 (0.4) [1]
疲労	0	1 (0.8) [1]	1 (0.4) [1]
傷害、中毒および処置合併症	1 (0.8) [1]	0	1 (0.4) [1]
大腿骨骨折	1 (0.8) [1]	0	1 (0.4) [1]
臨床検査	1 (0.8) [2]	2 (1.7) [3]	3 (1.2) [5]
アラニンアミノトランスフェラーゼ増加	1 (0.8) [1]	1 (0.8) [1]	2 (0.8) [2]
アスパラギン酸アミノトランスフェラーゼ増加	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]

LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Reference: Listing 7.4

表 1.1-49　全集団の治験薬の投与中止に至った有害事象（治療期間）：SS（続き）

Table 11.7.1

Incidence of TEAEs Leading to Discontinuation During the Treatment Period

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All Subjects N=242 n (%) [#]
神経系障害	0	4 (3.3) [4]	4 (1.7) [4]
浮動性めまい	0	2 (1.7) [2]	2 (0.8) [2]
ミオクローヌス性てんかん	0	1 (0.8) [1]	1 (0.4) [1]
てんかん重積状態	0	1 (0.8) [1]	1 (0.4) [1]
精神障害	1 (0.8) [1]	2 (1.7) [2]	3 (1.2) [3]
自殺念慮	0	2 (1.7) [2]	2 (0.8) [2]
うつ病	1 (0.8) [1]	0	1 (0.4) [1]
皮膚および皮下組織障害	2 (1.7) [2]	1 (0.8) [1]	3 (1.2) [3]
発疹	2 (1.7) [2]	1 (0.8) [1]	3 (1.2) [3]

LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Reference: Listing 7.4

1.1.4.2.8 その他の注目すべき有害事象

本治験の治療期間（増量期間+維持期間）に認められたその他の注目すべき有害事象を表 1.1-50（全集団）及び表 1.1-51（日本人集団）に示した。

本治験では、治験薬投与開始後に認められた有害事象のうち、その他の注目すべき有害事象として、心臓障害関連、自殺関連、並びに失神、意識消失、食欲障害、食欲減退、拒食、過小食、食物嫌悪及び異常行動の有害事象の有無を確認した。

表 1.1-50　全集団のその他の注目すべき有害事象（治療期間）：SS

Table 11.8.1

Incidence of Other Significant TEAEs During the Treatment Period

Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Placebo N=121 n (%) [#]	LCM N=121 n (%) [#]	All Subjects N=242 n (%) [#]
Any TEAE	2 (1.7) [2]	4 (3.3) [4]	6 (2.5) [6]
心臓障害	1 (0.8) [1]	0	1 (0.4) [1]
洞性徐脈	1 (0.8) [1]	0	1 (0.4) [1]
代謝および栄養障害	1 (0.8) [1]	1 (0.8) [1]	2 (0.8) [2]
食欲減退	1 (0.8) [1]	1 (0.8) [1]	2 (0.8) [2]
神経系障害	0	1 (0.8) [1]	1 (0.4) [1]
意識消失	0	1 (0.8) [1]	1 (0.4) [1]
精神障害	0	2 (1.7) [2]	2 (0.8) [2]
自殺念慮	0	2 (1.7) [2]	2 (0.8) [2]

LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Reference: Listing 7.2

表 1.1-51　日本人集団のその他の注目すべき有害事象（治療期間）：SS

Table 11.8.1.1

Incidence of Other Significant TEAEs During the Treatment Period

Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Placebo N=19 n (%) [#]	LCM N=11 n (%) [#]	All Subjects N=30 n (%) [#]
Any TEAE	1 (5.3) [1]	0	1 (3.3) [1]
心臓障害	1 (5.3) [1]	0	1 (3.3) [1]
洞性徐脈	1 (5.3) [1]	0	1 (3.3) [1]

LCM=Lacosamide, MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-emergent adverse event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.2

1.1.4.2.9 発作に関連する有害事象

全集団では、治療期間に発作に関連する有害事象（PT）として、てんかん重積状態（プラセボ群0 例及びラコサミド群 1 例、以下同順）、大発作痙攣（各 1 例）、ミオクローヌス（1 例及び 0 例）及びミオクローヌス性てんかん（0 例及び 3 例）が認められた。また、ラコサミド群では減量期間に大発作痙攣が 1 例に認められた。

日本人集団では、治療期間に発作に関連する有害事象は認められなかった。

1.1.4.3 その他の安全性評価項目

1.1.4.3.1 治療期間における欠神発作及びミオクロニー発作発現日数が増加した被験者の割合

本治験の SS での Prospective ベースライン期間に対する治療期間（増量期間+維持期間）の 28 日あたりの欠神発作発現日数が増加した被験者数及び割合をカテゴリー別に表 1.1-52（全集団）及び表 1.1-53（日本人集団）に示した。また、Prospective ベースライン期間に対する治療期間（増量期間+維持期間）の 28 日あたりのミオクロニー発作発現日数が増加した被験者数及び割合をカテゴリー別に表 1.1-54（全集団）及び表 1.1-55（日本人集団）に示した。

全集団では、Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作又はミオクロニー発作発現日数が増加した被験者は少なかった。プラセボ群及びラコサミド群で欠神発作発現日数が 25%以下増加した被験者は 4 例（9.5%）及び 1 例（2.0%）（以下同順）、25%超 50%以下増加した被験者は 2 例（4.8%）及び 1 例（2.0%）、50%超 75%以下増加した被験者は 1 例（2.4%）及び 0 例、75%超増加した被験者は 2 例（4.8%）及び 1 例（2.0%）であった。ミオクロニー発作発現日数が 25%以下増加した被験者は 0 例及び 1 例（2.1%）、25%超 50%以下増加した被験者は 1 例（2.0%）及び 1 例（2.1%）、50%超 75%以下増加した被験者は 1 例（2.0%）及び 0 例、75%超増加した被験者は 1 例（2.0%）及び 4 例（8.5%）であった。

日本人集団では、Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作発現日数が増加した被験者は、プラセボ群で 50%超 75%以下増加した被験者が 1 例（33.3%）であり、その他のカテゴリーでは認められなかった。また、ミオクロニー発作発現日数が増加した被験者は、ラコサミド群で 25%以下増加した被験者が 1 例（20.0%）であり、その他のカテゴリーでは認められなかった。

表 1.1-52　全集団の Prospective ベースライン期間に対する治療期間の欠神発作発現日数が増加した被験者数と割合：SS

Table 8.6.3

Increase in Days with Absence Seizures During the Treatment Period Compared to Prospective Baseline

Analysis Set: Safety Set

Variable	Placebo N=42 n (%)	LCM N=51 n (%)
<=25% increase	4 (9.5)	1 (2.0)
>25 - 50% increase	2 (4.8)	1 (2.0)
>50 - 75% increase	1 (2.4)	0
>75% increase	2 (4.8)	1 (2.0)

LCM=Lacosamide.

Note: Percentages are based on the number of subjects in the Safety Set who reported a history of absence seizures or an occurrence of absence seizures in the Combined Baseline or in the Treatment Period (N).

Reference: Listing 6.4

表 1.1-53　日本人集団の Prospective ベースライン期間に対する治療期間の欠神発作発現日数が増加した被験者数と割合：SS

Table 8.6.3.1.0

Increase in Days with Absence Seizures During the Treatment Period Compared to Prospective Baseline

Analysis Set: Safety Set - Japanese

Variable	Placebo N=3 n (%)	LCM N=3 n (%)
<=25% increase	0	0
>25 - 50% increase	0	0
>50 - 75% increase	1 (33.3)	0
>75% increase	0	0

LCM=Lacosamide.

Note: Percentages are based on the number of subjects in the Safety Set who reported a history of absence seizures or an occurrence of absence seizures in the Combined Baseline or in the Treatment Period (N).

Reference: Listing 6.4

表 1.1-54　全集団の Prospective ベースライン期間に対する治療期間のミオクロニー発作発現日数が増加した被験者数と割合：SS

Table 8.7.3

Increase in Days with Myoclonic Seizures During the Treatment Period Compared to Prospective Baseline

Analysis Set: Safety Set

Variable	Placebo N=49 n (%)	LCM N=47 n (%)
<=25% increase	0	1 (2.1)
>25 - 50% increase	1 (2.0)	1 (2.1)
>50 - 75% increase	1 (2.0)	0
>75% increase	1 (2.0)	4 (8.5)

LCM=Lacosamide.

Note: Percentages are based on the number of subjects in the Safety Set who reported a history of myoclonic seizures or an occurrence of myoclonic seizures in the Combined Baseline or in the Treatment Period (N).

Reference: Listing 6.4

表 1.1-55　日本人集団の Prospective ベースライン期間に対する治療期間のミオクロニー発作発現日数が増加した被験者数と割合：SS

Table 8.7.3.1.0

Increase in Days with Myoclonic Seizures During the Treatment Period Compared to Prospective Baseline

Analysis Set: Safety Set - Japanese

Variable	Placebo N=9 n (%)	LCM N=5 n (%)
<=25% increase	0	1 (20.0)
>25 - 50% increase	0	0
>50 - 75% increase	0	0
>75% increase	0	0

LCM=Lacosamide.

Note: Percentages are based on the number of subjects in the Safety Set who reported a history of myoclonic seizures or an occurrence of myoclonic seizures in the Combined Baseline or in the Treatment Period (N).

Reference: Listing 6.4

1.1.4.3.2 治療期間中に新たな発作型を発現した被験者の割合

発作歴又は Combined ベースライン期間と比較して本治験の治療期間（増量期間+維持期間）中に新たな発作型を発現した被験者の割合を表 1.1-56（全集団）及び表 1.1-57（日本人集団）に示した。

全集団では、発作歴又は 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を発現した被験者の割合は低く、プラセボ群とラコサミド群で同程度であった。発作歴又は Combined ベースライン期間にミオクロニー発作を発現せず、治療期間中に新たなミオクロニー発作を発現した被験者は、プラセボ群及びラコサミド群で各 1 例（0.8%）であった。また、新たな分類不能のてんかん発作がラコサミド群で 1 例（0.8%）に認められた。この他に治療期間中に新たな発作型を発現した被験者はいなかった。

日本人集団では、発作歴又は Combined ベースライン期間に発作を発現せず、治療期間中に新たな発作型を発現した被験者はいなかった。

表 1.1-56　全集団の発作歴又は 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を発現した被験者の割合：SS

Table 8.8.2

Incidence of New Seizure Types During Treatment Period as Compared to Seizure History

Analysis Set: Safety Set

Seizure Type	Present in history or Combined Baseline	Present During Treatment Period					
		Placebo N=121			LCM N=121		
		Yes n (%)	No n (%)	Total n (%)	Yes n (%)	No n (%)	Total n (%)
Generalized seizures							
Absence (IIA)	Yes	21 (17.4)	21 (17.4)	42 (34.7)	20 (16.5)	31 (25.6)	51 (42.1)
	No	0	79 (65.3)	79 (65.3)	0	70 (57.9)	70 (57.9)
	Total	21 (17.4)	100 (82.6)	121 (100)	20 (16.5)	101 (83.5)	121 (100)
Myoclonic (IIB)	Yes	21 (17.4)	27 (22.3)	48 (39.7)	27 (22.3)	19 (15.7)	46 (38.0)
	No	1 (0.8)	72 (59.5)	73 (60.3)	1 (0.8)	74 (61.2)	75 (62.0)
	Total	22 (18.2)	99 (81.8)	121 (100)	28 (23.1)	93 (76.9)	121 (100)
Clonic (IIC)	Yes	1 (0.8)	1 (0.8)	2 (1.7)	0	3 (2.5)	3 (2.5)
	No	0	119 (98.3)	119 (98.3)	0	118 (97.5)	118 (97.5)
	Total	1 (0.8)	120 (99.2)	121 (100)	0	121 (100)	121 (100)
Tonic (IID)	Yes	0	1 (0.8)	1 (0.8)	0	2 (1.7)	2 (1.7)
	No	0	120 (99.2)	120 (99.2)	0	119 (98.3)	119 (98.3)
	Total	0	121 (100)	121 (100)	0	121 (100)	121 (100)

LCM=Lacosamide.

Note: n=number of subjects reporting at least one new seizure in that type.

Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.2.1

表 1.1-56　全集団の発作歴又は 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を発現した被験者の割合：SS（続き）

Table 8.8.2

Incidence of New Seizure Types During Treatment Period as Compared to Seizure History

Analysis Set: Safety Set

Seizure Type	Present in history or Combined Baseline	Present During Treatment Period					
		Placebo N=121			LCM N=121		
		Yes n (%)	No n (%)	Total n (%)	Yes n (%)	No n (%)	Total n (%)
Generalized seizures							
Tonic-clonic (IIE)	Yes	98 (81.0)	23 (19.0)	121 (100)	79 (65.3)	42 (34.7)	121 (100)
	No	0	0	0	0	0	0
	Total	98 (81.0)	23 (19.0)	121 (100)	79 (65.3)	42 (34.7)	121 (100)
Atonic (IIF)	Yes	1 (0.8)	2 (1.7)	3 (2.5)	1 (0.8)	1 (0.8)	2 (1.7)
	No	0	118 (97.5)	118 (97.5)	0	119 (98.3)	119 (98.3)
	Total	1 (0.8)	120 (99.2)	121 (100)	1 (0.8)	120 (99.2)	121 (100)
Partial onset seizures							
Simple partial (IA)	Yes	0	0	0	1 (0.8)	0	1 (0.8)
	No	0	121 (100)	121 (100)	0	120 (99.2)	120 (99.2)
	Total	0	121 (100)	121 (100)	1 (0.8)	120 (99.2)	121 (100)
Complex partial (IB)	Yes	0	0	0	0	0	0
	No	0	121 (100)	121 (100)	0	121 (100)	121 (100)
	Total	0	121 (100)	121 (100)	0	121 (100)	121 (100)

LCM=Lacosamide.

Note: n=number of subjects reporting at least one new seizure in that type.

Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.2.1

表 1.1-56　全集団の発作歴又は 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を発現した被験者の割合：SS（続き）

Table 8.8.2

Incidence of New Seizure Types During Treatment Period as Compared to Seizure History

Analysis Set: Safety Set

Seizure Type	Present in history or Combined Baseline	Present During Treatment Period					
		Placebo N=121			LCM N=121		
		Yes n (%)	No n (%)	Total n (%)	Yes n (%)	No n (%)	Total n (%)
Partial onset seizures							
Partial evolving to secondarily generalized (IC)	Yes	0	0	0	0	0	0
	No	0	121 (100)	121 (100)	0	121 (100)	121 (100)
	Total	0	121 (100)	121 (100)	0	121 (100)	121 (100)
Unclassified epileptic seizures (III)	Yes	0	0	0	1 (0.8)	1 (0.8)	2 (1.7)
	No	0	121 (100)	121 (100)	1 (0.8)	118 (97.5)	119 (98.3)
	Total	0	121 (100)	121 (100)	2 (1.7)	119 (98.3)	121 (100)

LCM=Lacosamide.

Note: n=number of subjects reporting at least one new seizure in that type.

Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.2.1

表 1.1-57　日本人集団の発作歴又は 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を発現した被験者の割合：SS

Table 8.8.2.1
Incidence of New Seizure Types During Treatment Period as Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or Combined Baseline	Present During Treatment Period					
		Placebo N=19			LCM N=11		
		Yes n (%)	No n (%)	Total n (%)	Yes n (%)	No n (%)	Total n (%)
Generalized seizures							
Absence (IIA)	Yes	2 (10.5)	1 (5.3)	3 (15.8)	0	3 (27.3)	3 (27.3)
	No	0	16 (84.2)	16 (84.2)	0	8 (72.7)	8 (72.7)
	Total	2 (10.5)	17 (89.5)	19 (100)	0	11 (100)	11 (100)
Myoclonic (IIB)	Yes	2 (10.5)	7 (36.8)	9 (47.4)	2 (18.2)	3 (27.3)	5 (45.5)
	No	0	10 (52.6)	10 (52.6)	0	6 (54.5)	6 (54.5)
	Total	2 (10.5)	17 (89.5)	19 (100)	2 (18.2)	9 (81.8)	11 (100)
Clonic (IIC)	Yes	0	0	0	0	1 (9.1)	1 (9.1)
	No	0	19 (100)	19 (100)	0	10 (90.9)	10 (90.9)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)
Tonic (IID)	Yes	0	0	0	0	0	0
	No	0	19 (100)	19 (100)	0	11 (100)	11 (100)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)

LCM=Lacosamide.
Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.2.1.

表 1.1-57　日本人集団の発作歴又は 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を発現した被験者の割合：SS（続き）

Table 8.8.2.1
Incidence of New Seizure Types During Treatment Period as Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or Combined Baseline	Present During Treatment Period					
		Placebo N=19			LCM N=11		
		Yes n (%)	No n (%)	Total n (%)	Yes n (%)	No n (%)	Total n (%)
Generalized seizures							
Tonic-clonic (IIE)	Yes	17 (89.5)	2 (10.5)	19 (100)	5 (45.5)	6 (54.5)	11 (100)
	No	0	0	0	0	0	0
	Total	17 (89.5)	2 (10.5)	19 (100)	5 (45.5)	6 (54.5)	11 (100)
Atonic (IIF)	Yes	0	0	0	0	0	0
	No	0	19 (100)	19 (100)	0	11 (100)	11 (100)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)
Partial onset seizures							
Simple partial (IA)	Yes	0	0	0	0	0	0
	No	0	19 (100)	19 (100)	0	11 (100)	11 (100)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)
Complex partial (IB)	Yes	0	0	0	0	0	0
	No	0	19 (100)	19 (100)	0	11 (100)	11 (100)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)

LCM=Lacosamide.
Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.2.1.

表 1.1-57　日本人集団の発作歴又は 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を発現した被験者の割合：SS（続き）

Table 8.8.2.1

Incidence of New Seizure Types During Treatment Period as Compared to Seizure History

Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or Combined Baseline	Present During Treatment Period					
		Placebo N=19			LCM N=11		
		Yes n (%)	No n (%)	Total n (%)	Yes n (%)	No n (%)	Total n (%)
Partial onset seizures							
Partial evolving to secondarily generalized (IC)	Yes	0	0	0	0	0	0
	No	0	19 (100)	19 (100)	0	11 (100)	11 (100)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)
Unclassified epileptic seizures (III)	Yes	0	0	0	0	0	0
	No	0	19 (100)	19 (100)	0	11 (100)	11 (100)
	Total	0	19 (100)	19 (100)	0	11 (100)	11 (100)

LCM=Lacosamide.

Note: n=number of subjects reporting at least one new seizure in that type.

Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.2.1.

1.1.4.3.3 臨床検査、バイタルサイン（体重及び身長を含む）、12 誘導心電図及び身体所見（神経学的検査を含む）

本治験でのスクリーニング時、ベースライン及び各来院時の測定値、並びにベースラインからの変化量について、血液学的検査を表 1.1-58（全集団）及び表 1.1-59（日本人集団）に、血液生化学検査を表 1.1-60（全集団）及び表 1.1-61（日本人集団）に示した。また、バイタルサイン（体重及び身長を含む）のスクリーニング時、ベースライン及び各来院時の測定値、並びにベースラインからの変化量を表 1.1-62（全集団）及び表 1.1-63（日本人集団）に示した。

全体的に、臨床検査の結果から、ラコサミド投与に起因すると考えられる臨床的に重要な徴候は認められなかった。

12 誘導心電図では、PR 間隔の変化量（平均値）を除くすべてのパラメータにお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）が小さかった。PR 間隔の変化量（平均値）は、プラセボ群が−0.79 msec 及びラコサミド群が 9.96 msec であった。これは、既知のラコサミドの安全性プロファイルと一致していた。12 誘導心電図の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。全体的に、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、プラセボ群及びラコサミド群で同程度であった。

全体的に、バイタルサイン及び神経学的検査の結果から、ラコサミド投与に起因すると考えられる臨床的に重要な徴候は認められなかった。

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hemoglobin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	119	138.4	13.9	139.0	105	173						
V2, Wk 0 (BL)	116	138.3	13.6	139.0	108	163						
Baseline	121	138.4	13.4	139.0	108	163						
V3, Wk 2 (T)	115	138.7	14.0	138.0	106	167	115	0.3	5.6	0.0	-22	14
V5, Wk 6 (M)	70	138.0	14.4	138.0	107	173	70	0.2	7.2	0.0	-23	16
V7, Wk 12 (M)	53	137.3	14.5	136.0	112	166	53	-0.6	6.0	-1.0	-14	15
V9, Wk 20 (M)	37	138.9	14.4	142.0	107	168	37	0.5	5.8	0.0	-9	12
V10, Wk 24 (M)	37	138.1	13.9	138.0	109	165	37	-0.4	6.0	-1.0	-15	12
Early Termination Visit	78	136.1	15.7	137.0	59	164	78	-1.7	10.1	-1.0	-76	14
Last Visit	121	137.4	15.4	137.0	59	166	121	-1.1	9.1	-1.0	-76	15
Min Post-BL	121	134.2	15.1	135.0	59	164	121	-4.3	8.4	-3.0	-76	10
Max Post-BL	121	141.9	13.8	142.0	108	173	121	3.4	5.4	3.0	-11	16

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hemoglobin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	139.2	14.1	139.0	90	165						
V2, Wk 0 (BL)	120	139.1	15.0	139.0	87	172						
Baseline	121	139.1	14.9	139.0	87	172						
V3, Wk 2 (T)	114	138.0	14.7	139.0	88	169	114	-1.0	6.1	-1.0	-17	14
V5, Wk 6 (M)	79	139.2	15.6	139.0	91	172	79	0.2	6.2	1.0	-16	19
V7, Wk 12 (M)	69	138.0	14.6	138.0	92	164	69	-0.9	5.4	-1.0	-14	13
V9, Wk 20 (M)	58	140.2	16.3	140.0	85	169	58	0.4	5.5	0.0	-10	21
V10, Wk 24 (M)	60	139.7	15.8	141.0	92	170	60	-0.1	6.5	0.0	-12	28
Early Termination Visit	52	138.8	15.4	140.5	87	171	52	0.6	7.0	0.0	-16	17
Last Visit	119	139.5	15.3	140.0	87	171	119	0.4	6.6	0.0	-16	28
Min Post-BL	119	134.9	14.8	135.0	85	165	119	-4.2	5.9	-4.0	-17	11
Max Post-BL	119	142.9	14.8	144.0	91	172	119	3.8	6.0	3.0	-16	28

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hematocrit (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	119	42.41	4.39	42.70	33.1	53.6						
V2, Wk 0 (BL)	116	42.41	4.13	42.25	33.1	51.6						
Baseline	121	42.36	4.07	42.20	33.1	51.6						
V3, Wk 2 (T)	115	42.56	4.52	42.40	33.0	55.9	115	0.18	1.99	0.30	-6.5	6.4
V5, Wk 6 (M)	70	42.22	4.48	41.60	33.4	52.9	70	0.31	2.58	0.20	-6.2	7.8
V7, Wk 12 (M)	53	41.72	4.27	42.10	33.2	51.1	53	-0.05	2.45	0.40	-4.7	4.9
V9, Wk 20 (M)	37	41.76	4.21	42.20	33.2	51.0	37	-0.11	3.05	-0.20	-5.9	7.4
V10, Wk 24 (M)	37	41.42	3.71	41.70	33.3	48.6	37	-0.45	3.04	0.00	-6.2	6.0
Early Termination Visit	78	42.81	5.12	42.70	18.9	57.2	78	0.36	3.58	0.20	-23.0	7.7
Last Visit	121	42.57	4.76	42.40	18.9	57.2	121	0.21	3.41	0.10	-23.0	7.7
Min Post-BL	121	41.03	4.59	41.10	18.9	55.9	121	-1.33	2.95	-0.80	-23.0	6.4
Max Post-BL	121	44.19	4.35	44.00	34.4	57.2	121	1.83	2.22	1.70	-3.8	7.8

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hematocrit (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	42.58	4.43	42.30	29.8	55.0						
V2, Wk 0 (BL)	120	42.68	4.67	42.10	28.5	56.5						
Baseline	121	42.68	4.65	42.10	28.5	56.5						
V3, Wk 2 (T)	114	42.60	4.65	42.55	28.6	56.6	114	-0.07	2.30	-0.45	-6.8	5.6
V5, Wk 6 (M)	79	43.06	4.86	43.10	29.3	56.5	79	0.27	2.83	0.40	-6.6	10.5
V7, Wk 12 (M)	69	42.79	4.49	42.90	31.7	52.9	69	0.14	2.76	0.50	-8.0	5.1
V9, Wk 20 (M)	58	43.35	4.87	43.30	28.3	54.6	58	0.55	2.89	0.55	-6.5	6.8
V10, Wk 24 (M)	60	43.08	4.98	42.65	29.8	58.2	60	0.14	3.86	0.50	-7.8	11.5
Early Termination Visit	52	42.41	4.47	42.25	30.4	55.4	52	-0.09	2.00	-0.05	-4.8	3.6
Last Visit	119	42.83	4.67	42.50	29.8	58.2	119	0.13	3.08	0.40	-7.8	11.5
Min Post-BL	119	41.07	4.17	41.10	28.3	51.9	119	-1.63	2.33	-1.50	-8.0	3.3
Max Post-BL	119	44.61	4.85	44.00	30.8	58.2	119	1.91	2.71	1.60	-3.8	11.5

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Platelets (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	119	244.6	62.3	237.0	74	418						
V2, Wk 0 (BL)	114	241.3	65.6	239.5	79	440						
Baseline	120	242.4	66.2	239.0	79	440						
V3, Wk 2 (T)	115	245.9	70.0	236.0	76	429	114	3.5	39.7	1.5	-119	151
V5, Wk 6 (M)	68	242.9	67.1	242.0	68	410	67	3.3	37.5	-1.0	-82	178
V7, Wk 12 (M)	52	235.8	78.0	214.0	74	440	52	0.7	41.9	-4.0	-103	154
V9, Wk 20 (M)	37	235.5	61.8	229.0	110	348	37	5.2	29.7	1.0	-52	91
V10, Wk 24 (M)	37	236.3	53.5	234.0	109	325	37	6.0	36.6	5.0	-58	163
Early Termination Visit	78	243.1	67.7	235.0	52	426	77	-3.9	45.2	-1.0	-174	124
Last Visit	121	241.9	62.8	235.0	52	426	120	-0.2	42.5	3.0	-174	163
Min Post-BL	121	223.2	62.8	219.0	52	426	120	-18.9	38.3	-15.0	-174	91
Max Post-BL	121	263.9	69.2	255.0	95	440	120	22.0	37.0	17.5	-80	178

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Platelets (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	119	257.5	72.6	256.0	71	551						
V2, Wk 0 (BL)	120	256.2	67.9	258.5	79	450						
Baseline	121	256.4	67.6	260.0	79	450						
V3, Wk 2 (T)	114	255.8	66.0	249.5	130	561	114	-3.3	40.9	-3.5	-153	125
V5, Wk 6 (M)	79	258.3	68.5	247.0	126	494	79	-1.7	41.1	-4.0	-97	121
V7, Wk 12 (M)	69	256.0	70.0	245.0	127	565	69	-2.9	41.7	-5.0	-163	140
V9, Wk 20 (M)	58	251.9	69.6	238.5	111	490	58	-3.9	34.9	-1.0	-100	86
V10, Wk 24 (M)	60	247.8	76.8	239.0	101	560	60	-7.7	40.1	-8.0	-126	110
Early Termination Visit	50	251.3	75.0	241.5	78	473	50	-2.9	34.4	-3.0	-79	102
Last Visit	119	250.2	73.9	240.0	78	560	119	-6.4	39.1	-5.0	-153	110
Min Post-BL	119	230.9	64.0	229.0	78	490	119	-25.7	38.3	-25.0	-187	102
Max Post-BL	119	273.9	71.4	266.0	78	565	119	17.3	39.7	17.0	-153	140

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Erythrocytes (10^12/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	119	4.580	0.424	4.550	3.68	5.70						
V2, Wk 0 (BL)	116	4.580	0.412	4.580	3.74	5.65						
Baseline	121	4.578	0.411	4.590	3.74	5.65						
V3, Wk 2 (T)	115	4.569	0.439	4.560	3.58	5.62	115	-0.005	0.190	0.010	-0.76	0.52
V5, Wk 6 (M)	70	4.564	0.475	4.490	3.64	5.75	70	0.006	0.274	-0.005	-0.91	0.56
V7, Wk 12 (M)	53	4.528	0.466	4.510	3.25	5.57	53	-0.037	0.212	-0.040	-0.51	0.39
V9, Wk 20 (M)	37	4.559	0.382	4.510	3.94	5.56	37	-0.013	0.236	-0.020	-0.46	0.53
V10, Wk 24 (M)	37	4.535	0.367	4.560	3.71	5.34	37	-0.037	0.223	-0.040	-0.64	0.45
Early Termination Visit	78	4.506	0.498	4.550	1.95	5.53	78	-0.054	0.339	-0.040	-2.53	0.48
Last Visit	121	4.537	0.466	4.560	1.95	5.53	121	-0.041	0.305	-0.040	-2.53	0.48
Min Post-BL	121	4.417	0.472	4.430	1.95	5.38	121	-0.161	0.287	-0.110	-2.53	0.32
Max Post-BL	121	4.692	0.424	4.680	3.59	5.75	121	0.114	0.186	0.100	-0.24	0.56

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Erythrocytes (10^12/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	4.686	0.413	4.665	3.74	5.60						
V2, Wk 0 (BL)	120	4.666	0.435	4.620	3.82	5.90						
Baseline	121	4.667	0.433	4.620	3.82	5.90						
V3, Wk 2 (T)	114	4.632	0.417	4.610	3.86	5.70	114	-0.026	0.211	-0.050	-0.76	0.66
V5, Wk 6 (M)	79	4.656	0.445	4.610	3.37	5.80	79	0.010	0.239	0.020	-0.60	0.67
V7, Wk 12 (M)	69	4.622	0.402	4.590	3.55	5.53	69	-0.031	0.193	-0.040	-0.59	0.41
V9, Wk 20 (M)	58	4.721	0.415	4.710	3.97	5.58	58	0.023	0.198	0.000	-0.35	0.57
V10, Wk 24 (M)	60	4.700	0.417	4.740	3.53	5.54	60	0.003	0.196	-0.015	-0.32	0.51
Early Termination Visit	52	4.687	0.448	4.655	4.01	5.83	52	0.028	0.215	0.020	-0.41	0.53
Last Visit	119	4.690	0.434	4.730	3.53	5.83	119	0.022	0.202	0.020	-0.41	0.53
Min Post-BL	119	4.526	0.428	4.510	3.37	5.70	119	-0.142	0.208	-0.130	-0.76	0.37
Max Post-BL	119	4.808	0.424	4.790	3.91	5.83	119	0.140	0.196	0.150	-0.41	0.67

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Leukocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	119	6.86	2.07	6.60	2.9	14.6						
V2, Wk 0 (BL)	116	6.85	1.94	6.55	2.9	14.9						
Baseline	121	6.87	1.94	6.70	2.9	14.9						
V3, Wk 2 (T)	115	6.69	1.82	6.40	2.8	11.0	115	-0.14	1.57	-0.20	-5.0	3.8
V5, Wk 6 (M)	70	6.66	2.11	6.40	3.0	13.5	70	-0.16	2.04	0.05	-5.5	6.3
V7, Wk 12 (M)	53	6.56	2.27	6.40	2.5	13.4	53	-0.17	1.95	0.00	-5.0	3.8
V9, Wk 20 (M)	37	6.77	1.87	6.40	4.1	11.6	37	-0.09	1.39	-0.10	-4.0	3.4
V10, Wk 24 (M)	37	7.12	2.53	6.30	4.0	15.5	37	0.26	2.00	0.20	-4.9	6.7
Early Termination Visit	78	6.99	2.01	6.70	2.5	11.4	78	0.16	2.14	0.55	-7.1	5.3
Last Visit	121	7.05	2.14	6.70	2.5	15.5	121	0.17	2.16	0.40	-7.1	6.7
Min Post-BL	121	5.97	1.77	5.90	2.5	11.1	121	-0.90	1.69	-0.60	-7.1	3.1
Max Post-BL	121	8.00	2.17	7.50	4.3	15.5	121	1.13	1.93	1.10	-5.0	6.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Leukocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	119	6.92	2.10	6.70	3.4	13.4						
V2, Wk 0 (BL)	120	6.85	1.97	6.40	3.1	14.1						
Baseline	121	6.84	1.96	6.40	3.1	14.1						
V3, Wk 2 (T)	114	6.83	1.95	6.70	3.2	13.1	114	-0.05	1.38	0.00	-4.6	4.9
V5, Wk 6 (M)	78	6.55	1.79	6.50	3.6	11.9	78	-0.29	1.73	-0.20	-6.4	4.6
V7, Wk 12 (M)	69	6.59	2.12	6.00	3.5	15.3	69	-0.13	2.05	-0.10	-4.8	10.2
V9, Wk 20 (M)	58	6.54	1.79	6.30	3.6	11.7	58	-0.02	1.37	-0.20	-2.2	4.4
V10, Wk 24 (M)	60	6.46	1.81	6.00	3.2	11.3	60	-0.09	1.58	-0.10	-4.3	3.8
Early Termination Visit	51	7.02	1.99	6.80	2.9	12.9	51	-0.02	1.33	-0.10	-4.0	3.5
Last Visit	119	6.72	1.90	6.20	2.9	12.9	119	-0.12	1.51	-0.10	-4.6	3.8
Min Post-BL	119	5.83	1.62	5.60	2.9	11.4	119	-1.01	1.48	-1.00	-6.4	3.5
Max Post-BL	119	7.76	2.10	7.60	3.2	15.3	119	0.93	1.72	0.80	-4.6	10.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	0.03	0.05	0.00	0.0	0.2						
V2, Wk 0 (BL)	116	0.03	0.05	0.00	0.0	0.2						
Baseline	121	0.03	0.05	0.00	0.0	0.2						
V3, Wk 2 (T)	115	0.03	0.05	0.00	0.0	0.2	115	-0.00	0.05	0.00	-0.1	0.1
V5, Wk 6 (M)	69	0.02	0.05	0.00	0.0	0.2	69	0.00	0.04	0.00	-0.1	0.1
V7, Wk 12 (M)	53	0.02	0.04	0.00	0.0	0.1	53	0.01	0.04	0.00	-0.1	0.1
V9, Wk 20 (M)	35	0.02	0.04	0.00	0.0	0.1	35	0.00	0.05	0.00	-0.1	0.1
V10, Wk 24 (M)	37	0.02	0.04	0.00	0.0	0.1	37	-0.00	0.04	0.00	-0.1	0.1
Early Termination Visit	78	0.02	0.05	0.00	0.0	0.2	78	-0.01	0.04	0.00	-0.1	0.1
Last Visit	121	0.02	0.05	0.00	0.0	0.2	121	-0.00	0.04	0.00	-0.1	0.1
Min Post-BL	121	0.01	0.03	0.00	0.0	0.1	121	-0.02	0.04	0.00	-0.1	0.1
Max Post-BL	121	0.04	0.05	0.00	0.0	0.2	121	0.01	0.05	0.00	-0.1	0.1

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	0.03	0.05	0.00	0.0	0.2						
V2, Wk 0 (BL)	120	0.03	0.04	0.00	0.0	0.1						
Baseline	121	0.03	0.04	0.00	0.0	0.1						
V3, Wk 2 (T)	114	0.02	0.04	0.00	0.0	0.1	114	-0.00	0.05	0.00	-0.1	0.1
V5, Wk 6 (M)	77	0.02	0.05	0.00	0.0	0.2	77	-0.00	0.05	0.00	-0.1	0.2
V7, Wk 12 (M)	69	0.02	0.04	0.00	0.0	0.2	69	-0.01	0.05	0.00	-0.1	0.1
V9, Wk 20 (M)	58	0.02	0.04	0.00	0.0	0.2	58	-0.00	0.04	0.00	-0.1	0.2
V10, Wk 24 (M)	60	0.02	0.04	0.00	0.0	0.1	60	-0.00	0.05	0.00	-0.1	0.1
Early Termination Visit	51	0.02	0.04	0.00	0.0	0.1	51	-0.01	0.04	0.00	-0.1	0.1
Last Visit	119	0.02	0.04	0.00	0.0	0.1	119	-0.01	0.04	0.00	-0.1	0.1
Min Post-BL	119	0.01	0.03	0.00	0.0	0.1	119	-0.02	0.04	0.00	-0.1	0.1
Max Post-BL	119	0.04	0.05	0.00	0.0	0.2	119	0.01	0.05	0.00	-0.1	0.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	0.56	0.50	0.40	0.1	3.2						
V2, Wk 0 (BL)	116	0.55	0.39	0.40	0.1	2.0						
Baseline	121	0.55	0.39	0.40	0.1	2.0						
V3, Wk 2 (T)	115	0.56	0.43	0.40	0.0	2.9	115	0.01	0.31	0.00	-1.0	0.9
V5, Wk 6 (M)	69	0.58	0.50	0.50	0.1	3.0	69	0.04	0.34	0.00	-0.8	1.6
V7, Wk 12 (M)	53	0.51	0.35	0.40	0.1	1.7	53	0.05	0.27	0.00	-0.6	1.0
V9, Wk 20 (M)	36	0.49	0.28	0.45	0.0	1.1	36	0.02	0.22	0.00	-0.5	0.5
V10, Wk 24 (M)	37	0.48	0.33	0.40	0.1	1.7	37	0.02	0.26	0.00	-0.6	0.9
Early Termination Visit	78	0.59	0.53	0.50	0.1	3.6	78	-0.00	0.41	0.00	-1.3	1.8
Last Visit	121	0.55	0.46	0.50	0.1	3.6	121	-0.00	0.36	0.00	-1.3	1.8
Min Post-BL	121	0.39	0.30	0.30	0.0	2.2	121	-0.16	0.29	-0.10	-1.3	0.7
Max Post-BL	121	0.72	0.54	0.60	0.1	3.6	121	0.17	0.38	0.10	-1.3	1.8

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	0.55	0.44	0.40	0.0	2.7						
V2, Wk 0 (BL)	120	0.53	0.33	0.50	0.1	1.8						
Baseline	121	0.53	0.33	0.50	0.1	1.8						
V3, Wk 2 (T)	114	0.50	0.31	0.40	0.1	1.7	114	-0.02	0.30	0.00	-1.2	0.9
V5, Wk 6 (M)	77	0.54	0.45	0.40	0.1	2.5	77	-0.01	0.37	0.00	-1.2	1.7
V7, Wk 12 (M)	69	0.51	0.38	0.40	0.1	2.5	69	-0.02	0.39	0.00	-1.1	1.9
V9, Wk 20 (M)	58	0.55	0.47	0.40	0.1	2.7	58	0.04	0.35	0.00	-0.5	2.2
V10, Wk 24 (M)	60	0.55	0.45	0.40	0.1	2.5	60	0.02	0.37	0.00	-1.2	1.4
Early Termination Visit	51	0.48	0.33	0.40	0.1	1.4	51	-0.05	0.28	0.00	-0.9	0.7
Last Visit	119	0.51	0.39	0.40	0.1	2.5	119	-0.01	0.33	0.00	-1.2	1.4
Min Post-BL	119	0.36	0.24	0.30	0.1	1.3	119	-0.17	0.24	-0.10	-1.2	0.6
Max Post-BL	119	0.71	0.52	0.60	0.1	2.7	119	0.18	0.43	0.10	-1.1	2.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	0.15	0.12	0.10	0.0	0.7						
V2, Wk 0 (BL)	116	0.17	0.11	0.10	0.0	0.9						
Baseline	121	0.16	0.11	0.10	0.0	0.9						
V3, Wk 2 (T)	115	0.16	0.11	0.10	0.0	0.5	115	-0.01	0.10	0.00	-0.5	0.3
V5, Wk 6 (M)	69	0.17	0.15	0.10	0.0	0.9	69	0.01	0.16	0.00	-0.4	0.7
V7, Wk 12 (M)	53	0.17	0.14	0.10	0.0	0.6	53	0.02	0.12	0.00	-0.4	0.3
V9, Wk 20 (M)	36	0.16	0.12	0.10	0.0	0.5	36	0.00	0.15	0.00	-0.7	0.3
V10, Wk 24 (M)	37	0.18	0.13	0.10	0.0	0.6	37	0.02	0.17	0.00	-0.7	0.5
Early Termination Visit	78	0.16	0.14	0.10	0.0	0.8	78	-0.01	0.13	0.00	-0.3	0.4
Last Visit	121	0.17	0.13	0.10	0.0	0.8	121	0.00	0.14	0.00	-0.7	0.5
Min Post-BL	121	0.12	0.10	0.10	0.0	0.5	121	-0.04	0.12	0.00	-0.7	0.3
Max Post-BL	121	0.22	0.16	0.20	0.0	0.9	121	0.06	0.14	0.00	-0.4	0.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	0.18	0.20	0.10	0.0	1.7						
V2, Wk 0 (BL)	120	0.20	0.19	0.10	0.0	1.2						
Baseline	121	0.20	0.19	0.10	0.0	1.2						
V3, Wk 2 (T)	114	0.20	0.18	0.10	0.0	1.0	114	-0.01	0.13	0.00	-0.6	0.7
V5, Wk 6 (M)	77	0.20	0.19	0.10	0.0	1.1	77	-0.01	0.13	0.00	-0.6	0.5
V7, Wk 12 (M)	69	0.18	0.18	0.10	0.0	1.1	69	-0.03	0.15	0.00	-0.9	0.3
V9, Wk 20 (M)	58	0.22	0.24	0.20	0.0	1.6	58	0.01	0.19	0.00	-0.9	0.5
V10, Wk 24 (M)	60	0.19	0.26	0.10	0.0	1.8	60	-0.02	0.19	0.00	-0.9	0.6
Early Termination Visit	51	0.16	0.12	0.10	0.0	0.6	51	-0.02	0.11	0.00	-0.5	0.3
Last Visit	119	0.18	0.20	0.10	0.0	1.8	119	-0.02	0.15	0.00	-0.9	0.6
Min Post-BL	119	0.14	0.13	0.10	0.0	1.0	119	-0.06	0.13	0.00	-0.9	0.3
Max Post-BL	119	0.25	0.23	0.20	0.0	1.8	119	0.05	0.15	0.00	-0.6	0.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	2.22	1.69	1.75	0.0	10.7						
V2, Wk 0 (BL)	116	2.38	1.50	2.05	0.0	8.8						
Baseline	121	2.34	1.50	2.00	0.0	8.8						
V3, Wk 2 (T)	115	2.26	1.50	1.80	0.2	8.3	115	-0.07	1.25	0.00	-5.0	4.2
V5, Wk 6 (M)	69	2.52	1.73	2.10	0.3	8.7	69	0.19	1.58	0.10	-3.7	5.5
V7, Wk 12 (M)	53	2.47	2.02	1.90	0.1	10.7	53	0.35	1.67	0.10	-2.8	6.9
V9, Wk 20 (M)	36	2.53	1.75	2.15	0.6	8.1	36	0.34	1.71	0.30	-5.5	4.9
V10, Wk 24 (M)	37	2.61	2.11	1.70	0.1	10.1	37	0.44	2.09	0.20	-5.3	8.0
Early Termination Visit	78	2.47	2.07	1.80	0.1	11.4	78	0.00	1.91	-0.20	-4.9	5.9
Last Visit	121	2.45	2.04	1.70	0.1	11.4	121	0.12	1.93	-0.10	-5.3	8.0
Min Post-BL	121	1.69	1.37	1.20	0.1	8.3	121	-0.65	1.37	-0.50	-5.5	4.2
Max Post-BL	121	3.24	2.25	2.60	0.1	11.4	121	0.91	1.91	0.60	-3.3	8.0

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	2.46	2.96	1.95	0.0	29.6						
V2, Wk 0 (BL)	120	2.84	3.07	2.05	0.0	26.4						
Baseline	121	2.83	3.06	2.00	0.0	26.4						
V3, Wk 2 (T)	114	2.88	2.67	2.20	0.0	21.4	114	-0.02	1.97	0.00	-9.2	10.5
V5, Wk 6 (M)	77	2.83	2.54	2.30	0.0	17.7	77	-0.20	2.13	0.20	-11.3	4.7
V7, Wk 12 (M)	69	2.67	2.75	2.10	0.1	19.8	69	-0.39	2.26	0.00	-12.8	5.3
V9, Wk 20 (M)	58	3.30	4.18	2.15	0.4	30.0	58	0.03	2.90	0.00	-14.2	7.5
V10, Wk 24 (M)	60	2.91	3.95	2.05	0.4	30.1	60	-0.29	2.42	-0.10	-12.7	5.4
Early Termination Visit	51	2.28	1.53	1.90	0.2	7.0	51	-0.07	1.45	0.10	-5.8	3.9
Last Visit	119	2.66	3.01	2.00	0.2	30.1	119	-0.17	1.96	0.00	-12.7	5.4
Min Post-BL	119	1.96	1.95	1.50	0.0	17.7	119	-0.87	1.99	-0.40	-14.2	3.9
Max Post-BL	119	3.62	3.36	2.80	0.2	30.1	119	0.79	2.13	0.50	-9.2	10.5

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	2.31	0.76	2.15	1.2	5.5						
V2, Wk 0 (BL)	116	2.32	0.75	2.20	1.1	4.9						
Baseline	121	2.30	0.74	2.20	1.1	4.9						
V3, Wk 2 (T)	115	2.31	0.77	2.20	1.0	5.1	115	0.00	0.54	0.00	-1.4	1.9
V5, Wk 6 (M)	69	2.26	0.93	2.00	0.9	5.8	69	-0.02	0.74	-0.10	-2.2	2.9
V7, Wk 12 (M)	53	2.28	0.93	2.10	0.5	5.5	53	-0.02	0.66	-0.10	-1.4	2.5
V9, Wk 20 (M)	36	2.29	0.83	2.10	1.0	4.7	36	-0.07	0.66	-0.20	-1.4	1.8
V10, Wk 24 (M)	37	2.41	0.96	2.20	1.3	6.6	37	0.07	0.66	0.00	-1.2	2.1
Early Termination Visit	78	2.27	0.77	2.10	0.7	5.2	78	-0.03	0.55	0.00	-1.9	1.1
Last Visit	121	2.29	0.83	2.10	0.7	6.6	121	-0.01	0.59	0.00	-1.9	2.1
Min Post-BL	121	1.98	0.70	1.90	0.5	4.9	121	-0.32	0.55	-0.20	-2.2	0.9
Max Post-BL	121	2.60	0.92	2.40	1.2	6.6	121	0.29	0.62	0.20	-1.2	2.9

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	2.34	0.75	2.20	0.8	5.4						
V2, Wk 0 (BL)	120	2.37	0.78	2.30	0.7	4.8						
Baseline	121	2.37	0.78	2.30	0.7	4.8						
V3, Wk 2 (T)	114	2.34	0.79	2.20	0.8	4.9	114	-0.08	0.49	-0.10	-2.1	1.2
V5, Wk 6 (M)	77	2.24	0.69	2.10	0.8	4.2	77	-0.15	0.53	-0.20	-2.1	1.2
V7, Wk 12 (M)	69	2.34	0.79	2.20	1.0	4.5	69	-0.01	0.55	-0.10	-0.9	1.7
V9, Wk 20 (M)	58	2.28	0.67	2.10	1.0	3.7	58	-0.11	0.45	-0.10	-1.1	0.9
V10, Wk 24 (M)	60	2.20	0.65	2.20	0.9	3.7	60	-0.19	0.47	-0.20	-1.3	0.9
Early Termination Visit	51	2.32	0.82	2.20	1.0	4.7	51	-0.03	0.44	0.00	-1.0	0.8
Last Visit	119	2.25	0.74	2.20	0.9	4.7	119	-0.13	0.47	-0.20	-1.3	0.9
Min Post-BL	119	1.99	0.68	2.00	0.8	4.5	119	-0.39	0.44	-0.30	-2.1	0.6
Max Post-BL	119	2.62	0.83	2.50	1.0	4.9	119	0.24	0.46	0.20	-1.2	1.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	34.71	9.52	33.55	9.8	71.8						
V2, Wk 0 (BL)	116	34.66	9.75	33.75	13.4	74.3						
Baseline	121	34.41	9.75	33.60	13.4	74.3						
V3, Wk 2 (T)	115	35.05	9.05	33.30	17.1	75.3	115	0.36	7.39	0.20	-17.8	23.3
V5, Wk 6 (M)	69	35.08	10.43	33.30	9.5	62.1	69	0.88	9.91	0.70	-25.5	24.6
V7, Wk 12 (M)	53	35.06	9.35	33.10	18.3	58.4	53	-0.01	9.50	0.20	-23.6	26.0
V9, Wk 20 (M)	36	34.92	10.10	34.70	12.5	59.4	36	-0.66	9.82	-1.25	-20.3	28.7
V10, Wk 24 (M)	37	34.78	9.46	35.20	19.8	57.4	37	-0.65	8.67	-2.40	-16.1	18.3
Early Termination Visit	78	33.80	10.79	33.85	10.1	72.6	78	-0.71	8.74	-0.95	-27.4	25.7
Last Visit	121	33.69	10.38	33.70	10.1	72.6	121	-0.73	8.87	-1.40	-27.4	25.7
Min Post-BL	121	29.29	9.34	28.40	9.5	72.6	121	-5.13	8.04	-4.80	-27.4	12.2
Max Post-BL	121	38.51	9.95	38.00	10.5	75.3	121	4.10	7.86	3.60	-14.1	28.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	34.76	9.14	35.95	16.2	58.7						
V2, Wk 0 (BL)	120	35.24	9.01	34.20	12.9	55.8						
Baseline	121	35.29	8.99	34.40	12.9	55.8						
V3, Wk 2 (T)	114	35.08	9.66	34.65	10.4	64.2	114	-0.67	7.15	-0.80	-21.0	20.3
V5, Wk 6 (M)	77	35.36	9.09	35.20	13.3	60.2	77	-0.63	7.81	0.00	-23.1	16.8
V7, Wk 12 (M)	69	36.19	8.81	36.80	13.9	56.0	69	0.41	7.69	1.90	-20.4	17.2
V9, Wk 20 (M)	58	35.85	8.88	36.00	16.9	56.9	58	-1.29	7.56	-1.10	-19.4	19.2
V10, Wk 24 (M)	60	34.96	8.84	35.20	19.5	52.1	60	-2.24	7.22	-1.80	-21.3	19.2
Early Termination Visit	51	34.01	10.43	34.80	12.4	56.1	51	0.32	7.23	0.80	-13.8	18.4
Last Visit	119	34.32	9.44	34.90	12.4	56.1	119	-1.02	7.20	-0.50	-21.3	19.2
Min Post-BL	119	29.88	8.69	29.20	10.4	55.9	119	-5.45	7.62	-4.80	-23.1	18.4
Max Post-BL	119	39.39	9.34	39.00	12.4	64.2	119	4.05	6.72	3.90	-13.8	20.3

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	0.53	0.17	0.50	0.2	1.0						
V2, Wk 0 (BL)	116	0.57	0.21	0.50	0.2	1.3						
Baseline	121	0.57	0.20	0.50	0.2	1.3						
V3, Wk 2 (T)	115	0.55	0.21	0.50	0.1	1.3	115	-0.02	0.21	0.00	-0.6	0.6
V5, Wk 6 (M)	69	0.54	0.20	0.50	0.2	1.1	69	-0.04	0.21	0.00	-0.7	0.4
V7, Wk 12 (M)	53	0.55	0.18	0.60	0.3	1.1	53	-0.05	0.23	0.00	-0.7	0.6
V9, Wk 20 (M)	36	0.54	0.15	0.50	0.3	0.9	36	-0.08	0.20	0.00	-0.6	0.2
V10, Wk 24 (M)	37	0.57	0.16	0.60	0.3	1.1	37	-0.05	0.22	0.00	-0.7	0.4
Early Termination Visit	78	0.53	0.21	0.50	0.2	1.3	78	-0.01	0.19	0.00	-0.6	0.7
Last Visit	121	0.54	0.19	0.50	0.3	1.3	121	-0.02	0.20	0.00	-0.7	0.7
Min Post-BL	121	0.45	0.15	0.40	0.1	0.9	121	-0.12	0.19	-0.10	-0.7	0.3
Max Post-BL	121	0.64	0.22	0.60	0.3	1.3	121	0.08	0.20	0.10	-0.5	0.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	0.56	0.20	0.50	0.2	1.3						
V2, Wk 0 (BL)	120	0.55	0.21	0.50	0.0	1.3						
Baseline	121	0.55	0.21	0.50	0.0	1.3						
V3, Wk 2 (T)	114	0.55	0.20	0.50	0.2	1.3	114	-0.00	0.16	0.00	-0.5	0.5
V5, Wk 6 (M)	77	0.54	0.20	0.50	0.1	1.1	77	-0.01	0.16	0.00	-0.5	0.4
V7, Wk 12 (M)	69	0.55	0.22	0.50	0.2	1.3	69	-0.01	0.17	0.00	-0.4	0.7
V9, Wk 20 (M)	58	0.55	0.20	0.50	0.2	1.1	58	-0.00	0.15	0.00	-0.3	0.3
V10, Wk 24 (M)	60	0.55	0.19	0.50	0.2	1.2	60	0.00	0.20	0.00	-0.7	0.4
Early Termination Visit	51	0.58	0.20	0.50	0.3	1.2	51	0.03	0.21	0.00	-0.6	0.5
Last Visit	119	0.56	0.19	0.50	0.2	1.2	119	0.01	0.20	0.00	-0.7	0.5
Min Post-BL	119	0.46	0.16	0.40	0.1	0.9	119	-0.09	0.17	-0.10	-0.7	0.3
Max Post-BL	119	0.66	0.22	0.70	0.2	1.3	119	0.11	0.17	0.10	-0.5	0.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	8.05	2.50	7.80	2.6	16.6						
V2, Wk 0 (BL)	116	8.35	2.55	8.15	2.7	18.9						
Baseline	121	8.29	2.54	8.00	2.7	18.9						
V3, Wk 2 (T)	115	8.12	2.33	8.10	1.8	16.4	115	-0.17	2.14	-0.10	-6.0	7.2
V5, Wk 6 (M)	69	8.39	2.35	8.20	2.5	13.7	69	-0.16	2.37	0.20	-7.8	4.4
V7, Wk 12 (M)	53	8.75	2.98	8.10	4.1	21.1	53	-0.22	2.50	0.20	-6.1	6.6
V9, Wk 20 (M)	36	8.33	2.23	8.25	4.6	14.1	36	-0.64	2.25	-0.30	-6.9	3.7
V10, Wk 24 (M)	37	8.51	2.54	8.50	3.6	14.6	37	-0.37	3.00	-0.30	-9.5	9.6
Early Termination Visit	78	7.65	2.38	7.25	2.9	14.9	78	-0.34	2.10	-0.05	-5.6	5.0
Last Visit	121	7.92	2.50	7.60	2.9	14.9	121	-0.37	2.52	-0.20	-9.5	9.6
Min Post-BL	121	6.91	1.99	6.80	1.8	13.1	121	-1.38	2.12	-1.20	-9.5	4.2
Max Post-BL	121	9.25	2.86	8.80	2.9	21.1	121	0.96	2.28	0.70	-3.8	9.6

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	8.23	2.45	7.90	3.8	18.4						
V2, Wk 0 (BL)	120	8.09	2.42	7.70	0.3	14.9						
Baseline	121	8.11	2.41	7.70	0.3	14.9						
V3, Wk 2 (T)	114	8.19	2.36	7.90	3.7	16.1	114	0.05	1.61	0.00	-4.1	6.3
V5, Wk 6 (M)	77	8.30	2.48	8.00	3.2	16.7	77	0.27	1.69	0.20	-4.0	4.0
V7, Wk 12 (M)	69	8.29	2.37	8.00	3.4	14.9	69	0.05	1.77	0.10	-4.7	4.3
V9, Wk 20 (M)	58	8.17	2.24	7.45	3.4	13.3	58	-0.10	1.64	-0.10	-3.3	4.6
V10, Wk 24 (M)	60	8.54	3.20	7.80	4.3	23.4	60	0.34	3.11	0.15	-4.7	16.2
Early Termination Visit	51	8.30	2.30	7.90	4.5	15.5	51	0.28	2.53	0.10	-6.9	6.5
Last Visit	119	8.45	2.88	7.90	4.3	23.4	119	0.36	2.82	0.10	-6.9	16.2
Min Post-BL	119	7.16	2.00	7.00	3.2	13.7	119	-0.93	1.79	-0.80	-6.9	4.7
Max Post-BL	119	9.64	2.91	9.00	4.5	23.4	119	1.55	2.37	1.50	-3.8	16.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	3.86	1.73	3.60	1.1	12.3						
V2, Wk 0 (BL)	116	3.79	1.58	3.50	1.2	10.6						
Baseline	121	3.83	1.59	3.60	1.2	10.6						
V3, Wk 2 (T)	115	3.66	1.34	3.50	1.0	7.3	115	-0.12	1.29	-0.10	-4.6	3.4
V5, Wk 6 (M)	69	3.58	1.49	3.30	1.3	7.7	69	-0.22	1.65	-0.10	-5.8	5.4
V7, Wk 12 (M)	53	3.55	1.58	3.10	1.3	7.8	53	-0.14	1.64	0.00	-5.1	3.6
V9, Wk 20 (M)	36	3.70	1.59	3.10	1.8	9.1	36	-0.05	1.21	0.05	-2.6	3.4
V10, Wk 24 (M)	37	3.94	2.08	3.40	1.4	11.1	37	0.19	1.67	0.10	-4.6	5.7
Early Termination Visit	78	4.00	1.78	3.80	1.2	9.5	78	0.19	1.92	0.30	-7.2	5.2
Last Visit	121	4.02	1.86	3.70	1.3	11.1	121	0.19	1.88	0.20	-7.2	5.7
Min Post-BL	121	3.17	1.47	2.80	1.0	9.5	121	-0.66	1.43	-0.40	-7.2	3.2
Max Post-BL	121	4.80	1.83	4.50	1.5	11.1	121	0.97	1.69	0.90	-4.2	5.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	3.84	1.64	3.55	1.4	9.2						
V2, Wk 0 (BL)	120	3.70	1.47	3.40	1.2	8.8						
Baseline	121	3.69	1.46	3.40	1.2	8.8						
V3, Wk 2 (T)	114	3.71	1.50	3.35	1.4	7.7	114	0.03	1.19	0.10	-3.2	4.1
V5, Wk 6 (M)	77	3.49	1.34	3.20	1.5	8.1	77	-0.16	1.44	-0.10	-5.0	5.0
V7, Wk 12 (M)	69	3.51	1.54	3.10	1.4	10.0	69	-0.08	1.63	-0.10	-4.1	7.9
V9, Wk 20 (M)	58	3.48	1.42	3.10	1.2	7.5	58	0.08	1.19	-0.05	-1.9	4.1
V10, Wk 24 (M)	60	3.49	1.43	3.30	1.4	7.5	60	0.10	1.27	0.20	-3.4	3.8
Early Termination Visit	51	3.94	1.64	3.60	1.3	8.2	51	0.02	1.20	-0.20	-3.0	3.5
Last Visit	119	3.70	1.51	3.40	1.3	8.2	119	0.02	1.24	0.00	-3.4	3.8
Min Post-BL	119	2.97	1.17	2.70	1.2	7.2	119	-0.71	1.19	-0.50	-5.0	3.5
Max Post-BL	119	4.54	1.67	4.30	1.5	10.0	119	0.85	1.52	0.70	-3.2	7.9

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	118	54.46	10.95	54.05	21.7	84.7						
V2, Wk 0 (BL)	116	54.06	10.37	54.70	18.1	73.3						
Baseline	121	54.41	10.48	55.10	18.1	73.3						
V3, Wk 2 (T)	115	54.01	9.85	56.00	18.5	74.6	115	-0.13	7.78	0.10	-23.8	22.5
V5, Wk 6 (M)	69	53.44	11.27	54.30	28.5	82.4	69	-0.95	10.57	-0.40	-24.0	27.4
V7, Wk 12 (M)	53	53.21	10.26	53.80	27.3	72.4	53	-0.16	9.55	-0.80	-25.8	23.6
V9, Wk 20 (M)	36	53.73	11.11	53.95	29.6	78.5	36	0.94	9.68	1.70	-24.5	19.1
V10, Wk 24 (M)	37	53.62	10.89	51.10	29.4	73.3	37	0.56	9.20	1.40	-17.8	18.9
Early Termination Visit	78	55.49	12.37	55.85	21.0	85.4	78	1.06	10.83	1.00	-28.3	36.4
Last Visit	121	55.39	11.98	55.60	21.0	85.4	121	0.98	10.46	1.50	-28.3	36.4
Min Post-BL	121	50.01	11.11	50.00	18.5	85.4	121	-4.41	8.69	-3.40	-28.3	14.4
Max Post-BL	121	60.49	10.44	61.00	21.0	85.4	121	6.08	8.92	5.20	-11.9	36.4

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	118	54.00	10.67	53.40	25.6	74.5						
V2, Wk 0 (BL)	120	53.21	10.41	54.95	27.3	84.1						
Baseline	121	53.16	10.38	54.70	27.3	84.1						
V3, Wk 2 (T)	114	53.36	10.59	53.55	25.7	82.0	114	0.78	7.48	0.70	-21.1	22.8
V5, Wk 6 (M)	77	52.97	9.80	52.70	29.4	76.4	77	0.71	9.09	-0.20	-17.2	29.3
V7, Wk 12 (M)	69	52.33	10.04	51.80	32.0	80.6	69	-0.05	8.56	-1.00	-24.1	23.1
V9, Wk 20 (M)	58	52.13	10.33	52.80	26.5	74.4	58	1.32	8.27	0.55	-21.4	21.9
V10, Wk 24 (M)	60	53.04	10.30	53.25	26.9	73.7	60	2.18	7.88	2.40	-16.5	20.2
Early Termination Visit	51	54.93	11.38	55.10	29.0	80.0	51	-0.26	7.88	0.20	-20.3	15.1
Last Visit	119	54.06	10.56	54.00	26.9	80.0	119	0.94	7.76	0.40	-20.3	20.2
Min Post-BL	119	48.69	10.16	48.80	25.7	76.6	119	-4.43	7.19	-4.10	-24.1	15.1
Max Post-BL	119	58.86	9.63	58.00	33.5	82.0	119	5.74	8.57	4.80	-20.3	29.3

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes Atypical Qualitative

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Metamyelocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	1.0	-	1.0	1	1						
Last Visit	1	1.0	-	1.0	1	1						
Min Post-BL	1	1.0	-	1.0	1	1						
Max Post-BL	1	1.0	-	1.0	1	1						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Myelocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	2.0	-	2.0	2	2						
Last Visit	1	2.0	-	2.0	2	2						
Min Post-BL	1	2.0	-	2.0	2	2						
Max Post-BL	1	2.0	-	2.0	2	2						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Giant Platelets

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Promyelocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Nucleated Erythrocytes/Leukocytes (/100 WBC)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Reactive Lymphocytes Qualitative

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Smudge Cells

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Toxic Granulation

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Absolute Basophils Manual Calculated (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.00	-	0.00	0.0	0.0						
Last Visit	1	0.00	-	0.00	0.0	0.0						
Min Post-BL	1	0.00	-	0.00	0.0	0.0						
Max Post-BL	1	0.00	-	0.00	0.0	0.0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils Manual Differential (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Blasts/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Absolute Eosinophil Manual Calculated (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.00	-	0.00	0.0	0.0						
Last Visit	1	0.00	-	0.00	0.0	0.0						
Min Post-BL	1	0.00	-	0.00	0.0	0.0						
Max Post-BL	1	0.00	-	0.00	0.0	0.0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils Manual Differential (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hypersegmented Cells Qualitative

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Prothrombin Intl. Normalized Ratio

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	1.100	-	1.100	1.10	1.10						
Min Post-BL	1	1.100	-	1.100	1.10	1.10						
Max Post-BL	1	1.100	-	1.100	1.10	1.10						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes Manual Differential (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	44.0	-	44.0	44	44						
Last Visit	1	44.0	-	44.0	44	44						
Min Post-BL	1	44.0	-	44.0	44	44						
Max Post-BL	1	44.0	-	44.0	44	44						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Absolute Lymphocyte Manual Calculated (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	4.80	-	4.80	4.8	4.8						
Last Visit	1	4.80	-	4.80	4.8	4.8						
Min Post-BL	1	4.80	-	4.80	4.8	4.8						
Max Post-BL	1	4.80	-	4.80	4.8	4.8						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Absolute Monocyte Manual Calculated (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	1.00	-	1.00	1.0	1.0						
Last Visit	1	1.00	-	1.00	1.0	1.0						
Min Post-BL	1	1.00	-	1.00	1.0	1.0						
Max Post-BL	1	1.00	-	1.00	1.0	1.0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes Manual Differential (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	9.0	-	9.0	9	9						
Last Visit	1	9.0	-	9.0	9	9						
Min Post-BL	1	9.0	-	9.0	9	9						
Max Post-BL	1	9.0	-	9.0	9	9						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Absolute Neutrophil Manual Calculated (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	5.20	-	5.20	5.2	5.2						
Last Visit	1	5.20	-	5.20	5.2	5.2						
Min Post-BL	1	5.20	-	5.20	5.2	5.2						
Max Post-BL	1	5.20	-	5.20	5.2	5.2						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils Band Form Manual Different (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils, Segmented Manual Different (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	44.0	-	44.0	44	44						
Last Visit	1	44.0	-	44.0	44	44						
Min Post-BL	1	44.0	-	44.0	44	44						
Max Post-BL	1	44.0	-	44.0	44	44						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bizarre Platelets

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Prothrombin Time (sec)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	11.50	-	11.50	11.5	11.5						
Min Post-BL	1	11.50	-	11.50	11.5	11.5						
Max Post-BL	1	11.50	-	11.50	11.5	11.5						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening,
SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-58　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Leukocytes Other (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V5, Wk 6 (M)	1	0.0	-	0.0	0	0						
Last Visit	1	0.0	-	0.0	0	0						
Min Post-BL	1	0.0	-	0.0	0	0						
Max Post-BL	1	0.0	-	0.0	0	0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Hemoglobin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	135.8	17.4	138.0	105	163						
V2, Wk 0 (BL)	18	134.6	17.7	134.0	108	158						
Baseline	19	135.4	17.6	135.0	108	158						
V3, Wk 2 (T)	19	136.1	17.9	137.0	106	166	19	0.6	5.8	0.0	-7	10
V5, Wk 6 (M)	9	137.6	21.8	139.0	107	173	9	2.2	8.0	0.0	-12	15
V7, Wk 12 (M)	4	136.8	18.3	138.0	114	157	4	-1.5	2.5	-1.0	-5	1
V9, Wk 20 (M)	3	141.3	28.7	145.0	111	168	3	6.7	7.6	10.0	-2	12
V10, Wk 24 (M)	3	132.7	22.2	136.0	109	153	3	-2.0	4.4	-4.0	-5	3
Early Termination Visit	16	134.9	17.3	136.5	108	163	16	-0.7	6.7	-1.0	-13	14
Last Visit	19	134.5	17.5	136.0	108	163	19	-0.9	6.3	-1.0	-13	14
Min Post-BL	19	132.7	17.7	131.0	106	163	19	-2.7	5.7	-2.0	-13	7
Max Post-BL	19	138.9	18.4	140.0	108	173	19	3.5	6.6	4.0	-7	15

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Hemoglobin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	139.8	15.1	139.0	119	161						
V2, Wk 0 (BL)	11	140.7	16.4	137.0	117	169						
Baseline	11	140.7	16.4	137.0	117	169						
V3, Wk 2 (T)	11	139.4	17.4	134.0	116	169	11	-1.4	3.6	-1.0	-8	4
V5, Wk 6 (M)	11	140.4	16.1	133.0	122	165	11	-0.4	4.2	-1.0	-8	5
V7, Wk 12 (M)	10	141.7	16.2	140.5	114	164	10	-0.4	5.8	0.5	-9	9
V9, Wk 20 (M)	8	146.6	15.8	148.0	125	169	8	0.1	2.9	0.5	-4	4
V10, Wk 24 (M)	9	145.6	17.5	143.0	125	170	9	0.7	7.4	0.0	-12	10
Early Termination Visit	2	121.0	11.3	121.0	113	129	2	-1.0	4.2	-1.0	-4	2
Last Visit	11	141.1	18.9	135.0	113	170	11	0.4	6.8	0.0	-12	10
Min Post-BL	11	136.0	16.5	129.0	113	161	11	-4.7	4.3	-5.0	-12	1
Max Post-BL	11	144.7	17.2	139.0	122	170	11	4.0	3.7	4.0	-2	10

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Hematocrit (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	43.09	5.41	43.70	34.6	52.4						
V2, Wk 0 (BL)	18	43.03	5.30	43.25	33.9	51.6						
Baseline	19	43.09	5.16	43.90	33.9	51.6						
V3, Wk 2 (T)	19	43.32	6.00	42.80	34.8	55.9	19	0.23	2.19	0.30	-3.8	6.4
V5, Wk 6 (M)	9	43.90	6.89	44.00	33.5	52.9	9	0.81	3.18	0.60	-4.6	6.3
V7, Wk 12 (M)	4	44.15	5.31	44.80	37.7	49.3	4	-1.50	3.15	-2.40	-4.0	2.8
V9, Wk 20 (M)	3	43.90	5.60	44.10	38.2	49.4	3	-1.47	0.81	-1.60	-2.2	-0.6
V10, Wk 24 (M)	3	41.40	3.86	41.10	37.7	45.4	3	-3.97	2.61	-4.60	-6.2	-1.1
Early Termination Visit	16	43.77	6.31	43.15	34.3	57.2	16	1.11	2.77	0.30	-2.9	7.7
Last Visit	19	43.39	5.97	43.10	34.3	57.2	19	0.31	3.28	0.20	-6.2	7.7
Min Post-BL	19	42.25	5.75	41.10	33.5	55.9	19	-0.84	2.77	-0.60	-6.2	6.4
Max Post-BL	19	44.62	6.30	43.90	35.3	57.2	19	1.53	2.62	1.00	-2.9	7.7

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Hematocrit (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	45.48	4.37	44.50	38.2	53.0						
V2, Wk 0 (BL)	11	46.52	4.99	44.90	40.4	55.0						
Baseline	11	46.52	4.99	44.90	40.4	55.0						
V3, Wk 2 (T)	11	45.37	5.72	43.80	38.6	56.6	11	-1.15	1.33	-1.10	-3.1	1.6
V5, Wk 6 (M)	11	45.87	5.20	45.20	39.0	56.5	11	-0.65	1.58	-0.90	-2.9	1.6
V7, Wk 12 (M)	10	45.45	5.33	45.70	35.9	52.5	10	-1.55	2.22	-2.15	-4.5	2.1
V9, Wk 20 (M)	8	47.20	5.91	47.05	37.8	54.6	8	-0.89	3.34	-0.45	-5.3	5.2
V10, Wk 24 (M)	9	46.17	6.25	46.90	38.7	58.2	9	-1.57	5.31	-3.90	-5.0	10.6
Early Termination Visit	2	38.95	3.46	38.95	36.5	41.4	2	-2.10	2.55	-2.10	-3.9	-0.3
Last Visit	11	44.85	6.40	43.40	36.5	58.2	11	-1.66	4.82	-3.90	-5.0	10.6
Min Post-BL	11	42.68	4.77	41.50	35.9	49.7	11	-3.84	1.45	-4.60	-5.3	-0.9
Max Post-BL	11	47.97	6.29	45.90	41.0	58.2	11	1.45	3.32	0.30	-1.4	10.6

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Platelets (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	265.4	74.8	245.0	115	418						
V2, Wk 0 (BL)	18	266.9	82.4	257.5	81	394						
Baseline	19	263.3	81.7	254.0	81	394						
V3, Wk 2 (T)	19	268.5	76.0	249.0	119	414	19	5.2	27.1	7.0	-45	62
V5, Wk 6 (M)	9	263.0	75.2	270.0	121	350	9	6.6	40.3	-11.0	-36	77
V7, Wk 12 (M)	4	244.8	117.1	243.5	103	389	4	4.5	28.5	17.0	-38	22
V9, Wk 20 (M)	3	236.7	119.7	252.0	110	348	3	6.7	26.1	13.0	-22	29
V10, Wk 24 (M)	3	222.7	108.4	234.0	109	325	3	-7.3	36.6	-5.0	-45	28
Early Termination Visit	16	270.1	64.7	232.5	207	388	16	0.6	36.6	4.5	-70	64
Last Visit	19	262.6	71.5	233.0	109	388	19	-0.7	35.7	-1.0	-70	64
Min Post-BL	19	248.0	61.4	233.0	103	337	19	-15.3	30.3	-20.0	-70	56
Max Post-BL	19	286.2	81.5	261.0	121	414	19	22.9	25.0	20.0	-18	77

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Platelets (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	248.5	41.7	252.0	170	301						
V2, Wk 0 (BL)	11	260.6	69.4	271.0	121	378						
Baseline	11	260.6	69.4	271.0	121	378						
V3, Wk 2 (T)	11	244.6	41.5	249.0	165	309	11	-16.0	39.3	-20.0	-83	44
V5, Wk 6 (M)	11	243.1	50.0	228.0	160	319	11	-17.5	43.6	-13.0	-97	39
V7, Wk 12 (M)	10	242.8	41.1	246.5	169	306	10	-6.1	30.5	-10.5	-54	48
V9, Wk 20 (M)	8	247.5	43.7	247.5	201	336	8	8.6	41.3	11.0	-40	86
V10, Wk 24 (M)	9	233.8	47.8	238.0	157	312	9	-9.0	28.6	-9.0	-52	36
Early Termination Visit	2	318.5	36.1	318.5	293	344	2	-22.5	16.3	-22.5	-34	-11
Last Visit	11	249.2	56.0	241.0	157	344	11	-11.5	26.7	-11.0	-52	36
Min Post-BL	11	230.5	47.6	217.0	157	309	11	-30.1	37.8	-33.0	-97	36
Max Post-BL	11	269.6	47.1	262.0	206	344	11	9.0	34.9	15.0	-40	86

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Erythrocytes (10^12/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	4.563	0.467	4.490	3.78	5.47						
V2, Wk 0 (BL)	18	4.552	0.541	4.580	3.74	5.65						
Baseline	19	4.569	0.531	4.610	3.74	5.65						
V3, Wk 2 (T)	19	4.596	0.501	4.520	3.58	5.62	19	0.027	0.195	0.050	-0.33	0.41
V5, Wk 6 (M)	9	4.739	0.702	4.650	3.79	5.75	9	0.089	0.295	0.020	-0.45	0.51
V7, Wk 12 (M)	4	4.890	0.688	5.005	3.98	5.57	4	-0.005	0.058	0.000	-0.08	0.06
V9, Wk 20 (M)	3	4.840	0.624	4.510	4.45	5.56	3	0.197	0.361	0.320	-0.21	0.48
V10, Wk 24 (M)	3	4.540	0.463	4.480	4.11	5.03	3	-0.103	0.211	-0.210	-0.24	0.14
Early Termination Visit	16	4.543	0.498	4.670	3.59	5.38	16	-0.013	0.245	0.040	-0.38	0.48
Last Visit	19	4.542	0.480	4.660	3.59	5.38	19	-0.027	0.237	0.030	-0.38	0.48
Min Post-BL	19	4.475	0.483	4.520	3.58	5.38	19	-0.094	0.202	-0.090	-0.45	0.32
Max Post-BL	19	4.702	0.535	4.700	3.59	5.75	19	0.133	0.227	0.100	-0.24	0.51

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Erythrocytes (10^12/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	4.611	0.429	4.610	4.05	5.27						
V2, Wk 0 (BL)	11	4.660	0.441	4.580	4.09	5.35						
Baseline	11	4.660	0.441	4.580	4.09	5.35						
V3, Wk 2 (T)	11	4.580	0.459	4.560	4.04	5.24	11	-0.080	0.123	-0.090	-0.26	0.17
V5, Wk 6 (M)	11	4.614	0.461	4.490	4.02	5.33	11	-0.046	0.142	-0.070	-0.37	0.15
V7, Wk 12 (M)	10	4.641	0.434	4.610	4.10	5.49	10	-0.076	0.222	-0.055	-0.59	0.14
V9, Wk 20 (M)	8	4.799	0.401	4.935	4.21	5.23	8	-0.026	0.115	-0.025	-0.22	0.17
V10, Wk 24 (M)	9	4.789	0.502	4.870	4.15	5.46	9	0.011	0.204	0.030	-0.29	0.28
Early Termination Visit	2	4.105	0.134	4.105	4.01	4.20	2	-0.025	0.191	-0.025	-0.16	0.11
Last Visit	11	4.665	0.529	4.400	4.01	5.46	11	0.005	0.193	0.030	-0.29	0.28
Min Post-BL	11	4.443	0.420	4.290	4.01	5.22	11	-0.217	0.161	-0.160	-0.59	-0.02
Max Post-BL	11	4.774	0.471	4.750	4.20	5.49	11	0.114	0.118	0.150	-0.08	0.28

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Leukocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	5.70	2.06	4.80	3.3	9.8						
V2, Wk 0 (BL)	18	6.07	1.60	5.50	4.2	10.4						
Baseline	19	5.98	1.60	5.40	4.2	10.4						
V3, Wk 2 (T)	19	5.54	1.73	5.30	3.1	11.0	19	-0.44	1.59	-0.40	-4.5	3.1
V5, Wk 6 (M)	9	6.03	1.75	6.00	3.7	9.3	9	0.16	2.37	0.30	-3.3	5.1
V7, Wk 12 (M)	4	5.98	0.84	6.00	5.0	6.9	4	-0.25	2.25	0.55	-3.5	1.4
V9, Wk 20 (M)	3	5.50	0.82	5.30	4.8	6.4	3	-1.40	2.29	-0.50	-4.0	0.3
V10, Wk 24 (M)	3	4.97	1.19	4.60	4.0	6.3	3	-1.93	1.88	-1.00	-4.1	-0.7
Early Termination Visit	16	6.16	1.56	5.60	4.3	10.6	16	0.34	1.54	0.45	-2.2	3.2
Last Visit	19	5.97	1.54	5.60	4.0	10.6	19	-0.02	1.76	0.20	-4.1	3.2
Min Post-BL	19	4.96	1.17	4.80	3.1	7.1	19	-1.03	1.28	-0.80	-4.5	0.8
Max Post-BL	19	6.81	1.76	6.40	4.7	11.0	19	0.82	1.80	0.90	-3.3	5.1

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Leukocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	6.70	2.28	5.70	4.4	11.7						
V2, Wk 0 (BL)	11	6.41	1.75	6.40	4.1	9.5						
Baseline	11	6.41	1.75	6.40	4.1	9.5						
V3, Wk 2 (T)	11	6.15	1.53	5.80	4.2	9.0	11	-0.26	0.93	-0.10	-1.8	1.0
V5, Wk 6 (M)	11	5.86	1.58	5.90	3.7	9.1	11	-0.55	1.51	0.10	-3.9	1.2
V7, Wk 12 (M)	10	5.56	1.99	4.85	3.6	9.8	10	-0.85	1.90	-0.70	-4.8	1.8
V9, Wk 20 (M)	8	5.81	2.07	5.20	3.6	9.8	8	-0.12	1.14	0.05	-2.1	1.3
V10, Wk 24 (M)	9	5.83	2.42	4.80	3.2	11.3	9	-0.29	1.27	-0.20	-2.3	1.8
Early Termination Visit	2	7.50	0.99	7.50	6.8	8.2	2	-0.20	0.85	-0.20	-0.8	0.4
Last Visit	11	6.14	2.29	5.80	3.2	11.3	11	-0.27	1.17	-0.20	-2.3	1.8
Min Post-BL	11	5.11	1.45	4.70	3.2	8.0	11	-1.30	1.41	-1.00	-4.8	0.3
Max Post-BL	11	6.92	2.16	6.00	4.7	11.3	11	0.51	1.20	0.80	-1.7	1.8

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Basophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	0.06	0.05	0.10	0.0	0.1						
V2, Wk 0 (BL)	18	0.07	0.05	0.10	0.0	0.1						
Baseline	19	0.07	0.05	0.10	0.0	0.1						
V3, Wk 2 (T)	19	0.05	0.05	0.10	0.0	0.1	19	-0.02	0.07	0.00	-0.1	0.1
V5, Wk 6 (M)	9	0.09	0.06	0.10	0.0	0.2	9	0.01	0.06	0.00	-0.1	0.1
V7, Wk 12 (M)	4	0.08	0.05	0.10	0.0	0.1	4	0.03	0.05	0.00	0.0	0.1
V9, Wk 20 (M)	3	0.07	0.06	0.10	0.0	0.1	3	0.03	0.06	0.00	0.0	0.1
V10, Wk 24 (M)	3	0.07	0.06	0.10	0.0	0.1	3	0.03	0.06	0.00	0.0	0.1
Early Termination Visit	16	0.07	0.06	0.10	0.0	0.2	16	-0.01	0.06	0.00	-0.1	0.1
Last Visit	19	0.07	0.06	0.10	0.0	0.2	19	0.00	0.06	0.00	-0.1	0.1
Min Post-BL	19	0.04	0.05	0.00	0.0	0.1	19	-0.03	0.07	0.00	-0.1	0.1
Max Post-BL	19	0.08	0.06	0.10	0.0	0.2	19	0.02	0.06	0.00	-0.1	0.1

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Basophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	0.06	0.05	0.10	0.0	0.1						
V2, Wk 0 (BL)	11	0.08	0.04	0.10	0.0	0.1						
Baseline	11	0.08	0.04	0.10	0.0	0.1						
V3, Wk 2 (T)	11	0.05	0.05	0.10	0.0	0.1	11	-0.03	0.06	0.00	-0.1	0.1
V5, Wk 6 (M)	11	0.07	0.06	0.10	0.0	0.2	11	-0.01	0.08	0.00	-0.1	0.2
V7, Wk 12 (M)	10	0.04	0.07	0.00	0.0	0.2	10	-0.04	0.07	-0.05	-0.1	0.1
V9, Wk 20 (M)	8	0.05	0.05	0.05	0.0	0.1	8	-0.03	0.05	0.00	-0.1	0.0
V10, Wk 24 (M)	9	0.07	0.05	0.10	0.0	0.1	9	-0.01	0.06	0.00	-0.1	0.1
Early Termination Visit	2	0.10	0.00	0.10	0.1	0.1	2	0.00	0.00	0.00	0.0	0.0
Last Visit	11	0.07	0.05	0.10	0.0	0.1	11	-0.01	0.05	0.00	-0.1	0.1
Min Post-BL	11	0.04	0.05	0.00	0.0	0.1	11	-0.05	0.05	0.00	-0.1	0.0
Max Post-BL	11	0.12	0.04	0.10	0.1	0.2	11	0.04	0.07	0.00	0.0	0.2

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Basophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	1.12	0.79	1.00	0.2	3.2						
V2, Wk 0 (BL)	18	1.02	0.39	1.00	0.4	2.0						
Baseline	19	1.02	0.38	1.10	0.4	2.0						
V3, Wk 2 (T)	19	1.05	0.66	0.80	0.3	2.9	19	0.03	0.50	0.00	-0.8	0.9
V5, Wk 6 (M)	9	1.41	0.91	1.10	0.5	3.0	9	0.21	0.78	0.00	-0.7	1.6
V7, Wk 12 (M)	4	1.13	0.54	1.20	0.4	1.7	4	0.20	0.48	0.05	-0.2	0.9
V9, Wk 20 (M)	3	0.77	0.49	1.00	0.2	1.1	3	-0.07	0.31	0.00	-0.4	0.2
V10, Wk 24 (M)	3	1.10	0.60	1.10	0.5	1.7	3	0.27	0.55	0.00	-0.1	0.9
Early Termination Visit	16	1.01	0.57	0.70	0.4	2.2	16	-0.05	0.51	-0.05	-0.9	1.1
Last Visit	19	1.02	0.55	0.70	0.4	2.2	19	0.00	0.51	0.00	-0.9	1.1
Min Post-BL	19	0.75	0.47	0.60	0.2	2.2	19	-0.27	0.41	-0.30	-0.9	0.7
Max Post-BL	19	1.32	0.73	1.30	0.5	3.0	19	0.29	0.56	0.10	-0.4	1.6

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Basophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	1.05	0.66	0.80	0.4	2.5						
V2, Wk 0 (BL)	11	1.05	0.43	1.00	0.3	1.8						
Baseline	11	1.05	0.43	1.00	0.3	1.8						
V3, Wk 2 (T)	11	0.88	0.39	0.80	0.2	1.7	11	-0.17	0.46	-0.20	-1.0	0.7
V5, Wk 6 (M)	11	1.22	0.70	1.20	0.3	2.5	11	0.16	0.73	-0.20	-0.4	1.7
V7, Wk 12 (M)	10	1.01	0.63	0.80	0.4	2.5	10	0.02	0.77	-0.25	-0.7	1.9
V9, Wk 20 (M)	8	1.04	0.54	1.00	0.3	2.1	8	0.04	0.23	0.05	-0.4	0.3
V10, Wk 24 (M)	9	1.09	0.59	1.00	0.4	2.5	9	0.10	0.54	0.00	-0.6	1.3
Early Termination Visit	2	1.10	0.28	1.10	0.9	1.3	2	-0.25	0.78	-0.25	-0.8	0.3
Last Visit	11	1.09	0.54	1.00	0.4	2.5	11	0.04	0.56	0.00	-0.8	1.3
Min Post-BL	11	0.64	0.25	0.70	0.2	1.1	11	-0.42	0.26	-0.40	-1.0	-0.1
Max Post-BL	11	1.77	0.66	1.70	0.7	2.5	11	0.72	0.72	0.60	-0.4	1.9

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Eosinophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	0.15	0.17	0.10	0.0	0.7						
V2, Wk 0 (BL)	18	0.21	0.21	0.15	0.0	0.9						
Baseline	19	0.19	0.21	0.10	0.0	0.9						
V3, Wk 2 (T)	19	0.15	0.15	0.10	0.0	0.5	19	-0.04	0.13	0.00	-0.5	0.1
V5, Wk 6 (M)	9	0.17	0.17	0.10	0.0	0.5	9	-0.08	0.16	0.00	-0.4	0.1
V7, Wk 12 (M)	4	0.18	0.22	0.10	0.0	0.5	4	-0.13	0.19	-0.05	-0.4	0.0
V9, Wk 20 (M)	3	0.07	0.12	0.00	0.0	0.2	3	-0.30	0.35	-0.10	-0.7	-0.1
V10, Wk 24 (M)	3	0.10	0.10	0.10	0.0	0.2	3	-0.27	0.38	-0.10	-0.7	0.0
Early Termination Visit	16	0.19	0.20	0.10	0.0	0.8	16	0.03	0.16	0.00	-0.3	0.4
Last Visit	19	0.17	0.19	0.10	0.0	0.8	19	-0.02	0.22	0.00	-0.7	0.4
Min Post-BL	19	0.13	0.13	0.10	0.0	0.5	19	-0.07	0.18	0.00	-0.7	0.1
Max Post-BL	19	0.21	0.19	0.10	0.0	0.8	19	0.02	0.16	0.00	-0.4	0.4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Eosinophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	0.17	0.17	0.10	0.0	0.6						
V2, Wk 0 (BL)	11	0.18	0.17	0.10	0.0	0.6						
Baseline	11	0.18	0.17	0.10	0.0	0.6						
V3, Wk 2 (T)	11	0.21	0.22	0.10	0.0	0.8	11	0.03	0.08	0.00	-0.1	0.2
V5, Wk 6 (M)	11	0.24	0.31	0.10	0.0	1.1	11	0.05	0.17	0.00	-0.1	0.5
V7, Wk 12 (M)	10	0.20	0.22	0.10	0.0	0.7	10	0.01	0.10	0.00	-0.1	0.2
V9, Wk 20 (M)	8	0.23	0.18	0.20	0.0	0.5	8	0.06	0.13	0.00	-0.1	0.3
V10, Wk 24 (M)	9	0.19	0.18	0.10	0.0	0.5	9	0.04	0.12	0.00	-0.1	0.3
Early Termination Visit	2	0.35	0.35	0.35	0.1	0.6	2	0.00	0.00	0.00	0.0	0.0
Last Visit	11	0.22	0.20	0.10	0.0	0.6	11	0.04	0.11	0.00	-0.1	0.3
Min Post-BL	11	0.14	0.18	0.10	0.0	0.6	11	-0.05	0.05	0.00	-0.1	0.0
Max Post-BL	11	0.29	0.30	0.10	0.1	1.1	11	0.11	0.16	0.00	0.0	0.5

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Eosinophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	2.73	2.57	1.80	0.4	10.7						
V2, Wk 0 (BL)	18	2.97	2.29	2.10	0.5	8.8						
Baseline	19	2.86	2.27	2.10	0.5	8.8						
V3, Wk 2 (T)	19	2.58	2.24	1.60	0.5	8.3	19	-0.28	1.16	0.00	-2.9	1.7
V5, Wk 6 (M)	9	2.86	2.96	1.90	0.4	8.4	9	-0.48	1.94	-0.60	-3.7	3.3
V7, Wk 12 (M)	4	2.30	2.80	0.95	0.8	6.5	4	-1.15	0.81	-0.95	-2.3	-0.4
V9, Wk 20 (M)	3	1.50	1.56	0.60	0.6	3.3	3	-2.40	2.70	-1.10	-5.5	-0.6
V10, Wk 24 (M)	3	1.77	1.55	1.30	0.5	3.5	3	-2.13	2.75	-0.70	-5.3	-0.4
Early Termination Visit	16	3.17	2.94	2.00	0.4	11.4	16	0.50	2.14	0.25	-3.8	4.8
Last Visit	19	2.95	2.78	2.00	0.4	11.4	19	0.08	2.37	-0.30	-5.3	4.8
Min Post-BL	19	2.09	2.12	1.50	0.4	8.3	19	-0.77	1.71	-0.70	-5.5	1.7
Max Post-BL	19	3.57	2.90	3.30	0.5	11.4	19	0.71	1.78	0.10	-1.6	4.8

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Eosinophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	2.32	1.47	2.30	0.4	5.8						
V2, Wk 0 (BL)	11	2.58	1.82	2.30	0.3	6.9						
Baseline	11	2.58	1.82	2.30	0.3	6.9						
V3, Wk 2 (T)	11	3.13	2.36	2.80	0.9	9.5	11	0.55	0.82	0.50	-0.5	2.6
V5, Wk 6 (M)	11	3.49	3.22	2.10	0.5	11.6	11	0.91	1.68	0.30	-0.7	4.7
V7, Wk 12 (M)	10	3.26	2.14	2.70	0.7	7.5	10	0.51	0.89	0.50	-0.8	2.0
V9, Wk 20 (M)	8	3.40	2.34	2.85	1.1	7.7	8	0.86	2.25	-0.15	-0.9	5.2
V10, Wk 24 (M)	9	2.69	2.02	2.40	0.7	6.7	9	0.40	1.80	0.10	-1.5	4.2
Early Termination Visit	2	4.00	4.24	4.00	1.0	7.0	2	0.10	0.00	0.10	0.1	0.1
Last Visit	11	2.93	2.31	2.40	0.7	7.0	11	0.35	1.62	0.10	-1.5	4.2
Min Post-BL	11	2.23	1.88	2.00	0.5	7.0	11	-0.35	0.66	-0.30	-1.5	0.7
Max Post-BL	11	4.24	3.22	2.90	1.3	11.6	11	1.65	1.90	0.90	-0.2	5.2

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Lymphocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	1.97	0.38	2.00	1.3	2.6						
V2, Wk 0 (BL)	18	2.13	0.38	2.20	1.3	2.7						
Baseline	19	2.12	0.37	2.20	1.3	2.7						
V3, Wk 2 (T)	19	2.06	0.53	2.00	1.1	3.1	19	-0.05	0.46	-0.20	-0.7	1.1
V5, Wk 6 (M)	9	1.83	0.58	1.80	0.9	2.9	9	-0.19	0.46	-0.40	-0.6	0.8
V7, Wk 12 (M)	4	1.95	0.44	2.05	1.4	2.3	4	-0.07	0.31	0.00	-0.5	0.2
V9, Wk 20 (M)	3	1.87	0.23	2.00	1.6	2.0	3	-0.40	0.30	-0.40	-0.7	-0.1
V10, Wk 24 (M)	3	1.83	0.47	2.00	1.3	2.2	3	-0.43	0.49	-0.20	-1.0	-0.1
Early Termination Visit	16	2.18	0.56	2.05	1.4	3.5	16	0.09	0.45	0.00	-0.7	1.1
Last Visit	19	2.12	0.55	2.00	1.3	3.5	19	0.01	0.49	0.00	-1.0	1.1
Min Post-BL	19	1.84	0.47	1.80	0.9	3.1	19	-0.28	0.40	-0.40	-1.0	0.7
Max Post-BL	19	2.33	0.56	2.30	1.4	3.5	19	0.22	0.47	0.10	-0.5	1.1

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Lymphocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	2.29	0.52	2.20	1.4	3.1						
V2, Wk 0 (BL)	11	2.23	0.47	2.40	1.5	2.8						
Baseline	11	2.23	0.47	2.40	1.5	2.8						
V3, Wk 2 (T)	11	2.16	0.47	2.30	1.3	2.8	11	-0.06	0.31	0.00	-0.7	0.3
V5, Wk 6 (M)	11	2.11	0.74	2.00	1.0	3.1	11	-0.12	0.53	-0.20	-0.9	0.8
V7, Wk 12 (M)	10	2.09	0.56	2.15	1.3	3.0	10	-0.08	0.32	-0.10	-0.5	0.5
V9, Wk 20 (M)	8	1.90	0.49	2.15	1.1	2.4	8	-0.16	0.12	-0.15	-0.4	0.0
V10, Wk 24 (M)	9	1.82	0.79	2.30	0.9	2.7	9	-0.32	0.47	-0.40	-1.2	0.3
Early Termination Visit	2	2.40	0.14	2.40	2.3	2.5	2	-0.20	0.42	-0.20	-0.5	0.1
Last Visit	11	1.93	0.75	2.30	0.9	2.7	11	-0.30	0.44	-0.40	-1.2	0.3
Min Post-BL	11	1.74	0.63	2.00	0.9	2.5	11	-0.49	0.38	-0.50	-1.2	0.1
Max Post-BL	11	2.44	0.61	2.70	1.4	3.1	11	0.21	0.35	0.20	-0.5	0.8

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Lymphocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	37.12	8.39	40.00	17.9	46.7						
V2, Wk 0 (BL)	18	35.99	7.99	36.45	22.7	50.5						
Baseline	19	36.33	7.91	36.70	22.7	50.5						
V3, Wk 2 (T)	19	37.89	6.98	38.10	23.9	53.5	19	1.56	7.01	0.90	-11.3	15.6
V5, Wk 6 (M)	9	33.10	13.11	30.90	9.5	55.2	9	-2.08	12.25	-6.50	-20.1	19.0
V7, Wk 12 (M)	4	32.85	9.24	30.55	24.5	45.8	4	-1.20	10.55	-0.35	-14.0	9.9
V9, Wk 20 (M)	3	34.13	3.30	33.50	31.2	37.7	3	-1.40	8.97	-3.70	-9.0	8.5
V10, Wk 24 (M)	3	37.67	11.73	35.30	27.3	50.4	3	2.13	15.12	9.00	-15.2	12.6
Early Termination Visit	16	36.11	8.67	34.95	19.0	52.0	16	-0.38	8.97	1.15	-16.5	18.2
Last Visit	19	36.35	8.85	35.30	19.0	52.0	19	0.02	9.66	1.60	-16.5	18.2
Min Post-BL	19	32.27	9.25	33.10	9.5	49.1	19	-4.06	8.79	-3.70	-20.1	10.0
Max Post-BL	19	41.28	7.55	38.90	29.5	55.2	19	4.95	7.79	4.10	-6.9	19.0

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Lymphocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	35.70	8.20	33.80	21.4	49.9						
V2, Wk 0 (BL)	11	36.00	8.98	36.50	24.4	50.4						
Baseline	11	36.00	8.98	36.50	24.4	50.4						
V3, Wk 2 (T)	11	36.46	9.51	35.50	20.2	53.3	11	0.46	5.55	-0.80	-5.8	11.1
V5, Wk 6 (M)	11	35.64	8.71	33.90	22.9	50.4	11	-0.36	6.24	0.00	-11.1	8.0
V7, Wk 12 (M)	10	38.59	7.38	39.70	25.9	50.7	10	3.30	6.92	2.40	-7.2	17.2
V9, Wk 20 (M)	8	33.78	6.04	33.40	24.3	42.4	8	-2.42	6.45	-2.25	-9.6	10.9
V10, Wk 24 (M)	9	31.82	9.64	28.50	19.7	49.8	9	-4.43	7.82	-0.60	-21.3	3.6
Early Termination Visit	2	32.00	2.55	32.00	30.2	33.8	2	-2.85	9.12	-2.85	-9.3	3.6
Last Visit	11	31.85	8.66	30.20	19.7	49.8	11	-4.15	7.59	-0.60	-21.3	3.6
Min Post-BL	11	28.38	6.44	28.50	19.7	40.8	11	-7.62	6.13	-7.70	-21.3	1.2
Max Post-BL	11	41.15	6.24	41.20	33.4	53.3	11	5.15	5.78	4.50	-2.3	17.2

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Monocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	0.51	0.15	0.50	0.3	0.9						
V2, Wk 0 (BL)	18	0.54	0.20	0.50	0.3	1.1						
Baseline	19	0.53	0.19	0.50	0.3	1.1						
V3, Wk 2 (T)	19	0.45	0.16	0.40	0.2	0.9	19	-0.08	0.18	-0.10	-0.6	0.2
V5, Wk 6 (M)	9	0.46	0.13	0.40	0.3	0.7	9	-0.06	0.21	-0.10	-0.5	0.2
V7, Wk 12 (M)	4	0.45	0.13	0.45	0.3	0.6	4	-0.15	0.37	0.00	-0.7	0.1
V9, Wk 20 (M)	3	0.40	0.10	0.40	0.3	0.5	3	-0.23	0.32	-0.10	-0.6	0.0
V10, Wk 24 (M)	3	0.57	0.06	0.60	0.5	0.6	3	-0.07	0.40	0.00	-0.5	0.3
Early Termination Visit	16	0.52	0.18	0.45	0.3	0.8	16	0.01	0.12	0.00	-0.1	0.3
Last Visit	19	0.53	0.17	0.50	0.3	0.8	19	-0.01	0.17	0.00	-0.5	0.3
Min Post-BL	19	0.39	0.11	0.40	0.2	0.6	19	-0.14	0.15	-0.10	-0.7	0.0
Max Post-BL	19	0.57	0.17	0.60	0.3	0.9	19	0.04	0.18	0.10	-0.5	0.3

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Monocytes (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	0.47	0.21	0.40	0.2	0.8						
V2, Wk 0 (BL)	11	0.45	0.19	0.40	0.3	0.8						
Baseline	11	0.45	0.19	0.40	0.3	0.8						
V3, Wk 2 (T)	11	0.42	0.20	0.30	0.2	0.8	11	-0.03	0.06	0.00	-0.1	0.1
V5, Wk 6 (M)	11	0.39	0.18	0.30	0.1	0.6	11	-0.05	0.11	0.00	-0.2	0.1
V7, Wk 12 (M)	10	0.44	0.26	0.40	0.2	1.0	10	0.00	0.13	0.00	-0.2	0.2
V9, Wk 20 (M)	8	0.38	0.15	0.35	0.2	0.7	8	-0.04	0.09	-0.10	-0.1	0.1
V10, Wk 24 (M)	9	0.43	0.21	0.40	0.2	0.8	9	0.03	0.15	0.00	-0.1	0.4
Early Termination Visit	2	0.75	0.21	0.75	0.6	0.9	2	0.10	0.00	0.10	0.1	0.1
Last Visit	11	0.49	0.24	0.50	0.2	0.9	11	0.05	0.14	0.00	-0.1	0.4
Min Post-BL	11	0.35	0.18	0.30	0.1	0.6	11	-0.09	0.09	-0.10	-0.2	0.1
Max Post-BL	11	0.54	0.25	0.50	0.2	1.0	11	0.09	0.14	0.10	-0.1	0.4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Monocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	9.49	3.05	9.00	4.8	16.6						
V2, Wk 0 (BL)	18	8.91	2.96	9.05	4.7	15.0						
Baseline	19	8.95	2.88	9.20	4.7	15.0						
V3, Wk 2 (T)	19	8.11	1.89	8.10	3.5	12.0	19	-0.84	2.13	-1.30	-3.7	3.9
V5, Wk 6 (M)	9	8.04	1.81	7.90	5.5	11.9	9	-0.30	2.64	0.20	-4.9	2.9
V7, Wk 12 (M)	4	7.48	1.39	7.20	6.3	9.2	4	-1.55	2.75	-1.70	-4.1	1.3
V9, Wk 20 (M)	3	7.33	0.91	7.70	6.3	8.0	3	-0.67	1.76	-1.20	-2.1	1.3
V10, Wk 24 (M)	3	11.63	2.61	10.60	9.7	14.6	3	3.63	5.27	1.70	-0.4	9.6
Early Termination Visit	16	8.54	2.81	8.65	3.9	14.9	16	-0.58	1.61	-0.80	-4.7	2.4
Last Visit	19	9.03	2.95	8.90	3.9	14.9	19	0.08	2.78	-0.40	-4.7	9.6
Min Post-BL	19	7.11	1.77	7.00	3.5	11.9	19	-1.84	1.74	-1.70	-4.9	1.3
Max Post-BL	19	9.59	2.70	9.70	3.9	14.9	19	0.65	2.63	-0.10	-1.6	9.6

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Monocytes/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	6.85	1.84	7.40	3.8	10.1						
V2, Wk 0 (BL)	11	6.65	1.47	7.00	4.5	9.0						
Baseline	11	6.65	1.47	7.00	4.5	9.0						
V3, Wk 2 (T)	11	6.96	1.62	7.20	4.5	9.0	11	0.32	0.83	0.10	-0.6	1.9
V5, Wk 6 (M)	11	6.78	2.03	6.60	3.2	10.3	11	0.14	1.67	0.50	-2.5	2.5
V7, Wk 12 (M)	10	7.74	2.78	8.15	3.5	12.2	10	1.13	1.74	1.00	-1.7	4.1
V9, Wk 20 (M)	8	6.33	1.33	6.40	4.2	8.6	8	-0.25	1.32	-0.55	-2.1	1.4
V10, Wk 24 (M)	9	8.20	5.84	6.70	4.4	23.4	9	1.86	5.46	0.20	-1.4	16.2
Early Termination Visit	2	9.85	1.20	9.85	9.0	10.7	2	1.85	0.21	1.85	1.7	2.0
Last Visit	11	8.50	5.28	7.40	4.4	23.4	11	1.85	4.88	0.40	-1.4	16.2
Min Post-BL	11	5.81	1.72	6.00	3.2	8.9	11	-0.84	1.27	-1.00	-2.5	1.9
Max Post-BL	11	9.65	4.98	8.40	5.3	23.4	11	3.01	4.49	1.30	0.5	16.2

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Neutrophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	2.99	1.74	2.20	1.1	7.2						
V2, Wk 0 (BL)	18	3.19	1.23	2.90	1.5	6.0						
Baseline	19	3.13	1.22	2.80	1.5	6.0						
V3, Wk 2 (T)	19	2.84	1.25	2.60	1.0	7.3	19	-0.28	1.22	-0.20	-3.3	2.7
V5, Wk 6 (M)	9	3.48	1.90	3.20	1.3	7.7	9	0.38	2.31	0.30	-2.2	5.4
V7, Wk 12 (M)	4	3.40	0.67	3.70	2.4	3.8	4	0.08	1.75	0.60	-2.3	1.4
V9, Wk 20 (M)	3	3.07	0.47	2.90	2.7	3.6	3	-0.60	1.56	0.30	-2.4	0.3
V10, Wk 24 (M)	3	2.43	0.93	2.70	1.4	3.2	3	-1.23	1.55	-1.20	-2.8	0.3
Early Termination Visit	16	3.23	1.38	2.65	1.5	7.3	16	0.21	1.41	0.25	-2.2	3.0
Last Visit	19	3.11	1.33	2.70	1.4	7.3	19	-0.02	1.49	0.20	-2.8	3.0
Min Post-BL	19	2.35	0.82	2.30	1.0	3.9	19	-0.78	0.99	-0.50	-3.3	0.5
Max Post-BL	19	3.83	1.72	3.10	2.1	7.7	19	0.71	1.78	0.50	-2.2	5.4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Neutrophils (10^9/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	3.74	1.75	3.50	1.7	8.0						
V2, Wk 0 (BL)	11	3.51	1.30	3.40	1.6	5.8						
Baseline	11	3.51	1.30	3.40	1.6	5.8						
V3, Wk 2 (T)	11	3.26	1.18	3.10	1.6	5.9	11	-0.25	0.84	0.10	-1.6	0.9
V5, Wk 6 (M)	11	3.06	0.79	3.10	1.9	4.4	11	-0.45	1.07	-0.40	-2.7	1.4
V7, Wk 12 (M)	10	2.78	1.21	2.35	1.7	5.4	10	-0.78	1.47	-0.60	-4.1	1.0
V9, Wk 20 (M)	8	3.29	1.49	2.55	2.2	6.3	8	0.03	1.03	0.15	-1.9	1.3
V10, Wk 24 (M)	9	3.32	1.74	3.10	1.4	7.5	9	-0.07	0.97	-0.10	-1.6	1.7
Early Termination Visit	2	3.90	0.28	3.90	3.7	4.1	2	-0.15	1.20	-0.15	-1.0	0.7
Last Visit	11	3.43	1.58	3.20	1.4	7.5	11	-0.08	0.95	-0.10	-1.6	1.7
Min Post-BL	11	2.41	0.75	2.40	1.4	3.8	11	-1.10	1.18	-1.10	-4.1	-0.1
Max Post-BL	11	4.05	1.47	3.70	2.3	7.5	11	0.54	0.96	0.70	-1.5	1.7

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Neutrophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	49.55	10.39	47.00	33.5	73.1						
V2, Wk 0 (BL)	18	51.12	8.50	52.95	34.4	64.1						
Baseline	19	50.84	8.35	51.80	34.4	64.1						
V3, Wk 2 (T)	19	50.37	8.03	50.60	31.8	66.7	19	-0.46	7.41	-0.70	-11.5	13.7
V5, Wk 6 (M)	9	54.59	14.38	54.30	31.9	82.4	9	2.64	16.03	6.50	-24.0	27.4
V7, Wk 12 (M)	4	56.25	8.01	56.55	46.7	65.2	4	3.70	9.64	3.10	-5.1	13.7
V9, Wk 20 (M)	3	56.27	1.01	56.40	55.2	57.2	3	4.53	6.08	3.40	-0.9	11.1
V10, Wk 24 (M)	3	47.83	12.75	50.40	34.0	59.1	3	-3.90	15.62	-6.90	-17.8	13.0
Early Termination Visit	16	51.18	9.87	51.60	32.0	68.5	16	0.51	11.01	0.25	-18.3	19.6
Last Visit	19	50.65	10.04	51.30	32.0	68.5	19	-0.19	11.44	-1.00	-18.3	19.6
Min Post-BL	19	45.51	9.03	46.70	31.8	59.6	19	-5.33	9.40	-2.60	-24.0	6.5
Max Post-BL	19	56.60	10.12	56.40	38.6	82.4	19	5.76	10.86	7.50	-10.4	27.4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-59　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Neutrophils/Leukocytes (%)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	54.07	9.34	54.60	37.5	68.5						
V2, Wk 0 (BL)	11	53.72	8.74	54.70	39.4	67.9						
Baseline	11	53.72	8.74	54.70	39.4	67.9						
V3, Wk 2 (T)	11	52.56	9.71	53.60	35.0	66.7	11	-1.15	5.85	-0.50	-10.0	6.1
V5, Wk 6 (M)	11	52.87	9.37	50.50	39.3	66.9	11	-0.85	6.62	-1.00	-9.4	12.2
V7, Wk 12 (M)	10	49.40	8.18	51.60	36.6	64.4	10	-4.96	8.16	-2.65	-24.1	5.1
V9, Wk 20 (M)	8	55.46	7.06	55.65	46.4	64.4	8	1.77	6.98	2.35	-12.3	8.7
V10, Wk 24 (M)	9	56.20	11.49	53.30	39.9	73.7	9	2.08	5.68	-0.40	-4.3	12.6
Early Termination Visit	2	53.05	3.18	53.05	50.8	55.3	2	1.15	9.69	1.15	-5.7	8.0
Last Visit	11	55.63	10.40	53.30	39.9	73.7	11	1.91	5.94	-0.40	-5.7	12.6
Min Post-BL	11	46.23	6.86	47.20	35.0	55.6	11	-7.49	6.94	-5.30	-24.1	2.0
Max Post-BL	11	59.93	8.32	59.40	46.6	73.7	11	6.21	4.65	7.20	-1.4	12.6

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.1

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Calcium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	2.319	0.095	2.320	2.10	2.63						
V2, Wk 0 (BL)	120	2.305	0.079	2.310	2.07	2.57						
Baseline	121	2.305	0.079	2.310	2.07	2.57						
V3, Wk 2 (T)	117	2.308	0.088	2.300	2.11	2.58	117	0.003	0.081	0.000	-0.19	0.30
V5, Wk 6 (M)	69	2.302	0.104	2.310	2.08	2.50	69	0.003	0.091	0.000	-0.20	0.24
V7, Wk 12 (M)	54	2.287	0.101	2.275	2.11	2.50	54	-0.009	0.100	-0.010	-0.21	0.22
V9, Wk 20 (M)	37	2.298	0.095	2.320	2.11	2.55	37	-0.007	0.101	-0.020	-0.17	0.23
V10, Wk 24 (M)	37	2.279	0.090	2.280	1.97	2.44	37	-0.026	0.089	-0.050	-0.27	0.13
Early Termination Visit	78	2.295	0.073	2.300	2.06	2.44	78	-0.007	0.077	0.000	-0.24	0.14
Last Visit	121	2.295	0.082	2.300	1.97	2.48	121	-0.009	0.084	0.000	-0.27	0.22
Min Post-BL	121	2.248	0.086	2.250	1.97	2.42	121	-0.057	0.081	-0.050	-0.27	0.16
Max Post-BL	121	2.360	0.080	2.350	2.18	2.58	121	0.056	0.080	0.060	-0.14	0.30

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Calcium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	2.349	0.099	2.350	2.07	2.63						
V2, Wk 0 (BL)	121	2.345	0.106	2.340	2.10	2.69						
Baseline	121	2.345	0.106	2.340	2.10	2.69						
V3, Wk 2 (T)	113	2.324	0.106	2.330	2.11	2.63	113	-0.021	0.104	-0.020	-0.27	0.25
V5, Wk 6 (M)	79	2.323	0.132	2.330	1.94	2.67	79	-0.017	0.111	-0.010	-0.41	0.18
V7, Wk 12 (M)	69	2.327	0.095	2.330	2.09	2.58	69	-0.010	0.095	-0.020	-0.28	0.20
V9, Wk 20 (M)	59	2.336	0.107	2.350	2.06	2.57	59	-0.007	0.093	-0.020	-0.17	0.27
V10, Wk 24 (M)	60	2.323	0.102	2.325	2.07	2.55	60	-0.019	0.118	-0.010	-0.45	0.24
Early Termination Visit	53	2.336	0.101	2.340	2.18	2.61	53	-0.015	0.078	-0.010	-0.17	0.18
Last Visit	119	2.329	0.102	2.330	2.07	2.61	119	-0.016	0.101	-0.010	-0.45	0.24
Min Post-BL	119	2.263	0.099	2.260	1.94	2.60	119	-0.083	0.097	-0.090	-0.45	0.15
Max Post-BL	119	2.391	0.102	2.400	2.17	2.67	119	0.045	0.087	0.050	-0.17	0.27

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Phosphate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	120	1.240	0.258	1.215	0.70	2.26						
V2, Wk 0 (BL)	118	1.212	0.233	1.200	0.54	1.94						
Baseline	121	1.208	0.232	1.190	0.54	1.94						
V3, Wk 2 (T)	113	1.210	0.233	1.190	0.71	1.84	113	-0.001	0.159	0.000	-0.35	0.37
V5, Wk 6 (M)	68	1.212	0.238	1.210	0.58	1.78	68	0.012	0.179	0.005	-0.52	0.49
V7, Wk 12 (M)	54	1.192	0.224	1.190	0.80	1.73	54	-0.016	0.195	-0.070	-0.48	0.50
V9, Wk 20 (M)	36	1.235	0.228	1.200	0.90	1.70	36	0.019	0.185	-0.010	-0.37	0.44
V10, Wk 24 (M)	37	1.195	0.256	1.220	0.78	1.72	37	-0.018	0.207	-0.020	-0.45	0.46
Early Termination Visit	77	1.231	0.225	1.200	0.68	1.80	77	0.025	0.168	0.030	-0.49	0.39
Last Visit	121	1.220	0.234	1.200	0.68	1.80	121	0.012	0.189	0.020	-0.49	0.46
Min Post-BL	121	1.107	0.219	1.120	0.58	1.80	121	-0.102	0.166	-0.100	-0.52	0.26
Max Post-BL	121	1.312	0.212	1.300	0.81	1.84	121	0.104	0.172	0.110	-0.49	0.50

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Phosphate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	119	1.226	0.220	1.190	0.67	2.07						
V2, Wk 0 (BL)	118	1.216	0.230	1.210	0.54	1.84						
Baseline	121	1.215	0.227	1.210	0.54	1.84						
V3, Wk 2 (T)	112	1.225	0.239	1.180	0.71	1.89	112	0.006	0.201	0.005	-0.55	1.00
V5, Wk 6 (M)	79	1.224	0.219	1.190	0.78	1.81	79	0.007	0.173	-0.010	-0.42	0.47
V7, Wk 12 (M)	67	1.247	0.229	1.190	0.88	1.85	67	0.023	0.179	0.010	-0.41	0.49
V9, Wk 20 (M)	59	1.254	0.229	1.200	0.76	1.85	59	0.036	0.190	0.030	-0.46	0.68
V10, Wk 24 (M)	60	1.240	0.206	1.200	0.85	1.84	60	0.015	0.179	0.015	-0.42	0.59
Early Termination Visit	51	1.210	0.264	1.190	0.70	1.96	51	0.004	0.158	-0.020	-0.31	0.36
Last Visit	119	1.224	0.233	1.190	0.70	1.96	119	0.009	0.174	0.000	-0.46	0.59
Min Post-BL	119	1.112	0.225	1.080	0.70	1.75	119	-0.103	0.169	-0.100	-0.55	0.47
Max Post-BL	119	1.335	0.231	1.300	0.70	1.96	119	0.120	0.180	0.130	-0.31	1.00

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Sodium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	141.2	2.1	141.0	136	147						
V2, Wk 0 (BL)	120	141.6	2.0	141.0	137	150						
Baseline	121	141.6	2.0	141.0	137	150						
V3, Wk 2 (T)	117	141.4	2.0	141.0	136	146	117	-0.2	2.0	0.0	-6	6
V5, Wk 6 (M)	69	141.8	2.5	141.0	137	153	69	0.2	2.3	0.0	-4	10
V7, Wk 12 (M)	54	141.7	2.2	142.0	137	148	54	0.1	2.1	0.0	-5	6
V9, Wk 20 (M)	37	141.9	2.6	142.0	137	148	37	0.2	2.3	0.0	-4	8
V10, Wk 24 (M)	37	141.9	2.2	141.0	139	146	37	0.3	1.9	0.0	-4	4
Early Termination Visit	78	141.0	2.0	141.0	136	146	78	-0.4	1.8	0.0	-6	4
Last Visit	121	141.4	2.1	141.0	136	146	121	-0.2	1.9	0.0	-6	4
Min Post-BL	121	140.2	1.8	140.0	136	146	121	-1.3	1.7	-1.0	-6	3
Max Post-BL	121	142.6	2.3	142.0	137	153	121	1.1	2.1	1.0	-4	10

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Sodium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	141.5	2.1	141.0	134	149						
V2, Wk 0 (BL)	121	141.6	2.0	141.0	135	148						
Baseline	121	141.6	2.0	141.0	135	148						
V3, Wk 2 (T)	113	141.8	1.9	142.0	135	147	113	0.2	1.8	0.0	-4	6
V5, Wk 6 (M)	79	141.5	2.1	141.0	135	146	79	0.1	2.0	0.0	-5	4
V7, Wk 12 (M)	69	141.5	2.3	142.0	131	148	69	0.1	2.1	0.0	-5	7
V9, Wk 20 (M)	59	141.7	2.3	142.0	133	148	59	0.2	2.1	0.0	-5	6
V10, Wk 24 (M)	60	141.4	2.1	141.0	135	146	60	-0.1	2.1	0.0	-6	4
Early Termination Visit	53	141.4	1.9	141.0	137	146	53	-0.2	1.7	0.0	-4	4
Last Visit	119	141.4	2.1	141.0	135	146	119	-0.2	2.0	0.0	-6	4
Min Post-BL	119	140.4	2.0	141.0	131	146	119	-1.2	1.8	-1.0	-6	4
Max Post-BL	119	142.9	1.9	143.0	135	148	119	1.3	1.9	1.0	-4	7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Potassium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	4.40	0.51	4.40	3.6	8.6						
V2, Wk 0 (BL)	119	4.36	0.38	4.30	3.6	5.7						
Baseline	121	4.37	0.38	4.30	3.6	5.7						
V3, Wk 2 (T)	115	4.37	0.30	4.40	3.6	5.2	115	-0.01	0.36	0.00	-1.0	0.8
V5, Wk 6 (M)	68	4.31	0.34	4.20	3.7	5.5	68	0.00	0.40	0.00	-1.1	1.0
V7, Wk 12 (M)	54	4.31	0.42	4.30	3.5	5.6	54	-0.01	0.41	0.00	-0.9	1.4
V9, Wk 20 (M)	36	4.33	0.34	4.30	3.6	5.1	36	-0.04	0.46	0.00	-1.0	0.8
V10, Wk 24 (M)	37	4.36	0.35	4.30	3.8	5.4	37	0.01	0.45	0.10	-1.1	0.8
Early Termination Visit	78	4.32	0.31	4.30	3.5	5.1	78	-0.06	0.34	-0.10	-0.9	0.7
Last Visit	121	4.33	0.32	4.30	3.5	5.4	121	-0.04	0.38	0.00	-1.1	0.8
Min Post-BL	121	4.13	0.27	4.10	3.5	4.7	121	-0.23	0.34	-0.20	-1.1	0.5
Max Post-BL	121	4.55	0.34	4.50	3.5	5.6	121	0.19	0.37	0.20	-0.8	1.4

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Potassium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	4.51	0.41	4.50	3.5	6.0						
V2, Wk 0 (BL)	118	4.42	0.41	4.40	3.4	5.8						
Baseline	121	4.42	0.40	4.40	3.4	5.8						
V3, Wk 2 (T)	113	4.47	0.40	4.40	3.6	5.8	113	0.04	0.43	0.00	-1.0	1.2
V5, Wk 6 (M)	79	4.47	0.42	4.40	3.7	5.5	79	0.07	0.44	0.10	-1.0	1.1
V7, Wk 12 (M)	67	4.44	0.37	4.40	3.6	5.1	67	0.02	0.40	0.00	-1.0	1.2
V9, Wk 20 (M)	59	4.42	0.37	4.40	3.5	5.3	59	0.01	0.39	0.00	-1.0	1.0
V10, Wk 24 (M)	60	4.50	0.37	4.45	3.4	5.5	60	0.10	0.42	0.20	-0.9	1.0
Early Termination Visit	52	4.39	0.37	4.40	3.6	5.6	52	-0.04	0.42	0.00	-1.2	0.8
Last Visit	119	4.47	0.40	4.40	3.4	5.8	119	0.05	0.43	0.10	-1.2	1.0
Min Post-BL	119	4.21	0.34	4.20	3.4	5.8	119	-0.21	0.40	-0.20	-1.2	0.8
Max Post-BL	119	4.71	0.40	4.70	3.8	5.8	119	0.29	0.41	0.30	-0.8	1.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Chloride (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	106.1	3.0	106.0	100	116						
V2, Wk 0 (BL)	120	106.2	3.0	106.0	100	115						
Baseline	121	106.1	3.0	106.0	100	115						
V3, Wk 2 (T)	117	106.2	2.9	106.0	99	115	117	0.1	2.1	0.0	-4	6
V5, Wk 6 (M)	69	106.9	3.0	107.0	100	114	69	0.3	2.3	0.0	-4	8
V7, Wk 12 (M)	54	106.6	3.3	106.0	100	117	54	0.4	2.4	0.5	-5	6
V9, Wk 20 (M)	37	105.9	3.5	106.0	100	118	37	-0.7	2.7	-1.0	-11	4
V10, Wk 24 (M)	37	106.7	3.1	106.0	101	115	37	0.1	2.0	0.0	-6	4
Early Termination Visit	78	105.9	2.8	105.5	100	112	78	-0.2	2.3	0.0	-5	6
Last Visit	121	106.2	2.8	106.0	100	115	121	0.1	2.3	0.0	-6	6
Min Post-BL	121	104.9	2.8	105.0	99	114	121	-1.2	2.2	-1.0	-11	4
Max Post-BL	121	107.5	3.0	107.0	101	118	121	1.4	2.2	1.0	-3	8

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Chloride (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	106.0	2.8	106.0	98	114						
V2, Wk 0 (BL)	121	105.6	2.8	105.0	100	115						
Baseline	121	105.6	2.8	105.0	100	115						
V3, Wk 2 (T)	113	106.2	2.8	106.0	100	114	113	0.6	2.3	1.0	-5	6
V5, Wk 6 (M)	79	105.7	2.4	106.0	99	113	79	0.6	2.3	1.0	-6	6
V7, Wk 12 (M)	69	105.9	3.0	106.0	94	113	69	0.7	2.4	1.0	-6	6
V9, Wk 20 (M)	59	105.9	2.7	105.0	99	114	59	0.6	2.2	1.0	-6	7
V10, Wk 24 (M)	60	105.6	2.8	105.0	95	113	60	0.4	2.1	1.0	-5	5
Early Termination Visit	53	105.9	2.8	106.0	98	111	53	-0.1	2.6	1.0	-6	5
Last Visit	119	105.7	2.9	106.0	95	113	119	0.1	2.3	1.0	-6	5
Min Post-BL	119	104.6	2.9	104.0	94	112	119	-1.0	2.2	-1.0	-6	4
Max Post-BL	119	107.5	2.5	107.0	100	114	119	1.9	2.2	2.0	-4	8

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bicarbonate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	110	24.9	3.5	25.0	17	34						
V2, Wk 0 (BL)	111	25.4	3.6	26.0	17	33						
Baseline	114	25.4	3.5	26.0	17	33						
V3, Wk 2 (T)	109	25.4	3.8	26.0	18	34	107	-0.0	2.6	0.0	-7	6
V5, Wk 6 (M)	66	24.6	3.3	24.5	17	34	65	-0.1	2.5	0.0	-6	5
V7, Wk 12 (M)	50	24.6	3.2	24.0	18	31	49	-0.1	2.4	0.0	-6	6
V9, Wk 20 (M)	35	24.8	3.0	25.0	18	33	34	0.8	2.1	1.0	-2	6
V10, Wk 24 (M)	37	24.1	3.0	24.0	18	29	35	0.1	2.3	0.0	-4	5
Early Termination Visit	72	25.7	3.7	25.0	17	34	71	-0.1	2.7	0.0	-7	6
Last Visit	116	25.2	3.6	25.0	17	34	113	-0.2	2.8	0.0	-7	8
Min Post-BL	116	23.7	3.5	23.0	17	32	113	-1.7	2.3	-2.0	-7	4
Max Post-BL	116	26.7	3.5	27.0	17	34	113	1.4	2.6	1.0	-5	8

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bicarbonate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	110	24.9	3.5	25.0	16	34						
V2, Wk 0 (BL)	110	25.4	2.9	25.0	20	32						
Baseline	113	25.4	2.9	25.0	20	32						
V3, Wk 2 (T)	104	24.8	2.7	25.0	18	32	103	-0.6	2.2	0.0	-9	4
V5, Wk 6 (M)	72	25.4	3.0	25.0	19	34	72	-0.4	2.4	-0.5	-5	5
V7, Wk 12 (M)	63	24.8	3.4	25.0	17	32	63	-0.7	2.6	-1.0	-8	5
V9, Wk 20 (M)	49	25.4	2.9	26.0	20	32	49	-0.3	2.4	0.0	-5	5
V10, Wk 24 (M)	56	25.1	3.0	24.5	19	32	54	-0.5	2.4	0.0	-7	5
Early Termination Visit	52	25.2	3.1	25.0	20	33	52	-0.0	2.7	0.0	-7	9
Last Visit	112	25.1	3.0	25.0	19	33	110	-0.3	2.6	0.0	-7	9
Min Post-BL	112	23.3	2.6	23.0	17	29	110	-2.1	2.4	-2.0	-9	4
Max Post-BL	112	26.5	2.8	26.0	20	34	110	1.1	2.1	1.0	-5	9

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatinine (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	69.2	75.3	63.0	30	877						
V2, Wk 0 (BL)	120	63.4	13.9	64.0	28	98						
Baseline	121	63.3	13.9	64.0	28	98						
V3, Wk 2 (T)	116	65.2	14.5	66.5	22	100	116	1.7	7.5	2.0	-22	25
V5, Wk 6 (M)	67	62.2	14.6	61.0	35	103	67	-0.5	7.0	0.0	-19	14
V7, Wk 12 (M)	54	63.6	14.8	65.0	34	102	54	0.2	8.1	-1.0	-21	15
V9, Wk 20 (M)	37	63.8	15.9	63.0	35	110	37	0.5	9.0	1.0	-22	18
V10, Wk 24 (M)	37	63.0	14.4	64.0	32	100	37	-0.4	8.6	1.0	-22	15
Early Termination Visit	78	62.6	12.4	63.0	34	90	78	0.2	7.0	-1.0	-16	14
Last Visit	121	63.4	13.1	64.0	32	100	121	0.1	7.5	-1.0	-22	15
Min Post-BL	121	59.5	13.3	61.0	22	100	121	-3.8	6.6	-3.0	-22	9
Max Post-BL	121	68.2	14.4	68.0	34	110	121	5.0	6.9	4.0	-13	25

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatinine (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	65.0	16.4	65.0	26	103						
V2, Wk 0 (BL)	119	65.8	17.8	65.0	27	114						
Baseline	121	65.8	17.6	65.0	27	114						
V3, Wk 2 (T)	112	66.4	16.2	67.0	30	112	112	0.7	8.5	1.0	-36	35
V5, Wk 6 (M)	79	64.7	15.5	65.0	29	105	79	-1.1	8.0	-1.0	-24	14
V7, Wk 12 (M)	68	66.2	16.4	67.0	28	122	68	0.2	6.3	0.0	-15	13
V9, Wk 20 (M)	59	65.5	15.9	65.0	32	110	59	-1.0	8.6	-1.0	-30	25
V10, Wk 24 (M)	60	65.9	15.5	64.5	32	114	60	-0.3	9.2	1.0	-28	19
Early Termination Visit	53	65.3	17.4	67.0	28	105	53	1.0	7.8	1.0	-17	20
Last Visit	119	66.4	16.8	67.0	28	114	119	0.6	8.5	1.0	-28	20
Min Post-BL	119	61.1	15.3	61.0	28	102	119	-4.7	7.8	-4.0	-36	15
Max Post-BL	119	71.1	17.7	71.0	29	122	119	5.3	7.6	5.0	-15	35

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urea Nitrogen (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	4.76	2.24	4.50	1.7	24.1						
V2, Wk 0 (BL)	120	4.68	1.40	4.50	2.3	10.7						
Baseline	121	4.67	1.40	4.50	2.3	10.7						
V3, Wk 2 (T)	117	4.69	1.34	4.30	2.4	8.4	117	-0.01	1.22	0.10	-3.2	3.2
V5, Wk 6 (M)	69	4.63	1.23	4.30	2.3	7.2	69	0.03	1.12	0.10	-3.6	2.6
V7, Wk 12 (M)	54	4.59	1.39	4.20	2.3	8.7	54	0.02	1.25	0.00	-2.1	5.4
V9, Wk 20 (M)	37	4.87	1.23	4.80	2.4	8.0	37	0.08	1.21	0.30	-2.5	2.5
V10, Wk 24 (M)	37	4.90	1.24	4.70	2.8	7.3	37	0.11	1.23	0.30	-3.1	2.4
Early Termination Visit	78	4.64	1.42	4.40	2.1	9.4	78	0.03	1.21	0.10	-4.0	2.4
Last Visit	121	4.77	1.40	4.60	2.1	9.4	121	0.10	1.30	0.20	-4.0	5.4
Min Post-BL	121	4.01	1.14	3.70	2.1	7.1	121	-0.67	1.13	-0.50	-4.3	2.1
Max Post-BL	121	5.35	1.37	5.10	2.9	9.4	121	0.68	1.17	0.70	-3.2	5.4

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urea Nitrogen (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	4.61	1.26	4.40	1.7	10.1						
V2, Wk 0 (BL)	120	4.64	1.21	4.45	1.5	7.1						
Baseline	120	4.64	1.21	4.45	1.5	7.1						
V3, Wk 2 (T)	112	4.58	1.30	4.40	2.1	7.9	112	-0.07	0.92	-0.15	-2.2	2.5
V5, Wk 6 (M)	79	4.55	1.50	4.50	1.8	10.1	78	-0.04	1.24	-0.05	-3.2	4.6
V7, Wk 12 (M)	68	4.47	1.29	4.35	2.5	8.6	68	-0.16	1.16	-0.30	-3.3	2.9
V9, Wk 20 (M)	58	4.63	1.33	4.40	2.2	8.1	58	-0.10	1.07	0.00	-3.1	2.2
V10, Wk 24 (M)	59	4.75	1.37	4.60	1.9	8.4	59	0.04	1.11	-0.10	-2.5	2.2
Early Termination Visit	53	4.54	1.09	4.10	2.9	7.6	53	-0.02	0.99	-0.10	-2.2	2.6
Last Visit	118	4.64	1.24	4.55	1.9	8.4	118	0.00	1.06	-0.10	-2.5	2.6
Min Post-BL	119	3.84	1.07	3.60	1.8	6.8	118	-0.79	0.85	-0.75	-3.3	1.8
Max Post-BL	119	5.26	1.36	5.10	1.8	10.1	118	0.64	1.07	0.65	-1.6	4.6

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Aspartate Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	120	22.1	7.3	20.0	8	46						
V2, Wk 0 (BL)	119	22.4	7.6	21.0	8	53						
Baseline	121	22.3	7.5	21.0	8	53						
V3, Wk 2 (T)	115	25.0	19.7	21.0	12	215	115	2.7	17.9	1.0	-27	176
V5, Wk 6 (M)	69	23.0	8.8	22.0	10	63	69	0.6	9.7	-1.0	-29	47
V7, Wk 12 (M)	54	23.4	12.0	21.0	9	87	54	0.6	10.3	0.0	-37	49
V9, Wk 20 (M)	37	21.5	5.9	20.0	10	37	37	-1.2	8.5	-1.0	-37	13
V10, Wk 24 (M)	37	22.8	12.5	20.0	10	88	37	0.0	14.4	-1.0	-42	68
Early Termination Visit	78	21.9	8.6	19.0	9	52	78	-0.1	6.6	-1.0	-14	24
Last Visit	121	22.1	9.7	19.0	9	88	121	-0.2	9.6	-1.0	-42	68
Min Post-BL	121	19.6	6.1	19.0	9	43	121	-2.7	6.4	-2.0	-42	16
Max Post-BL	121	29.1	21.4	24.0	11	215	121	6.8	19.2	3.0	-27	176

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Aspartate Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	22.6	7.4	21.0	3	50						
V2, Wk 0 (BL)	120	23.4	12.3	20.0	13	134						
Baseline	121	23.4	12.2	20.0	13	134						
V3, Wk 2 (T)	112	24.1	19.4	21.0	13	214	112	0.5	9.4	0.5	-20	80
V5, Wk 6 (M)	79	22.8	7.7	21.0	14	57	79	0.9	7.4	0.0	-17	38
V7, Wk 12 (M)	69	23.7	12.0	22.0	11	103	69	1.9	10.8	0.0	-12	75
V9, Wk 20 (M)	59	21.8	5.8	21.0	12	36	59	0.4	4.4	1.0	-11	12
V10, Wk 24 (M)	60	22.0	6.2	20.0	14	44	60	0.5	5.0	0.0	-13	17
Early Termination Visit	52	23.0	8.7	20.5	12	58	52	-0.3	6.9	0.0	-21	25
Last Visit	119	23.3	11.1	20.0	12	111	119	-0.1	6.2	0.0	-23	25
Min Post-BL	119	20.4	10.1	19.0	11	111	119	-3.1	4.9	-2.0	-23	7
Max Post-BL	119	28.1	20.5	24.0	14	214	119	4.6	12.0	3.0	-20	80

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alanine Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	120	22.5	13.6	18.0	6	77						
V2, Wk 0 (BL)	119	23.0	12.9	18.0	6	77						
Baseline	121	23.0	12.9	18.0	6	77						
V3, Wk 2 (T)	115	26.8	32.2	19.0	8	336	115	4.0	28.9	0.0	-26	298
V5, Wk 6 (M)	69	25.5	20.0	18.0	7	111	69	1.9	16.9	-1.0	-23	91
V7, Wk 12 (M)	54	25.1	18.3	19.0	10	112	54	2.8	12.2	-0.5	-18	56
V9, Wk 20 (M)	37	23.2	14.3	20.0	11	88	37	-0.1	11.7	0.0	-31	28
V10, Wk 24 (M)	37	23.3	14.9	20.0	8	88	37	-0.1	12.0	1.0	-32	35
Early Termination Visit	78	22.1	14.6	16.0	8	82	78	-0.7	9.6	-1.0	-40	35
Last Visit	121	22.5	14.4	18.0	8	88	121	-0.5	10.3	0.0	-40	35
Min Post-BL	121	19.5	11.6	15.0	7	74	121	-3.5	8.3	-2.0	-40	19
Max Post-BL	121	32.6	35.1	22.0	9	339	121	9.6	30.5	3.0	-11	301

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alanine Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	23.2	14.3	19.0	9	102						
V2, Wk 0 (BL)	120	23.2	13.2	19.0	10	89						
Baseline	121	23.4	13.3	19.0	10	89						
V3, Wk 2 (T)	112	24.0	17.4	19.5	9	121	112	0.1	9.7	0.0	-27	43
V5, Wk 6 (M)	79	23.9	14.6	19.0	9	97	79	1.6	11.9	-1.0	-16	63
V7, Wk 12 (M)	69	24.3	18.2	18.0	9	129	69	1.8	16.2	-1.0	-22	106
V9, Wk 20 (M)	59	23.3	12.4	20.0	9	64	59	0.9	9.2	0.0	-25	32
V10, Wk 24 (M)	60	23.8	12.7	20.0	11	69	60	1.5	8.9	0.5	-20	28
Early Termination Visit	52	23.2	16.3	18.5	9	101	52	0.5	9.2	0.0	-36	32
Last Visit	119	24.3	15.6	20.0	9	101	119	0.8	9.2	0.0	-36	32
Min Post-BL	119	19.3	12.7	16.0	9	93	119	-4.2	7.2	-3.0	-36	10
Max Post-BL	119	30.8	22.0	23.0	11	129	119	7.3	15.5	3.0	-27	106

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bilirubin (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	120	7.82	3.85	6.80	2.9	24.1						
V2, Wk 0 (BL)	119	7.86	4.25	6.60	3.1	29.8						
Baseline	121	7.81	4.23	6.60	3.1	29.8						
V3, Wk 2 (T)	115	7.76	4.01	6.80	3.4	29.1	115	-0.12	3.41	0.00	-10.0	17.2
V5, Wk 6 (M)	69	9.12	5.93	8.00	3.0	42.0	69	0.78	4.56	0.00	-12.6	19.0
V7, Wk 12 (M)	54	8.71	4.97	7.30	3.4	27.4	54	-0.12	3.06	-0.35	-8.8	8.0
V9, Wk 20 (M)	37	8.14	3.34	6.90	3.4	19.9	37	0.04	3.67	0.10	-11.9	5.6
V10, Wk 24 (M)	37	8.36	4.48	7.00	3.0	26.8	37	0.26	2.42	0.30	-8.5	4.0
Early Termination Visit	78	7.56	3.65	6.75	3.4	24.6	78	-0.12	3.03	0.00	-9.2	7.6
Last Visit	121	7.76	3.97	6.90	3.0	27.1	121	-0.05	2.80	0.00	-9.2	7.6
Min Post-BL	121	6.09	2.47	5.40	3.0	17.2	121	-1.71	2.85	-1.20	-12.6	4.7
Max Post-BL	121	9.75	5.60	8.40	3.4	42.0	121	1.95	3.80	1.70	-6.8	19.0

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bilirubin (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	120	7.30	3.22	6.80	2.9	23.4						
V2, Wk 0 (BL)	120	7.63	3.90	6.80	1.7	30.8						
Baseline	121	7.65	3.89	6.80	1.7	30.8						
V3, Wk 2 (T)	112	7.15	3.32	6.80	2.7	27.5	112	-0.34	3.71	0.00	-24.0	9.1
V5, Wk 6 (M)	79	7.49	3.26	6.80	2.6	19.2	79	-0.54	3.64	-0.10	-18.8	9.4
V7, Wk 12 (M)	69	7.15	2.95	6.90	3.3	17.2	69	-0.82	2.58	-0.70	-7.3	5.7
V9, Wk 20 (M)	59	7.02	2.58	6.20	3.1	13.6	59	-1.06	3.10	-0.80	-10.3	8.9
V10, Wk 24 (M)	60	8.05	4.41	6.90	3.4	28.8	60	-0.01	4.27	-0.30	-10.3	24.2
Early Termination Visit	52	6.48	2.78	6.00	1.7	17.1	52	-0.61	3.82	-0.25	-20.5	9.0
Last Visit	119	7.49	3.88	6.80	1.7	28.8	119	-0.17	4.07	0.00	-20.5	24.2
Min Post-BL	119	5.65	2.44	5.10	1.7	17.1	119	-2.01	3.31	-1.60	-24.0	5.5
Max Post-BL	119	9.06	4.30	8.40	3.4	28.8	119	1.40	3.96	0.90	-18.8	24.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alkaline Phosphatase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	88.6	68.5	68.0	28	526						
V2, Wk 0 (BL)	120	86.4	58.2	70.0	29	320						
Baseline	121	86.4	58.0	70.0	29	320						
V3, Wk 2 (T)	117	86.3	64.7	67.0	30	429	117	1.3	15.3	0.0	-36	109
V5, Wk 6 (M)	69	83.9	52.8	68.0	31	337	69	1.2	13.6	1.0	-41	46
V7, Wk 12 (M)	54	86.6	56.2	67.5	27	358	54	0.6	15.5	-0.5	-44	64
V9, Wk 20 (M)	37	85.8	61.6	69.0	27	332	37	0.1	20.9	0.0	-57	74
V10, Wk 24 (M)	37	86.7	61.9	66.0	29	354	37	1.0	19.3	0.0	-41	62
Early Termination Visit	78	89.3	78.1	67.0	35	576	78	4.3	33.4	0.0	-36	256
Last Visit	121	89.5	72.4	67.0	29	576	121	3.1	29.0	0.0	-41	256
Min Post-BL	121	81.9	62.0	64.0	27	429	121	-4.4	16.2	-4.0	-57	109
Max Post-BL	121	96.2	74.9	71.0	31	576	121	9.8	28.4	5.0	-14	256

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alkaline Phosphatase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	92.5	62.8	73.0	37	438						
V2, Wk 0 (BL)	121	91.8	59.2	71.0	36	406						
Baseline	121	91.8	59.2	71.0	36	406						
V3, Wk 2 (T)	113	91.2	56.6	74.0	36	358	113	-0.8	11.0	0.0	-52	30
V5, Wk 6 (M)	79	91.8	61.7	70.0	35	396	79	-1.0	13.6	0.0	-54	55
V7, Wk 12 (M)	69	94.1	68.7	72.0	35	410	69	-0.7	15.3	-1.0	-35	84
V9, Wk 20 (M)	59	90.4	65.0	72.0	39	394	59	-2.3	9.5	-1.0	-32	22
V10, Wk 24 (M)	60	95.4	73.0	73.0	36	387	60	-0.1	14.9	0.5	-21	84
Early Termination Visit	53	89.1	44.7	76.0	40	272	53	-1.4	14.7	0.0	-79	19
Last Visit	119	91.5	59.9	75.0	36	387	119	-0.6	14.4	0.0	-79	84
Min Post-BL	119	84.1	53.4	68.0	35	358	119	-8.1	12.4	-5.0	-79	11
Max Post-BL	119	98.4	63.4	78.0	39	410	119	6.2	11.9	4.0	-17	84

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Gamma Glutamyl Transferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	37.7	54.7	20.0	5	402						
V2, Wk 0 (BL)	119	37.6	52.6	21.0	3	320						
Baseline	121	37.2	52.3	21.0	3	320						
V3, Wk 2 (T)	117	36.0	45.0	21.0	2	320	117	-1.8	19.5	0.0	-133	33
V5, Wk 6 (M)	69	28.9	24.6	22.0	3	148	69	-3.0	21.2	-1.0	-127	51
V7, Wk 12 (M)	54	27.7	25.4	20.5	3	159	54	-2.1	15.3	0.0	-56	46
V9, Wk 20 (M)	37	30.5	48.2	20.0	9	300	37	-1.6	22.0	0.0	-64	90
V10, Wk 24 (M)	37	29.9	42.3	20.0	8	268	37	-2.2	16.0	0.0	-63	58
Early Termination Visit	78	44.2	76.9	20.5	7	509	78	3.6	32.5	1.0	-166	189
Last Visit	121	39.7	66.6	20.0	7	509	121	2.4	28.1	1.0	-166	189
Min Post-BL	121	30.5	42.4	17.0	2	315	121	-6.7	22.8	-2.0	-166	30
Max Post-BL	121	45.9	70.9	23.0	8	509	121	8.6	29.3	2.0	-91	189

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Gamma Glutamyl Transferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	35.6	57.1	20.0	4	411						
V2, Wk 0 (BL)	121	34.9	52.4	20.0	5	416						
Baseline	121	34.9	52.4	20.0	5	416						
V3, Wk 2 (T)	113	36.9	53.3	21.0	6	409	113	0.8	10.7	1.0	-47	48
V5, Wk 6 (M)	79	32.6	41.6	21.0	7	343	79	3.7	13.8	1.0	-16	97
V7, Wk 12 (M)	69	31.1	31.9	21.0	8	215	69	2.0	9.7	2.0	-31	52
V9, Wk 20 (M)	59	27.1	21.4	19.0	6	116	59	1.8	9.1	1.0	-26	35
V10, Wk 24 (M)	60	25.8	20.5	18.5	6	119	60	0.5	8.3	0.0	-31	31
Early Termination Visit	53	46.3	64.9	23.0	6	349	53	0.6	16.5	1.0	-67	36
Last Visit	119	36.4	48.1	20.0	6	349	119	1.2	13.7	1.0	-67	61
Min Post-BL	119	31.2	46.2	18.0	6	349	119	-4.0	12.3	-2.0	-67	48
Max Post-BL	119	43.3	57.4	23.0	6	409	119	8.2	14.7	4.0	-44	97

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Glucose (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	5.15	1.30	4.90	3.5	12.1						
V2, Wk 0 (BL)	119	5.06	1.48	4.80	3.5	18.0						
Baseline	121	5.14	1.68	4.80	3.5	18.0						
V3, Wk 2 (T)	115	5.33	1.41	5.00	2.9	12.8	115	0.16	1.31	0.10	-10.2	3.5
V5, Wk 6 (M)	68	5.07	0.91	4.90	4.0	10.4	68	0.02	1.18	0.00	-7.6	2.5
V7, Wk 12 (M)	54	5.18	2.15	4.80	3.2	19.9	54	0.34	2.07	0.00	-2.0	13.9
V9, Wk 20 (M)	36	4.90	0.70	4.80	3.1	6.6	36	-0.02	0.74	-0.05	-1.9	2.0
V10, Wk 24 (M)	37	5.08	0.72	4.90	3.9	7.1	37	0.17	0.78	0.00	-1.4	2.3
Early Termination Visit	78	5.46	2.56	4.90	2.4	19.3	78	0.18	1.68	0.10	-3.4	9.2
Last Visit	121	5.30	2.10	4.90	2.4	19.3	121	0.16	1.42	0.10	-3.4	9.2
Min Post-BL	121	4.75	1.29	4.60	2.4	12.8	121	-0.38	1.21	-0.20	-10.2	2.7
Max Post-BL	121	5.90	2.30	5.30	3.6	19.9	121	0.76	1.68	0.40	-1.8	13.9

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Glucose (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	4.93	0.61	4.90	3.7	8.1						
V2, Wk 0 (BL)	120	4.99	0.80	4.90	3.4	9.9						
Baseline	121	4.99	0.80	4.90	3.4	9.9						
V3, Wk 2 (T)	113	5.07	0.71	5.00	3.4	8.2	113	0.06	0.85	0.10	-2.9	2.8
V5, Wk 6 (M)	79	5.10	0.83	4.90	3.4	9.2	79	0.03	0.78	-0.10	-2.2	3.3
V7, Wk 12 (M)	67	5.06	0.67	5.00	3.6	7.6	67	-0.02	0.84	0.00	-2.3	2.6
V9, Wk 20 (M)	59	5.12	0.85	5.00	4.1	8.5	59	0.01	0.90	0.10	-3.3	2.3
V10, Wk 24 (M)	60	5.06	0.75	4.90	3.6	8.2	60	-0.05	0.83	0.05	-3.0	2.3
Early Termination Visit	52	5.05	1.03	4.75	3.7	9.1	52	0.17	1.07	0.10	-2.2	3.9
Last Visit	119	5.08	0.89	4.90	3.6	9.1	119	0.08	0.95	0.10	-3.0	3.9
Min Post-BL	119	4.60	0.55	4.60	3.4	6.7	119	-0.40	0.72	-0.30	-3.3	1.5
Max Post-BL	119	5.58	0.95	5.40	4.2	9.2	119	0.59	0.94	0.40	-2.2	3.9

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Albumin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	44.7	2.6	44.0	39	51						
V2, Wk 0 (BL)	120	44.5	2.4	45.0	39	51						
Baseline	121	44.5	2.4	45.0	39	51						
V3, Wk 2 (T)	117	44.4	2.7	44.0	38	51	117	-0.0	2.0	0.0	-6	4
V5, Wk 6 (M)	69	44.8	2.9	44.0	38	51	69	0.3	2.0	0.0	-4	6
V7, Wk 12 (M)	54	44.3	2.8	44.5	34	49	54	-0.3	2.5	0.0	-7	4
V9, Wk 20 (M)	37	44.6	2.8	44.0	40	51	37	-0.4	2.3	0.0	-4	4
V10, Wk 24 (M)	37	44.1	2.3	44.0	40	49	37	-0.8	1.7	-1.0	-5	3
Early Termination Visit	78	44.0	2.4	44.0	39	50	78	-0.2	2.1	0.0	-7	5
Last Visit	121	44.1	2.4	44.0	39	51	121	-0.3	2.1	0.0	-7	5
Min Post-BL	121	43.1	2.5	43.0	34	50	121	-1.4	1.9	-1.0	-7	3
Max Post-BL	121	45.6	2.6	45.0	40	53	121	1.2	1.9	1.0	-3	7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Albumin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	45.5	2.8	46.0	39	53						
V2, Wk 0 (BL)	121	45.3	2.8	45.0	36	53						
Baseline	121	45.3	2.8	45.0	36	53						
V3, Wk 2 (T)	113	45.1	2.7	45.0	39	51	113	-0.2	2.3	0.0	-11	6
V5, Wk 6 (M)	79	45.1	2.9	45.0	38	52	79	-0.1	2.2	0.0	-5	6
V7, Wk 12 (M)	69	44.9	3.0	45.0	38	50	69	-0.3	2.4	0.0	-6	5
V9, Wk 20 (M)	59	45.2	2.9	45.0	39	51	59	-0.2	2.4	0.0	-5	6
V10, Wk 24 (M)	60	45.1	2.8	45.0	39	50	60	-0.2	2.5	0.0	-6	7
Early Termination Visit	53	45.3	2.8	45.0	40	52	53	-0.0	2.5	0.0	-5	5
Last Visit	119	45.3	2.8	45.0	39	52	119	-0.1	2.5	0.0	-6	7
Min Post-BL	119	43.7	2.7	44.0	38	51	119	-1.6	2.2	-2.0	-11	5
Max Post-BL	119	46.6	2.6	47.0	41	52	119	1.2	2.1	1.0	-5	7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Protein (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	72.4	4.1	72.0	63	87						
V2, Wk 0 (BL)	120	72.1	4.0	72.0	63	83						
Baseline	121	72.1	4.0	72.0	63	83						
V3, Wk 2 (T)	117	71.9	4.3	72.0	62	83	117	-0.1	3.2	-1.0	-8	8
V5, Wk 6 (M)	69	72.3	4.8	72.0	62	84	69	0.4	3.6	0.0	-7	10
V7, Wk 12 (M)	54	71.7	5.2	71.5	59	84	54	-0.2	3.5	0.0	-9	7
V9, Wk 20 (M)	37	71.9	4.1	72.0	65	80	37	-0.6	3.0	0.0	-5	7
V10, Wk 24 (M)	37	71.3	4.1	71.0	64	82	37	-1.3	2.7	-1.0	-7	4
Early Termination Visit	78	71.3	4.0	71.0	62	79	78	-0.5	3.2	-1.0	-7	8
Last Visit	121	71.5	4.0	71.0	62	82	121	-0.6	3.3	-1.0	-7	9
Min Post-BL	121	69.8	3.8	70.0	59	78	121	-2.3	3.0	-3.0	-9	5
Max Post-BL	121	74.0	4.1	74.0	64	85	121	1.9	3.1	2.0	-5	12

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Protein (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	73.4	4.1	73.0	63	86						
V2, Wk 0 (BL)	121	72.9	4.2	72.0	64	84						
Baseline	121	72.9	4.2	72.0	64	84						
V3, Wk 2 (T)	113	72.6	4.0	73.0	64	87	113	-0.4	3.8	-1.0	-12	9
V5, Wk 6 (M)	79	72.4	4.1	72.0	62	84	79	-0.4	3.5	-1.0	-8	10
V7, Wk 12 (M)	69	72.0	4.5	72.0	62	82	69	-0.6	3.7	-1.0	-11	10
V9, Wk 20 (M)	59	72.1	4.3	72.0	62	82	59	-0.6	3.5	0.0	-7	8
V10, Wk 24 (M)	60	72.0	3.7	72.0	63	81	60	-0.6	3.7	-1.0	-8	7
Early Termination Visit	53	73.2	4.8	73.0	63	85	53	-0.2	3.9	0.0	-8	8
Last Visit	119	72.6	4.4	73.0	63	85	119	-0.3	3.7	0.0	-8	8
Min Post-BL	119	70.2	3.9	70.0	62	82	119	-2.7	3.4	-3.0	-12	7
Max Post-BL	119	74.9	4.0	75.0	66	87	119	1.9	3.4	2.0	-7	10

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urate (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	121	298.2	92.7	285.0	77	651						
V2, Wk 0 (BL)	120	292.1	85.3	283.0	89	626						
Baseline	121	292.2	85.0	283.0	89	626						
V3, Wk 2 (T)	117	299.6	80.3	302.0	83	489	117	5.7	47.7	7.0	-276	134
V5, Wk 6 (M)	69	287.5	87.0	276.0	95	504	69	6.2	55.8	0.0	-130	202
V7, Wk 12 (M)	54	290.4	87.5	287.0	83	521	54	4.6	53.0	7.0	-139	147
V9, Wk 20 (M)	37	305.2	86.8	286.0	207	653	37	11.4	52.8	8.0	-54	212
V10, Wk 24 (M)	37	300.6	72.5	288.0	186	473	37	6.9	46.5	5.0	-83	146
Early Termination Visit	78	295.5	91.7	290.5	83	483	78	3.4	57.4	-5.0	-224	160
Last Visit	121	298.2	85.8	292.0	83	483	121	6.1	54.4	-2.0	-224	160
Min Post-BL	121	268.7	74.8	262.0	83	441	121	-23.5	43.5	-23.0	-276	111
Max Post-BL	121	329.6	92.8	321.0	95	653	121	37.4	58.4	31.0	-224	212

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urate (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	121	300.3	95.3	288.0	116	590						
V2, Wk 0 (BL)	121	292.7	90.7	283.0	125	571						
Baseline	121	292.7	90.7	283.0	125	571						
V3, Wk 2 (T)	113	297.9	89.4	302.0	136	552	113	4.4	42.0	4.0	-145	130
V5, Wk 6 (M)	79	297.9	78.8	288.0	106	475	79	4.4	47.5	4.0	-129	119
V7, Wk 12 (M)	69	304.5	78.7	292.0	169	470	69	8.6	42.6	9.0	-98	111
V9, Wk 20 (M)	59	302.8	84.5	296.0	157	486	59	5.7	57.5	-1.0	-225	131
V10, Wk 24 (M)	60	307.5	84.1	302.5	158	523	60	10.2	47.8	9.0	-120	160
Early Termination Visit	53	282.9	92.7	262.0	121	528	53	-4.5	47.2	5.0	-154	84
Last Visit	119	297.8	88.0	285.0	121	528	119	4.1	47.6	9.0	-154	160
Min Post-BL	119	270.9	81.1	261.0	106	528	119	-22.8	45.1	-22.0	-225	79
Max Post-BL	119	321.8	90.3	311.0	136	552	119	28.1	45.0	25.0	-154	160

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatinine Clearance (mL/min/1.73m2)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
V1, Wk -4 (SCR)	1	13.0	-	13.0	13	13						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatinine Clearance (mL/min/1.73m2)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)												
V1, Wk -4 (SCR)	2	28.5	40.3	28.5	0	57						
Baseline	2	28.5	40.3	28.5	0	57						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Amylase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	45.0	-	45.0	45	45						
Min Post-BL	1	45.0	-	45.0	45	45						
Max Post-BL	1	45.0	-	45.0	45	45						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Direct Bilirubin (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	3.40	-	3.40	3.4	3.4						
Min Post-BL	1	3.40	-	3.40	3.4	3.4						
Max Post-BL	1	3.40	-	3.40	3.4	3.4						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening,
SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Indirect Bilirubin (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	0.00	-	0.00	0.0	0.0						
Min Post-BL	1	0.00	-	0.00	0.0	0.0						
Max Post-BL	1	0.00	-	0.00	0.0	0.0						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening,
SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatine Kinase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	80.0	-	80.0	80	80						
Min Post-BL	1	80.0	-	80.0	80	80						
Max Post-BL	1	80.0	-	80.0	80	80						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-60　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lactate Dehydrogenase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)												
Last Visit	1	207.0	-	207.0	207	207						
Min Post-BL	1	207.0	-	207.0	207	207						
Max Post-BL	1	207.0	-	207.0	207	207						

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Calcium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	2.309	0.078	2.300	2.16	2.43						
V2, Wk 0 (BL)	19	2.301	0.076	2.310	2.17	2.43						
Baseline	19	2.301	0.076	2.310	2.17	2.43						
V3, Wk 2 (T)	19	2.318	0.081	2.320	2.17	2.47	19	0.017	0.086	0.020	-0.19	0.16
V5, Wk 6 (M)	9	2.330	0.128	2.340	2.17	2.49	9	0.021	0.093	0.020	-0.12	0.16
V7, Wk 12 (M)	4	2.375	0.111	2.425	2.21	2.44	4	0.052	0.082	0.030	-0.02	0.17
V9, Wk 20 (M)	3	2.343	0.160	2.350	2.18	2.50	3	0.003	0.085	0.000	-0.08	0.09
V10, Wk 24 (M)	3	2.303	0.061	2.290	2.25	2.37	3	-0.037	0.097	-0.060	-0.12	0.07
Early Termination Visit	16	2.301	0.057	2.295	2.20	2.40	16	0.007	0.073	0.005	-0.11	0.14
Last Visit	19	2.301	0.056	2.290	2.20	2.40	19	0.000	0.076	0.000	-0.12	0.14
Min Post-BL	19	2.271	0.067	2.260	2.17	2.38	19	-0.031	0.074	-0.030	-0.19	0.14
Max Post-BL	19	2.365	0.083	2.350	2.25	2.50	19	0.064	0.076	0.080	-0.10	0.17

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Calcium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	2.322	0.088	2.360	2.17	2.44						
V2, Wk 0 (BL)	11	2.341	0.058	2.340	2.24	2.42						
Baseline	11	2.341	0.058	2.340	2.24	2.42						
V3, Wk 2 (T)	11	2.304	0.076	2.290	2.20	2.43	11	-0.037	0.065	-0.050	-0.14	0.08
V5, Wk 6 (M)	11	2.349	0.093	2.320	2.25	2.58	11	0.008	0.075	-0.010	-0.09	0.16
V7, Wk 12 (M)	10	2.326	0.117	2.325	2.15	2.50	10	-0.010	0.112	-0.025	-0.17	0.16
V9, Wk 20 (M)	9	2.307	0.075	2.280	2.22	2.42	9	-0.020	0.068	-0.040	-0.12	0.08
V10, Wk 24 (M)	9	2.296	0.065	2.290	2.18	2.39	9	-0.031	0.058	-0.020	-0.13	0.05
Early Termination Visit	2	2.385	0.078	2.385	2.33	2.44	2	-0.020	0.057	-0.020	-0.06	0.02
Last Visit	11	2.312	0.073	2.290	2.18	2.44	11	-0.029	0.055	-0.020	-0.13	0.05
Min Post-BL	11	2.247	0.055	2.250	2.15	2.33	11	-0.094	0.042	-0.090	-0.17	-0.04
Max Post-BL	11	2.404	0.088	2.410	2.27	2.58	11	0.063	0.065	0.050	-0.01	0.16

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Phosphate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	1.282	0.240	1.300	0.91	1.70						
V2, Wk 0 (BL)	19	1.242	0.229	1.140	0.94	1.75						
Baseline	19	1.242	0.229	1.140	0.94	1.75						
V3, Wk 2 (T)	19	1.251	0.207	1.190	0.88	1.84	19	0.009	0.134	0.020	-0.22	0.23
V5, Wk 6 (M)	9	1.254	0.175	1.280	0.92	1.43	9	-0.018	0.147	-0.010	-0.32	0.14
V7, Wk 12 (M)	4	1.330	0.180	1.275	1.18	1.59	4	0.027	0.200	0.065	-0.22	0.20
V9, Wk 20 (M)	3	1.340	0.261	1.210	1.17	1.64	3	-0.023	0.275	-0.020	-0.30	0.25
V10, Wk 24 (M)	3	1.370	0.223	1.330	1.17	1.61	3	0.007	0.115	-0.060	-0.06	0.14
Early Termination Visit	16	1.284	0.232	1.255	1.01	1.80	16	0.065	0.143	0.050	-0.21	0.37
Last Visit	19	1.297	0.226	1.320	1.01	1.80	19	0.056	0.137	0.050	-0.21	0.37
Min Post-BL	19	1.184	0.200	1.170	0.88	1.80	19	-0.057	0.132	-0.060	-0.32	0.14
Max Post-BL	19	1.344	0.225	1.360	1.03	1.84	19	0.102	0.140	0.120	-0.21	0.37

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Phosphate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	1.291	0.122	1.250	1.06	1.46						
V2, Wk 0 (BL)	11	1.312	0.176	1.220	1.14	1.65						
Baseline	11	1.312	0.176	1.220	1.14	1.65						
V3, Wk 2 (T)	11	1.260	0.168	1.260	1.00	1.54	11	-0.052	0.202	-0.040	-0.55	0.18
V5, Wk 6 (M)	11	1.215	0.178	1.180	0.97	1.56	11	-0.097	0.099	-0.060	-0.27	0.02
V7, Wk 12 (M)	10	1.173	0.096	1.155	1.04	1.33	10	-0.108	0.137	-0.110	-0.41	0.11
V9, Wk 20 (M)	9	1.219	0.179	1.190	0.83	1.48	9	-0.021	0.193	0.000	-0.46	0.25
V10, Wk 24 (M)	9	1.192	0.153	1.220	1.00	1.45	9	-0.048	0.143	-0.040	-0.29	0.15
Early Termination Visit	2	1.595	0.007	1.595	1.59	1.60	2	-0.040	0.028	-0.040	-0.06	-0.02
Last Visit	11	1.265	0.213	1.220	1.00	1.60	11	-0.046	0.129	-0.040	-0.29	0.15
Min Post-BL	11	1.096	0.159	1.080	0.83	1.42	11	-0.215	0.153	-0.170	-0.55	-0.06
Max Post-BL	11	1.369	0.140	1.350	1.18	1.60	11	0.057	0.099	0.050	-0.06	0.25

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Sodium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	141.7	1.7	142.0	139	144						
V2, Wk 0 (BL)	19	141.7	1.5	142.0	139	144						
Baseline	19	141.7	1.5	142.0	139	144						
V3, Wk 2 (T)	19	141.6	1.9	142.0	136	144	19	-0.1	1.9	0.0	-6	2
V5, Wk 6 (M)	9	141.8	2.0	141.0	139	145	9	-0.1	1.7	1.0	-3	2
V7, Wk 12 (M)	4	141.0	1.4	140.5	140	143	4	-1.0	1.4	-1.5	-2	1
V9, Wk 20 (M)	3	141.7	2.5	142.0	139	144	3	-1.0	1.7	0.0	-3	0
V10, Wk 24 (M)	3	140.3	0.6	140.0	140	141	3	-2.3	0.6	-2.0	-3	-2
Early Termination Visit	16	141.9	1.9	141.5	139	145	16	0.4	1.9	0.0	-2	4
Last Visit	19	141.7	1.9	141.0	139	145	19	-0.1	2.0	0.0	-3	4
Min Post-BL	19	140.7	1.8	141.0	136	144	19	-1.0	1.8	-1.0	-6	2
Max Post-BL	19	142.7	1.6	142.0	140	145	19	0.9	1.5	1.0	-2	4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Sodium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	141.4	2.2	141.0	137	145						
V2, Wk 0 (BL)	11	141.5	1.5	141.0	140	145						
Baseline	11	141.5	1.5	141.0	140	145						
V3, Wk 2 (T)	11	141.4	1.2	141.0	139	143	11	-0.2	1.3	0.0	-2	2
V5, Wk 6 (M)	11	141.5	1.9	142.0	138	145	11	-0.1	2.0	0.0	-3	3
V7, Wk 12 (M)	10	141.3	1.6	141.5	139	144	10	-0.1	2.4	0.0	-5	4
V9, Wk 20 (M)	9	141.9	2.2	143.0	139	145	9	0.6	1.9	0.0	-2	4
V10, Wk 24 (M)	9	141.0	1.7	141.0	138	144	9	-0.3	2.4	-1.0	-4	4
Early Termination Visit	2	143.0	0.0	143.0	143	143	2	0.5	0.7	0.5	0	1
Last Visit	11	141.4	1.7	142.0	138	144	11	-0.2	2.2	0.0	-4	4
Min Post-BL	11	139.8	1.3	140.0	138	142	11	-1.7	1.7	-1.0	-5	0
Max Post-BL	11	143.1	1.4	143.0	141	145	11	1.5	1.8	1.0	-1	4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Potassium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	4.24	0.24	4.20	3.8	4.8						
V2, Wk 0 (BL)	19	4.19	0.29	4.10	3.8	4.7						
Baseline	19	4.19	0.29	4.10	3.8	4.7						
V3, Wk 2 (T)	19	4.28	0.37	4.20	3.6	5.2	19	0.09	0.32	0.10	-0.8	0.5
V5, Wk 6 (M)	9	4.23	0.26	4.20	3.9	4.7	9	0.16	0.41	0.20	-0.7	0.7
V7, Wk 12 (M)	4	4.05	0.19	4.10	3.8	4.2	4	0.00	0.22	-0.05	-0.2	0.3
V9, Wk 20 (M)	3	3.97	0.32	4.10	3.6	4.2	3	-0.07	0.32	-0.20	-0.3	0.3
V10, Wk 24 (M)	3	4.40	0.26	4.50	4.1	4.6	3	0.37	0.21	0.30	0.2	0.6
Early Termination Visit	16	4.20	0.23	4.15	3.8	4.6	16	-0.02	0.21	-0.10	-0.4	0.3
Last Visit	19	4.23	0.24	4.20	3.8	4.6	19	0.04	0.25	0.10	-0.4	0.6
Min Post-BL	19	4.08	0.27	4.10	3.6	4.5	19	-0.11	0.25	-0.20	-0.8	0.3
Max Post-BL	19	4.42	0.29	4.40	4.0	5.2	19	0.23	0.27	0.20	-0.4	0.7

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Potassium (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	4.33	0.27	4.30	3.9	4.8						
V2, Wk 0 (BL)	11	4.22	0.20	4.20	3.9	4.6						
Baseline	11	4.22	0.20	4.20	3.9	4.6						
V3, Wk 2 (T)	11	4.17	0.33	4.20	3.6	4.7	11	-0.05	0.32	0.00	-0.5	0.5
V5, Wk 6 (M)	11	4.11	0.26	4.10	3.7	4.6	11	-0.11	0.23	0.00	-0.4	0.2
V7, Wk 12 (M)	10	4.28	0.53	4.20	3.6	5.1	10	0.08	0.50	0.05	-0.6	1.0
V9, Wk 20 (M)	9	4.13	0.30	4.30	3.5	4.4	9	-0.07	0.35	-0.10	-0.8	0.3
V10, Wk 24 (M)	9	4.26	0.16	4.30	3.9	4.4	9	0.06	0.25	0.10	-0.4	0.3
Early Termination Visit	2	4.35	0.07	4.35	4.3	4.4	2	0.05	0.07	0.05	0.0	0.1
Last Visit	11	4.27	0.15	4.30	3.9	4.4	11	0.05	0.23	0.10	-0.4	0.3
Min Post-BL	11	3.90	0.26	3.90	3.5	4.3	11	-0.32	0.26	-0.30	-0.8	0.0
Max Post-BL	11	4.54	0.30	4.40	4.2	5.1	11	0.32	0.32	0.30	-0.1	1.0

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Chloride (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	106.2	3.1	105.0	102	116						
V2, Wk 0 (BL)	19	105.8	2.8	105.0	102	115						
Baseline	19	105.8	2.8	105.0	102	115						
V3, Wk 2 (T)	19	105.1	2.8	105.0	101	114	19	-0.7	1.5	-1.0	-4	2
V5, Wk 6 (M)	9	107.1	4.0	108.0	100	114	9	0.0	2.0	0.0	-3	4
V7, Wk 12 (M)	4	105.0	0.8	105.0	104	106	4	-0.5	1.3	-0.5	-2	1
V9, Wk 20 (M)	3	103.3	2.5	103.0	101	106	3	-3.0	1.7	-4.0	-4	-1
V10, Wk 24 (M)	3	106.3	1.5	106.0	105	108	3	0.0	1.0	0.0	-1	1
Early Termination Visit	16	105.8	2.0	105.0	103	110	16	0.1	2.1	1.0	-5	2
Last Visit	19	105.8	1.9	105.0	103	110	19	0.1	1.9	1.0	-5	2
Min Post-BL	19	104.4	2.5	104.0	100	110	19	-1.4	2.0	-1.0	-5	2
Max Post-BL	19	106.6	2.5	106.0	103	114	19	0.8	1.2	1.0	-1	4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Chloride (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	105.6	2.6	105.0	103	112						
V2, Wk 0 (BL)	11	105.0	2.3	105.0	102	110						
Baseline	11	105.0	2.3	105.0	102	110						
V3, Wk 2 (T)	11	105.5	3.6	105.0	100	112	11	0.5	2.5	1.0	-4	4
V5, Wk 6 (M)	11	105.8	3.0	105.0	103	113	11	0.8	2.3	1.0	-3	4
V7, Wk 12 (M)	10	105.9	2.5	106.5	102	111	10	0.9	1.7	1.5	-2	3
V9, Wk 20 (M)	9	106.9	2.5	107.0	103	110	9	1.9	2.2	1.0	0	5
V10, Wk 24 (M)	9	106.1	2.7	105.0	103	111	9	1.1	2.3	2.0	-4	3
Early Termination Visit	2	104.5	2.1	104.5	103	106	2	-0.5	2.1	-0.5	-2	1
Last Visit	11	105.8	2.6	105.0	103	111	11	0.8	2.3	1.0	-4	3
Min Post-BL	11	104.1	2.6	104.0	100	110	11	-0.9	1.5	-1.0	-4	1
Max Post-BL	11	107.6	2.5	107.0	104	113	11	2.6	1.8	3.0	0	5

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Bicarbonate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	18	27.4	3.6	27.0	18	34						
V2, Wk 0 (BL)	19	28.5	2.9	28.0	22	33						
Baseline	19	28.5	2.9	28.0	22	33						
V3, Wk 2 (T)	19	29.4	2.9	29.0	22	34	19	0.8	2.4	1.0	-4	5
V5, Wk 6 (M)	9	27.4	3.9	27.0	22	34	9	0.6	2.7	0.0	-3	5
V7, Wk 12 (M)	4	27.8	3.6	28.5	23	31	4	1.0	2.2	1.5	-2	3
V9, Wk 20 (M)	3	29.7	3.5	30.0	26	33	3	2.7	1.5	3.0	1	4
V10, Wk 24 (M)	3	27.7	2.3	29.0	25	29	3	0.7	1.2	0.0	0	2
Early Termination Visit	16	29.0	3.0	29.0	22	34	16	0.2	2.5	0.5	-4	6
Last Visit	19	28.8	2.9	29.0	22	34	19	0.3	2.3	0.0	-4	6
Min Post-BL	19	27.4	2.5	29.0	22	30	19	-1.1	1.8	-1.0	-4	2
Max Post-BL	19	30.5	3.1	31.0	22	34	19	1.9	2.0	1.0	-1	6

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Bicarbonate (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	28.0	4.4	28.0	20	34						
V2, Wk 0 (BL)	11	28.6	3.1	29.0	22	32						
Baseline	11	28.6	3.1	29.0	22	32						
V3, Wk 2 (T)	11	26.5	3.4	26.0	21	32	11	-2.1	3.0	-3.0	-9	2
V5, Wk 6 (M)	11	27.7	2.6	28.0	22	31	11	-0.9	2.5	-1.0	-5	3
V7, Wk 12 (M)	10	27.2	3.2	27.5	20	32	10	-1.4	2.3	-2.0	-5	3
V9, Wk 20 (M)	8	28.3	2.9	28.5	22	32	8	0.4	2.0	0.5	-3	3
V10, Wk 24 (M)	9	27.4	3.0	27.0	22	32	9	-0.9	2.5	0.0	-7	2
Early Termination Visit	2	32.5	0.7	32.5	32	33	2	2.5	2.1	2.5	1	4
Last Visit	11	28.4	3.4	29.0	22	33	11	-0.3	2.7	0.0	-7	4
Min Post-BL	11	25.7	2.9	26.0	20	29	11	-2.9	2.5	-3.0	-9	1
Max Post-BL	11	29.6	2.7	30.0	24	33	11	1.0	2.3	1.0	-5	4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Creatinine (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	59.9	12.5	63.0	34	77						
V2, Wk 0 (BL)	19	58.8	10.7	59.0	33	75						
Baseline	19	58.8	10.7	59.0	33	75						
V3, Wk 2 (T)	19	61.1	12.6	61.0	33	88	19	2.2	6.8	1.0	-9	25
V5, Wk 6 (M)	9	63.7	12.4	64.0	44	83	9	1.1	6.5	2.0	-14	8
V7, Wk 12 (M)	4	60.8	6.8	63.0	51	66	4	-2.5	5.9	-3.0	-8	4
V9, Wk 20 (M)	3	63.7	10.0	63.0	54	74	3	-1.7	10.7	-4.0	-11	10
V10, Wk 24 (M)	3	61.0	9.8	58.0	53	72	3	-4.3	2.1	-5.0	-6	-2
Early Termination Visit	16	58.6	11.5	59.0	34	79	16	1.0	4.5	1.0	-6	9
Last Visit	19	59.0	11.1	58.0	34	79	19	0.2	4.6	0.0	-6	9
Min Post-BL	19	56.1	10.6	58.0	33	73	19	-2.7	4.9	-1.0	-14	5
Max Post-BL	19	63.8	13.0	61.0	34	88	19	5.0	5.7	4.0	-2	25

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Creatinine (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	55.2	11.7	54.0	38	72						
V2, Wk 0 (BL)	10	56.7	14.1	57.5	36	79						
Baseline	11	57.1	13.4	61.0	36	79						
V3, Wk 2 (T)	11	54.5	14.9	52.0	34	82	11	-2.5	5.6	-1.0	-13	4
V5, Wk 6 (M)	11	53.2	14.6	53.0	29	76	11	-3.9	6.3	-3.0	-17	7
V7, Wk 12 (M)	10	56.9	11.0	56.0	41	75	10	-2.3	6.5	-4.5	-13	6
V9, Wk 20 (M)	9	58.0	13.0	61.0	39	76	9	-1.9	3.6	-1.0	-7	3
V10, Wk 24 (M)	9	56.0	14.9	60.0	37	79	9	-3.9	5.3	-3.0	-9	7
Early Termination Visit	2	43.0	1.4	43.0	42	44	2	-1.5	13.4	-1.5	-11	8
Last Visit	11	53.6	14.3	59.0	37	79	11	-3.5	6.4	-3.0	-11	8
Min Post-BL	11	49.3	13.6	46.0	29	70	11	-7.8	4.9	-9.0	-17	-1
Max Post-BL	11	59.4	13.2	61.0	41	82	11	2.3	4.7	3.0	-5	8

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Urea Nitrogen (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	4.58	0.90	4.40	3.3	6.4						
V2, Wk 0 (BL)	19	4.75	0.84	4.70	3.1	6.0						
Baseline	19	4.75	0.84	4.70	3.1	6.0						
V3, Wk 2 (T)	19	4.64	1.22	4.20	3.1	7.3	19	-0.11	1.07	-0.10	-2.3	1.9
V5, Wk 6 (M)	9	4.68	1.26	4.30	3.2	7.2	9	-0.13	1.29	-0.40	-1.9	2.1
V7, Wk 12 (M)	4	3.93	0.25	3.95	3.6	4.2	4	-0.63	0.85	-0.45	-1.7	0.1
V9, Wk 20 (M)	3	4.10	0.79	3.80	3.5	5.0	3	-0.33	0.49	-0.10	-0.9	0.0
V10, Wk 24 (M)	3	5.30	2.01	6.20	3.0	6.7	3	0.87	1.50	0.80	-0.6	2.4
Early Termination Visit	16	4.73	0.91	4.90	3.2	6.6	16	-0.08	0.87	0.15	-2.3	1.0
Last Visit	19	4.82	1.09	5.00	3.0	6.7	19	0.07	1.00	0.20	-2.3	2.4
Min Post-BL	19	4.01	0.76	3.70	3.0	5.4	19	-0.74	0.79	-0.70	-2.3	0.5
Max Post-BL	19	5.32	1.00	5.30	3.9	7.3	19	0.57	0.86	0.70	-0.8	2.4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Urea Nitrogen (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	4.50	0.66	4.30	3.7	5.6						
V2, Wk 0 (BL)	11	4.72	0.90	4.20	3.6	6.1						
Baseline	11	4.72	0.90	4.20	3.6	6.1						
V3, Wk 2 (T)	11	4.26	0.81	4.30	3.1	5.9	11	-0.45	0.89	-0.50	-2.2	0.6
V5, Wk 6 (M)	11	4.66	0.56	4.60	3.5	5.4	11	-0.05	0.82	-0.10	-1.6	1.1
V7, Wk 12 (M)	10	4.25	0.86	4.25	3.0	5.4	10	-0.55	1.17	-0.50	-2.2	1.3
V9, Wk 20 (M)	9	4.11	0.67	4.00	3.2	5.3	9	-0.54	0.68	-0.40	-1.9	0.2
V10, Wk 24 (M)	9	4.37	1.25	4.00	2.9	6.5	9	-0.29	0.89	-0.10	-1.5	1.1
Early Termination Visit	2	4.50	0.85	4.50	3.9	5.1	2	-0.50	2.40	-0.50	-2.2	1.2
Last Visit	11	4.39	1.15	4.00	2.9	6.5	11	-0.33	1.10	-0.10	-2.2	1.2
Min Post-BL	11	3.60	0.58	3.50	2.9	4.9	11	-1.12	0.69	-0.90	-2.2	0.0
Max Post-BL	11	5.10	0.75	5.10	4.0	6.5	11	0.38	0.96	0.80	-1.6	1.3

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Aspartate Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	21.9	5.9	20.0	14	38						
V2, Wk 0 (BL)	19	21.6	5.9	23.0	13	32						
Baseline	19	21.6	5.9	23.0	13	32						
V3, Wk 2 (T)	19	23.7	9.3	23.0	14	49	19	2.1	8.0	0.0	-8	28
V5, Wk 6 (M)	9	20.4	3.7	22.0	16	26	9	-1.2	5.9	-1.0	-10	9
V7, Wk 12 (M)	4	21.0	2.4	21.0	18	24	4	1.0	5.2	1.0	-5	7
V9, Wk 20 (M)	3	19.7	2.3	21.0	17	21	3	1.7	4.7	0.0	-2	7
V10, Wk 24 (M)	3	22.0	5.3	20.0	18	28	3	4.0	4.4	6.0	-1	7
Early Termination Visit	16	21.9	5.6	19.5	13	32	16	-0.4	5.0	-0.5	-9	8
Last Visit	19	21.9	5.4	20.0	13	32	19	0.3	5.1	0.0	-9	8
Min Post-BL	19	19.9	5.2	19.0	13	32	19	-1.7	4.4	-1.0	-10	7
Max Post-BL	19	25.3	8.6	23.0	15	49	19	3.7	7.8	2.0	-8	28

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Aspartate Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	20.5	4.6	19.0	14	29						
V2, Wk 0 (BL)	11	19.7	3.9	21.0	14	25						
Baseline	11	19.7	3.9	21.0	14	25						
V3, Wk 2 (T)	11	21.5	5.0	22.0	14	31	11	1.8	2.1	2.0	-1	6
V5, Wk 6 (M)	11	21.0	6.0	19.0	14	34	11	1.3	3.8	0.0	-5	9
V7, Wk 12 (M)	10	22.7	6.6	20.5	14	33	10	2.9	6.1	0.5	-2	18
V9, Wk 20 (M)	9	20.2	3.6	20.0	15	28	9	-0.1	2.8	-1.0	-4	4
V10, Wk 24 (M)	9	20.6	5.4	19.0	15	33	9	0.2	3.3	-1.0	-3	8
Early Termination Visit	2	17.5	3.5	17.5	15	20	2	0.5	0.7	0.5	0	1
Last Visit	11	20.0	5.1	19.0	15	33	11	0.3	2.9	0.0	-3	8
Min Post-BL	11	18.5	4.1	17.0	14	28	11	-1.3	2.3	-1.0	-5	3
Max Post-BL	11	24.4	6.2	23.0	15	34	11	4.6	5.1	3.0	0	18

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Alanine Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	18.9	10.5	14.0	9	44						
V2, Wk 0 (BL)	19	20.8	14.5	16.0	6	52						
Baseline	19	20.8	14.5	16.0	6	52						
V3, Wk 2 (T)	19	21.7	14.3	18.0	8	65	19	0.8	6.4	1.0	-13	13
V5, Wk 6 (M)	9	21.4	10.3	17.0	11	41	9	-2.6	11.0	-3.0	-19	17
V7, Wk 12 (M)	4	16.8	6.7	15.5	10	26	4	2.8	9.5	4.0	-10	13
V9, Wk 20 (M)	3	17.3	4.2	16.0	14	22	3	5.3	3.2	4.0	3	9
V10, Wk 24 (M)	3	19.3	5.9	17.0	15	26	3	7.3	4.9	5.0	4	13
Early Termination Visit	16	20.3	13.6	14.0	9	54	16	-2.2	7.6	0.0	-19	6
Last Visit	19	20.2	12.6	14.0	9	54	19	-0.7	8.0	1.0	-19	13
Min Post-BL	19	18.2	11.4	13.0	8	54	19	-2.7	7.6	-1.0	-19	7
Max Post-BL	19	23.6	15.0	18.0	9	65	19	2.8	6.4	2.0	-7	17

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Alanine Aminotransferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	17.2	6.8	14.0	10	31						
V2, Wk 0 (BL)	11	15.7	5.8	13.0	10	28						
Baseline	11	15.7	5.8	13.0	10	28						
V3, Wk 2 (T)	11	18.8	8.5	15.0	9	37	11	3.1	4.8	1.0	-2	13
V5, Wk 6 (M)	11	18.5	9.6	14.0	11	41	11	2.8	5.3	2.0	-2	17
V7, Wk 12 (M)	10	20.3	10.3	16.0	13	45	10	4.3	4.9	3.0	-1	17
V9, Wk 20 (M)	9	18.3	7.5	16.0	11	32	9	1.7	3.3	3.0	-3	5
V10, Wk 24 (M)	9	20.8	8.2	19.0	11	36	9	4.1	4.0	3.0	-2	12
Early Termination Visit	2	13.0	2.8	13.0	11	15	2	1.5	0.7	1.5	1	2
Last Visit	11	19.4	8.1	18.0	11	36	11	3.6	3.7	3.0	-2	12
Min Post-BL	11	15.6	6.7	14.0	9	29	11	-0.1	2.5	0.0	-3	5
Max Post-BL	11	23.0	10.7	19.0	13	45	11	7.3	5.3	6.0	2	17

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Bilirubin (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	7.98	4.69	6.30	3.4	21.3						
V2, Wk 0 (BL)	19	6.61	2.45	6.10	4.1	15.6						
Baseline	19	6.61	2.45	6.10	4.1	15.6						
V3, Wk 2 (T)	19	7.26	2.49	7.30	4.7	14.8	19	0.65	1.89	0.20	-3.1	4.2
V5, Wk 6 (M)	9	9.11	3.90	8.00	5.6	17.9	9	1.57	2.15	1.70	-0.9	5.9
V7, Wk 12 (M)	4	10.23	4.57	10.05	6.0	14.8	4	1.95	4.31	0.95	-2.1	8.0
V9, Wk 20 (M)	3	11.33	7.56	8.50	5.6	19.9	3	2.57	2.75	4.00	-0.6	4.3
V10, Wk 24 (M)	3	8.70	4.78	7.00	5.0	14.1	3	-0.07	1.25	0.50	-1.5	0.8
Early Termination Visit	16	6.99	2.54	6.80	3.7	12.6	16	0.78	2.20	0.20	-1.7	5.9
Last Visit	19	7.26	2.89	7.00	3.7	14.1	19	0.65	2.08	0.30	-1.7	5.9
Min Post-BL	19	6.31	2.16	5.70	3.7	13.5	19	-0.31	1.56	-0.60	-3.1	3.0
Max Post-BL	19	8.83	3.79	7.80	4.7	19.9	19	2.22	2.50	1.70	-0.9	8.0

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Bilirubin (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	7.23	1.86	7.40	4.0	10.1						
V2, Wk 0 (BL)	11	9.29	3.51	8.80	4.1	13.5						
Baseline	11	9.29	3.51	8.80	4.1	13.5						
V3, Wk 2 (T)	11	7.10	2.41	7.20	3.5	11.8	11	-2.19	3.16	-1.00	-7.6	1.6
V5, Wk 6 (M)	11	8.62	3.89	6.90	4.8	16.6	11	-0.67	4.62	-0.10	-8.3	4.7
V7, Wk 12 (M)	10	8.39	1.64	8.05	5.8	11.1	10	-1.42	3.18	-1.50	-6.2	3.1
V9, Wk 20 (M)	9	7.22	2.07	6.70	4.6	11.1	9	-2.22	2.44	-1.10	-6.8	0.2
V10, Wk 24 (M)	9	8.90	3.72	8.90	4.4	16.3	9	-0.54	3.79	-1.10	-4.3	8.3
Early Termination Visit	2	4.95	1.06	4.95	4.2	5.7	2	-3.65	5.30	-3.65	-7.4	0.1
Last Visit	11	8.18	3.71	7.60	4.2	16.3	11	-1.11	3.98	-1.10	-7.4	8.3
Min Post-BL	11	5.73	1.59	5.50	3.5	8.9	11	-3.56	3.29	-2.70	-8.3	0.2
Max Post-BL	11	10.25	3.66	9.90	5.1	16.6	11	0.96	3.75	1.00	-4.7	8.3

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Alkaline Phosphatase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	83.8	62.3	61.0	28	259						
V2, Wk 0 (BL)	19	88.2	67.3	66.0	29	290						
Baseline	19	88.2	67.3	66.0	29	290						
V3, Wk 2 (T)	19	90.7	68.8	65.0	30	298	19	2.5	6.7	3.0	-10	14
V5, Wk 6 (M)	9	67.1	24.8	60.0	31	113	9	2.8	6.8	2.0	-6	17
V7, Wk 12 (M)	4	69.3	32.8	72.5	27	105	4	3.5	11.0	4.0	-9	15
V9, Wk 20 (M)	3	54.7	25.8	59.0	27	78	3	5.0	7.0	5.0	-2	12
V10, Wk 24 (M)	3	57.3	29.0	56.0	29	87	3	7.7	11.6	2.0	0	21
Early Termination Visit	16	94.5	71.4	69.5	35	293	16	-0.9	13.3	0.5	-26	28
Last Visit	19	88.6	67.3	67.0	29	293	19	0.4	13.2	2.0	-26	28
Min Post-BL	19	84.4	66.4	62.0	27	293	19	-3.8	9.6	-2.0	-26	9
Max Post-BL	19	95.2	69.2	67.0	31	298	19	6.9	8.4	6.0	-7	28

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Alkaline Phosphatase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	76.2	44.0	61.0	37	193						
V2, Wk 0 (BL)	11	75.1	45.9	60.0	41	201						
Baseline	11	75.1	45.9	60.0	41	201						
V3, Wk 2 (T)	11	77.1	52.2	61.0	38	220	11	2.0	7.5	1.0	-10	19
V5, Wk 6 (M)	11	75.1	43.1	65.0	39	194	11	0.0	6.6	0.0	-12	11
V7, Wk 12 (M)	10	62.9	20.0	59.5	39	102	10	0.4	5.9	2.0	-11	7
V9, Wk 20 (M)	9	66.8	20.8	66.0	42	106	9	2.9	4.7	1.0	-5	11
V10, Wk 24 (M)	9	68.2	23.3	70.0	39	106	9	4.3	7.1	4.0	-8	16
Early Termination Visit	2	115.0	99.0	115.0	45	185	2	-10.5	7.8	-10.5	-16	-5
Last Visit	11	76.7	42.1	70.0	39	185	11	1.6	9.1	3.0	-16	16
Min Post-BL	11	70.1	42.4	61.0	38	185	11	-5.0	6.7	-4.0	-16	4
Max Post-BL	11	83.1	50.2	71.0	42	220	11	8.0	6.0	7.0	-1	19

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Gamma Glutamyl Transferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	39.8	69.4	17.0	5	276						
V2, Wk 0 (BL)	19	38.5	70.7	17.0	3	301						
Baseline	19	38.5	70.7	17.0	3	301						
V3, Wk 2 (T)	19	41.6	76.8	18.0	5	320	19	3.1	7.7	2.0	-5	28
V5, Wk 6 (M)	9	18.6	10.3	18.0	4	40	9	2.6	6.6	1.0	-3	17
V7, Wk 12 (M)	4	18.5	13.8	14.5	7	38	4	5.3	6.8	3.5	-1	15
V9, Wk 20 (M)	3	21.7	13.6	20.0	9	36	3	6.3	6.1	5.0	1	13
V10, Wk 24 (M)	3	19.0	11.0	19.0	8	30	3	3.7	3.5	4.0	0	7
Early Termination Visit	16	45.6	80.2	16.0	8	315	16	2.8	5.7	0.5	-5	14
Last Visit	19	41.4	74.0	17.0	8	315	19	2.9	5.4	1.0	-5	14
Min Post-BL	19	39.1	74.6	15.0	4	315	19	0.6	4.7	-1.0	-5	14
Max Post-BL	19	44.1	76.2	18.0	8	320	19	5.6	8.1	3.0	-5	28

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Gamma Glutamyl Transferase (U/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	18.7	22.5	10.0	4	81						
V2, Wk 0 (BL)	11	19.1	17.5	11.0	8	65						
Baseline	11	19.1	17.5	11.0	8	65						
V3, Wk 2 (T)	11	21.5	25.1	11.0	6	91	11	2.5	8.2	1.0	-5	26
V5, Wk 6 (M)	11	24.2	27.0	12.0	9	98	11	5.1	9.9	1.0	-1	33
V7, Wk 12 (M)	10	29.6	32.9	17.5	8	117	10	9.6	15.4	5.5	-1	52
V9, Wk 20 (M)	9	25.8	20.9	15.0	10	66	9	4.8	10.4	3.0	-8	29
V10, Wk 24 (M)	9	24.2	18.8	17.0	7	61	9	3.2	9.8	2.0	-14	24
Early Termination Visit	2	11.5	0.7	11.5	11	12	2	1.0	1.4	1.0	0	2
Last Visit	11	21.9	17.6	15.0	7	61	11	2.8	8.9	2.0	-14	24
Min Post-BL	11	17.3	14.9	10.0	6	51	11	-1.8	4.8	-1.0	-14	3
Max Post-BL	11	30.6	32.8	15.0	10	117	11	11.5	15.6	6.0	1	52

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Glucose (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	5.04	0.49	5.00	4.4	6.1						
V2, Wk 0 (BL)	19	5.19	0.60	5.20	4.3	6.4						
Baseline	19	5.19	0.60	5.20	4.3	6.4						
V3, Wk 2 (T)	19	5.33	0.55	5.20	4.6	6.3	19	0.14	0.79	0.10	-1.7	1.4
V5, Wk 6 (M)	9	5.41	0.64	5.40	4.5	6.4	9	0.31	0.97	0.20	-1.3	2.1
V7, Wk 12 (M)	4	5.05	0.58	5.05	4.5	5.6	4	-0.17	1.31	-0.10	-1.8	1.3
V9, Wk 20 (M)	3	5.00	0.36	4.90	4.7	5.4	3	-0.30	0.70	-0.30	-1.0	0.4
V10, Wk 24 (M)	3	5.83	1.02	5.40	5.1	7.0	3	0.53	1.63	1.10	-1.3	1.8
Early Termination Visit	16	4.76	0.82	4.80	2.4	5.9	16	-0.41	0.92	-0.20	-3.2	0.6
Last Visit	19	4.93	0.91	5.00	2.4	7.0	19	-0.26	1.06	-0.10	-3.2	1.8
Min Post-BL	19	4.66	0.70	4.70	2.4	5.9	19	-0.53	0.87	-0.30	-3.2	0.5
Max Post-BL	19	5.59	0.60	5.40	4.6	7.0	19	0.41	0.82	0.30	-1.1	2.1

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Glucose (mmol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	4.78	0.56	4.80	3.9	6.0						
V2, Wk 0 (BL)	11	5.23	1.60	4.80	4.0	9.9						
Baseline	11	5.23	1.60	4.80	4.0	9.9						
V3, Wk 2 (T)	11	5.60	1.08	5.20	4.7	8.2	11	0.37	1.32	0.50	-2.9	2.7
V5, Wk 6 (M)	11	5.05	0.90	4.70	4.6	7.7	11	-0.18	0.83	-0.10	-2.2	1.2
V7, Wk 12 (M)	10	5.38	0.94	5.15	4.3	7.6	10	0.12	1.09	0.25	-2.3	1.5
V9, Wk 20 (M)	9	4.93	0.74	4.70	4.2	6.6	9	-0.47	1.19	0.10	-3.3	0.6
V10, Wk 24 (M)	9	5.19	0.90	5.10	3.9	6.9	9	-0.21	1.29	0.10	-3.0	1.2
Early Termination Visit	2	3.95	0.35	3.95	3.7	4.2	2	-0.50	0.99	-0.50	-1.2	0.2
Last Visit	11	4.96	0.96	4.80	3.7	6.9	11	-0.26	1.20	0.10	-3.0	1.2
Min Post-BL	11	4.57	0.75	4.60	3.7	6.6	11	-0.65	1.05	-0.30	-3.3	0.2
Max Post-BL	11	5.89	1.12	5.50	4.7	8.2	11	0.66	1.21	0.70	-2.2	2.7

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Albumin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	44.1	2.5	44.0	39	49						
V2, Wk 0 (BL)	19	43.6	2.1	44.0	39	47						
Baseline	19	43.6	2.1	44.0	39	47						
V3, Wk 2 (T)	19	44.5	2.1	44.0	41	48	19	0.9	1.6	1.0	-3	4
V5, Wk 6 (M)	9	45.2	3.1	45.0	40	50	9	1.4	2.2	1.0	-2	6
V7, Wk 12 (M)	4	46.3	3.6	47.5	41	49	4	2.0	0.8	2.0	1	3
V9, Wk 20 (M)	3	46.0	5.6	47.0	40	51	3	2.0	1.7	1.0	1	4
V10, Wk 24 (M)	3	43.3	2.9	45.0	40	45	3	-0.7	1.5	-1.0	-2	1
Early Termination Visit	16	44.3	2.0	45.0	41	47	16	0.8	1.7	1.0	-2	5
Last Visit	19	44.2	2.1	45.0	40	47	19	0.6	1.7	1.0	-2	5
Min Post-BL	19	43.5	2.0	44.0	40	47	19	-0.1	1.4	0.0	-3	2
Max Post-BL	19	45.5	2.5	45.0	42	51	19	1.9	1.6	2.0	-1	6

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Albumin (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	44.3	2.1	45.0	41	47						
V2, Wk 0 (BL)	11	45.1	2.3	45.0	42	49						
Baseline	11	45.1	2.3	45.0	42	49						
V3, Wk 2 (T)	11	44.5	2.1	44.0	41	48	11	-0.6	1.8	-1.0	-3	2
V5, Wk 6 (M)	11	44.9	2.0	45.0	42	49	11	-0.2	2.0	0.0	-4	4
V7, Wk 12 (M)	10	44.6	3.1	46.0	38	48	10	-0.1	3.3	0.5	-5	4
V9, Wk 20 (M)	9	44.1	1.7	45.0	42	46	9	-0.3	1.8	-1.0	-3	3
V10, Wk 24 (M)	9	44.2	2.4	44.0	41	48	9	-0.2	1.8	0.0	-2	3
Early Termination Visit	2	46.0	1.4	46.0	45	47	2	-2.0	0.0	-2.0	-2	-2
Last Visit	11	44.5	2.3	45.0	41	48	11	-0.5	1.8	-1.0	-2	3
Min Post-BL	11	42.7	2.2	42.0	38	46	11	-2.4	2.0	-3.0	-5	1
Max Post-BL	11	46.4	1.8	47.0	43	49	11	1.3	2.1	1.0	-2	4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Protein (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	72.2	3.8	74.0	66	79						
V2, Wk 0 (BL)	19	71.5	3.7	72.0	63	77						
Baseline	19	71.5	3.7	72.0	63	77						
V3, Wk 2 (T)	19	72.8	2.9	73.0	68	77	19	1.3	3.1	2.0	-6	7
V5, Wk 6 (M)	9	72.6	4.0	73.0	65	78	9	1.3	3.9	1.0	-4	10
V7, Wk 12 (M)	4	71.5	3.7	73.0	66	74	4	2.3	1.7	2.5	0	4
V9, Wk 20 (M)	3	71.7	7.6	70.0	65	80	3	3.3	3.2	2.0	1	7
V10, Wk 24 (M)	3	67.7	1.5	68.0	66	69	3	-0.7	4.0	0.0	-5	3
Early Termination Visit	16	72.8	3.4	73.0	68	78	16	0.8	3.2	2.0	-4	8
Last Visit	19	72.0	3.7	72.0	66	78	19	0.5	3.3	2.0	-5	8
Min Post-BL	19	70.8	2.9	71.0	65	76	19	-0.7	2.9	-1.0	-6	4
Max Post-BL	19	74.7	3.1	75.0	68	80	19	3.2	2.8	3.0	-2	10

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Protein (g/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	71.5	4.3	71.0	65	77						
V2, Wk 0 (BL)	11	73.2	3.9	74.0	65	78						
Baseline	11	73.2	3.9	74.0	65	78						
V3, Wk 2 (T)	11	72.1	2.9	73.0	67	75	11	-1.1	3.5	-1.0	-7	3
V5, Wk 6 (M)	11	72.0	4.3	73.0	65	77	11	-1.2	3.0	-1.0	-7	4
V7, Wk 12 (M)	10	71.3	6.8	71.5	62	82	10	-1.7	4.9	-1.5	-10	4
V9, Wk 20 (M)	9	70.8	4.9	71.0	62	79	9	-1.9	2.3	-2.0	-6	1
V10, Wk 24 (M)	9	71.6	4.7	73.0	63	78	9	-1.1	2.8	-2.0	-4	4
Early Termination Visit	2	73.0	0.0	73.0	73	73	2	-2.5	0.7	-2.5	-3	-2
Last Visit	11	71.8	4.3	73.0	63	78	11	-1.4	2.6	-2.0	-4	4
Min Post-BL	11	68.7	4.1	70.0	62	74	11	-4.5	2.7	-4.0	-10	0
Max Post-BL	11	74.5	4.0	75.0	68	82	11	1.4	2.8	2.0	-4	4

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Urate (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)												
V1, Wk -4 (SCR)	19	321.7	90.5	314.0	162	549						
V2, Wk 0 (BL)	19	310.3	78.3	291.0	176	480						
Baseline	19	310.3	78.3	291.0	176	480						
V3, Wk 2 (T)	19	318.2	81.5	324.0	178	471	19	7.9	30.4	11.0	-52	57
V5, Wk 6 (M)	9	313.7	116.6	327.0	163	504	9	44.7	72.8	29.0	-24	202
V7, Wk 12 (M)	4	307.8	96.0	322.0	191	396	4	30.8	49.2	25.0	-21	94
V9, Wk 20 (M)	3	317.0	75.7	292.0	257	402	3	48.3	39.5	67.0	3	75
V10, Wk 24 (M)	3	306.7	123.2	262.0	212	446	3	38.0	69.3	30.0	-27	111
Early Termination Visit	16	335.2	97.4	311.0	167	483	16	17.1	53.4	19.5	-56	160
Last Visit	19	330.7	98.5	304.0	167	483	19	20.4	54.5	21.0	-56	160
Min Post-BL	19	299.8	84.9	295.0	163	441	19	-10.4	31.6	-19.0	-56	52
Max Post-BL	19	363.2	93.7	362.0	206	504	19	52.9	56.3	32.0	-23	202

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-61　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 13.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Urate (umol/L)

Treatment Group Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)												
V1, Wk -4 (SCR)	11	297.9	55.3	298.0	197	400						
V2, Wk 0 (BL)	11	305.1	75.0	276.0	203	463						
Baseline	11	305.1	75.0	276.0	203	463						
V3, Wk 2 (T)	11	275.7	67.5	254.0	202	430	11	-29.4	39.8	-22.0	-84	41
V5, Wk 6 (M)	11	292.5	74.8	266.0	218	475	11	-12.6	29.9	-16.0	-58	23
V7, Wk 12 (M)	10	291.9	77.6	278.5	184	470	10	-16.1	36.2	-6.0	-80	21
V9, Wk 20 (M)	9	280.6	77.4	262.0	183	451	9	-30.9	42.8	-20.0	-105	23
V10, Wk 24 (M)	9	288.8	79.9	274.0	172	450	9	-22.7	36.3	-19.0	-96	28
Early Termination Visit	2	249.0	100.4	249.0	178	320	2	-27.5	101.1	-27.5	-99	44
Last Visit	11	281.5	79.8	274.0	172	450	11	-23.5	45.6	-19.0	-99	44
Min Post-BL	11	254.2	71.9	233.0	172	430	11	-50.9	33.0	-36.0	-105	-22
Max Post-BL	11	310.9	68.7	297.0	218	475	11	5.8	33.7	15.0	-56	44

BL=Baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 8.1.2

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V1, Wk -4 (SCR)													
Supine	3	121	117.9	14.0	118.0	90	159						
Standing	1	117	119.1	15.8	120.0	80	176						
Standing	3	116	117.8	14.8	119.0	84	160						
V2, Wk 0 (BL)													
Supine	3	121	116.5	13.2	116.0	90	155						
Standing	1	117	117.4	14.6	117.0	82	158						
Standing	3	116	117.4	14.1	117.0	88	159						
V3, Wk 2 (T)													
Supine	3	118	116.5	13.0	117.0	88	151	118	-0.4	8.6	1.0	-25	22
Standing	1	117	117.7	14.4	118.0	75	160	115	0.1	11.8	0.0	-28	42
Standing	3	118	117.1	14.2	118.0	80	151	114	-0.1	10.4	0.0	-30	41

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V4, Wk 4 (T)													
Supine	3	114	117.4	13.1	119.0	90	148	114	0.5	9.6	0.0	-20	30
Standing	1	113	119.3	13.3	120.0	90	155	111	1.4	11.0	1.0	-25	39
Standing	3	114	118.2	13.7	118.0	85	152	110	0.7	11.0	-0.5	-29	40
V5, Wk 6 (M)													
Supine	3	70	115.7	13.6	115.5	91	154	70	-1.0	9.7	0.0	-22	24
Standing	1	70	117.6	13.4	117.0	92	161	68	1.0	10.7	0.0	-26	38
Standing	3	70	117.4	12.4	116.5	95	145	67	0.1	9.2	0.0	-17	37
V6, Wk 8 (M)													
Supine	3	64	116.2	12.8	115.0	94	156	64	-1.0	9.5	-2.0	-17	29
Standing	1	63	118.1	13.9	118.0	97	157	61	1.6	11.2	0.0	-26	38
Standing	3	63	117.1	14.3	117.0	93	156	60	0.3	9.6	-1.0	-21	30

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening,
SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V7, Wk 12 (M)													
Supine	3	54	117.4	12.5	115.0	88	152	54	0.3	10.1	0.0	-20	32
Standing	1	54	118.6	12.3	118.5	93	151	52	3.3	10.9	1.0	-16	36
Standing	3	54	118.1	13.1	118.0	97	162	51	2.2	11.0	3.0	-24	29
V8, Wk 16 (M)													
Supine	3	48	117.9	12.8	116.0	95	149	48	0.8	11.6	0.0	-18	34
Standing	1	48	118.7	13.0	116.0	98	153	46	3.8	12.2	1.0	-24	37
Standing	3	48	118.1	11.3	118.0	99	144	45	1.7	10.7	0.0	-20	29
V9, Wk 20 (M)													
Supine	3	37	114.3	10.3	112.0	90	136	37	-4.0	9.2	-3.0	-26	18
Standing	1	37	116.2	10.1	115.0	98	134	37	-0.3	10.8	0.0	-31	26
Standing	3	37	116.4	11.7	113.0	99	148	36	-0.9	9.3	0.0	-20	18

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V10, Wk 24 (M)													
Supine	3	37	114.0	12.4	112.0	90	140	37	-4.3	8.3	-4.0	-25	15
Standing	1	37	116.7	12.1	116.0	92	140	37	0.2	10.0	0.0	-18	25
Standing	3	37	116.8	12.5	118.0	93	148	36	-0.5	9.4	-1.0	-20	22
Early Termination Visit													
Supine	3	78	116.2	13.4	116.0	90	145	78	0.9	10.7	1.0	-29	30
Standing	1	77	117.7	14.2	117.0	80	150	76	0.0	12.6	0.0	-42	51
Standing	3	78	117.6	15.4	116.5	82	152	76	0.6	10.6	1.0	-33	33
Last Visit													
Supine	3	121	115.5	12.8	114.0	90	145	121	-1.0	10.2	0.0	-29	30
Standing	1	120	117.9	13.4	118.0	80	150	118	0.6	11.8	0.0	-42	51
Standing	3	121	117.7	14.3	118.0	82	152	117	0.5	10.2	0.0	-33	33

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
Min Post-BL													
Supine	3	121	109.1	11.9	109.0	88	140	121	-7.3	9.4	-8.0	-29	22
Standing	1	120	110.4	12.7	110.0	75	141	118	-6.9	10.5	-7.0	-42	36
Standing	3	121	110.3	13.0	110.0	80	144	117	-6.7	9.6	-6.0	-33	23
Max Post-BL													
Supine	3	121	124.1	12.8	122.0	96	156	121	7.7	8.7	5.0	-11	34
Standing	1	120	126.4	13.8	127.0	80	161	118	9.2	11.3	8.0	-15	51
Standing	3	121	125.3	13.7	124.0	82	162	117	8.2	9.8	5.0	-12	41

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V1, Wk -4 (SCR)													
Supine	3	121	116.7	12.9	119.0	89	140						
Standing	1	118	116.3	13.0	117.5	83	168						
Standing	3	116	116.9	12.7	118.5	80	167						
V2, Wk 0 (BL)													
Supine	3	121	116.9	12.2	118.0	86	146						
Standing	1	120	116.8	11.7	116.0	88	157						
Standing	3	118	117.1	11.3	118.0	90	149						
V3, Wk 2 (T)													
Supine	3	115	116.5	13.8	116.0	84	150	115	-0.6	10.4	0.0	-36	36
Standing	1	112	118.1	13.3	119.0	88	160	112	1.4	9.7	0.5	-27	41
Standing	3	112	118.1	13.2	119.5	82	159	112	0.9	9.4	0.0	-22	33

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V4, Wk 4 (T)													
Supine	3	112	118.7	14.3	120.0	86	152	112	1.6	11.3	0.0	-25	42
Standing	1	112	118.7	14.7	119.0	79	165	111	2.0	11.6	0.0	-24	56
Standing	3	112	119.8	14.4	119.5	90	167	109	2.6	10.4	1.0	-20	50
V5, Wk 6 (M)													
Supine	3	82	118.0	12.7	117.5	92	154	82	0.5	10.5	0.0	-25	31
Standing	1	82	119.8	12.7	120.0	93	171	82	2.3	10.2	0.5	-22	42
Standing	3	82	119.4	12.4	120.0	93	153	80	1.8	8.6	0.0	-21	32
V6, Wk 8 (M)													
Supine	3	75	117.8	10.7	119.0	95	142	75	0.3	8.4	0.0	-24	22
Standing	1	75	119.0	13.0	120.0	90	164	75	1.1	8.4	0.0	-22	25
Standing	3	75	118.6	12.5	120.0	91	168	73	1.1	9.1	0.0	-17	27

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V7, Wk 12 (M)													
Supine	3	71	116.9	12.0	118.0	89	150	71	-0.1	9.6	0.0	-24	27
Standing	1	71	117.5	12.5	118.0	91	155	71	0.1	9.3	0.0	-27	20
Standing	3	71	117.6	12.0	120.0	93	155	69	0.3	8.6	0.0	-19	32
V8, Wk 16 (M)													
Supine	3	65	117.3	13.3	119.0	90	145	65	0.6	10.0	0.0	-37	22
Standing	1	65	119.4	12.3	120.0	90	146	65	2.1	8.2	1.0	-27	16
Standing	3	65	117.8	12.9	118.0	90	144	64	0.2	8.8	0.0	-25	21
V9, Wk 20 (M)													
Supine	3	60	118.5	13.2	120.0	86	164	60	1.2	10.8	1.0	-19	48
Standing	1	60	119.7	14.2	120.0	70	150	60	2.2	11.0	2.0	-30	32
Standing	3	60	118.2	12.8	120.0	90	145	59	0.9	10.0	0.0	-23	25

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V10, Wk 24 (M)													
Supine	3	60	117.7	12.4	118.5	90	146	60	0.5	9.9	0.0	-23	32
Standing	1	60	118.8	11.4	119.0	93	145	60	1.4	9.6	2.0	-33	22
Standing	3	60	118.1	11.9	120.0	87	140	59	0.6	10.0	0.0	-32	35
Early Termination Visit													
Supine	3	57	117.5	12.9	119.0	90	155	57	2.3	11.6	3.0	-30	34
Standing	1	57	118.1	14.1	117.0	96	167	56	2.8	13.2	0.0	-19	61
Standing	3	57	117.4	13.9	118.0	95	171	55	1.7	12.1	2.0	-23	45
Last Visit													
Supine	3	120	117.5	12.3	119.0	90	155	120	0.8	11.1	0.5	-30	34
Standing	1	120	118.6	12.6	118.0	93	167	119	2.2	11.3	2.0	-33	61
Standing	3	120	117.8	12.7	119.0	87	171	117	1.0	10.9	0.0	-32	45

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
Min Post-BL													
Supine	3	120	109.6	11.7	110.0	84	142	120	-7.1	10.5	-7.0	-37	34
Standing	1	120	110.5	11.8	112.0	70	141	119	-6.0	9.8	-5.0	-33	29
Standing	3	120	110.9	11.4	112.0	82	141	117	-5.9	8.5	-6.0	-32	19
Max Post-BL													
Supine	3	120	124.7	13.7	124.5	90	164	120	8.0	10.4	6.0	-25	48
Standing	1	120	126.4	14.0	126.0	96	171	119	9.7	10.6	8.0	-16	61
Standing	3	120	125.7	13.9	125.0	96	171	117	8.6	10.3	7.0	-14	50

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V1, Wk -4 (SCR)													
Supine	3	121	73.4	10.7	72.0	51	105						
Standing	1	117	76.7	11.5	75.0	52	119						
Standing	3	116	77.3	11.3	77.0	55	115						
V2, Wk 0 (BL)													
Supine	3	121	71.8	10.7	71.0	39	97						
Standing	1	117	75.8	12.5	75.0	46	112						
Standing	3	116	76.4	11.0	77.0	49	102						
V3, Wk 2 (T)													
Supine	3	118	71.7	10.4	71.5	47	98	118	-0.3	8.6	0.0	-23	25
Standing	1	117	76.7	10.2	77.0	53	112	115	0.7	9.5	0.0	-49	25
Standing	3	118	75.8	10.1	76.0	43	102	114	-0.8	8.2	0.0	-28	23

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V4, Wk 4 (T)													
Supine	3	114	72.5	9.9	72.0	48	92	114	0.5	9.1	0.0	-33	25
Standing	1	113	77.1	10.5	76.0	55	114	111	1.0	10.2	1.0	-34	47
Standing	3	114	77.2	10.0	77.0	49	110	110	0.7	9.5	0.0	-26	32
V5, Wk 6 (M)													
Supine	3	70	71.2	9.8	70.0	49	94	70	-0.2	8.7	0.0	-30	25
Standing	1	70	75.0	11.1	74.5	50	115	68	-0.0	8.6	0.0	-21	15
Standing	3	70	76.0	9.1	75.0	55	106	67	-0.2	8.5	0.0	-23	18
V6, Wk 8 (M)													
Supine	3	64	72.9	9.2	74.0	54	96	64	1.3	9.9	0.5	-25	31
Standing	1	63	76.0	10.3	75.0	53	108	61	1.9	8.6	1.0	-16	28
Standing	3	63	75.6	10.4	76.0	55	113	60	-0.0	8.0	-1.0	-19	26

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V7, Wk 12 (M)													
Supine	3	54	71.4	10.9	72.0	37	91	54	-0.7	10.5	0.0	-32	30
Standing	1	54	76.1	10.8	76.5	46	108	52	2.3	11.2	2.0	-25	20
Standing	3	54	76.1	10.8	76.5	45	113	51	1.4	9.6	2.0	-23	23
V8, Wk 16 (M)													
Supine	3	48	71.2	9.1	70.5	42	85	48	-1.2	8.4	-2.0	-20	20
Standing	1	48	73.7	8.4	75.5	47	90	46	0.2	9.8	-0.5	-18	23
Standing	3	48	74.6	9.7	76.0	42	96	45	-0.1	11.3	-1.0	-26	35
V9, Wk 20 (M)													
Supine	3	37	69.5	8.8	70.0	52	86	37	-2.9	9.9	-3.0	-21	19
Standing	1	37	74.1	8.7	72.0	58	97	37	-0.0	9.7	-1.0	-16	17
Standing	3	37	75.6	9.2	75.0	59	106	36	0.8	9.4	0.0	-17	29

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V10, Wk 24 (M)													
Supine	3	37	69.2	9.0	70.0	52	91	37	-3.1	8.2	-3.0	-15	23
Standing	1	37	73.2	10.9	75.0	48	99	37	-0.9	9.3	0.0	-20	15
Standing	3	37	73.8	10.6	73.0	58	103	36	-1.2	8.7	-1.5	-20	20
Early Termination Visit													
Supine	3	78	71.5	9.8	71.5	50	95	78	0.3	9.5	0.0	-34	22
Standing	1	77	76.3	11.7	76.0	48	117	76	-0.1	10.8	0.0	-29	36
Standing	3	78	77.8	10.4	77.0	56	119	76	1.0	8.8	0.0	-18	21
Last Visit													
Supine	3	121	70.7	9.5	70.0	50	95	121	-1.1	9.4	0.0	-34	23
Standing	1	120	75.3	11.3	75.5	48	117	118	-0.4	10.3	0.0	-29	36
Standing	3	121	76.6	10.4	76.0	56	119	117	0.4	8.9	0.0	-20	21

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
Min Post-BL													
Supine	3	121	65.1	9.6	65.0	37	90	121	-6.7	9.3	-7.0	-34	20
Standing	1	120	69.3	9.6	70.0	46	98	118	-6.5	9.5	-5.0	-49	12
Standing	3	121	69.8	9.4	69.0	42	97	117	-6.4	8.7	-6.0	-28	15
Max Post-BL													
Supine	3	121	78.1	8.8	80.0	54	98	121	6.3	8.5	5.0	-15	31
Standing	1	120	82.8	10.0	82.0	53	117	118	7.0	9.7	6.0	-29	47
Standing	3	121	82.7	9.9	82.0	56	119	117	6.6	8.8	5.0	-15	35

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V1, Wk -4 (SCR)													
Supine	3	121	73.9	9.7	74.0	50	93						
Standing	1	118	77.4	10.4	77.0	51	125						
Standing	3	116	77.5	9.3	78.0	52	125						
V2, Wk 0 (BL)													
Supine	3	121	73.5	9.1	74.0	54	96						
Standing	1	120	77.1	9.7	76.0	55	121						
Standing	3	118	77.9	9.7	78.0	48	110						
V3, Wk 2 (T)													
Supine	3	115	74.5	10.7	76.0	46	98	115	0.7	7.9	0.0	-20	25
Standing	1	113	78.7	10.2	80.0	50	125	113	1.5	7.9	1.0	-20	24
Standing	3	112	79.1	11.5	80.0	50	124	112	1.2	7.9	1.0	-27	21

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V4, Wk 4 (T)													
Supine	3	112	74.3	10.1	75.0	46	100	112	0.6	8.3	0.0	-25	28
Standing	1	112	78.3	10.9	80.0	47	107	111	1.2	8.9	1.0	-20	27
Standing	3	112	79.6	11.2	80.0	57	122	109	1.7	7.6	1.0	-20	30
V5, Wk 6 (M)													
Supine	3	82	75.2	10.2	75.0	50	100	82	1.2	7.6	1.0	-20	26
Standing	1	82	79.3	11.8	80.0	48	126	82	2.1	9.0	1.0	-19	25
Standing	3	82	80.0	11.8	80.0	53	130	80	2.3	7.7	1.0	-18	27
V6, Wk 8 (M)													
Supine	3	75	74.1	9.3	74.0	47	104	75	-0.2	7.4	0.0	-22	20
Standing	1	75	78.8	10.2	78.0	60	116	75	1.2	8.0	0.0	-19	20
Standing	3	75	78.9	10.6	80.0	55	115	73	0.8	7.7	0.0	-13	22

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)													
V7, Wk 12 (M)													
Supine	3	71	73.0	11.3	73.0	49	110	71	-0.8	8.7	0.0	-33	28
Standing	1	71	78.2	9.6	79.0	57	110	71	0.7	9.2	0.0	-38	24
Standing	3	71	77.9	9.4	78.0	60	112	69	-0.1	8.2	0.0	-33	23
V8, Wk 16 (M)													
Supine	3	65	72.8	9.0	72.0	55	90	65	-0.5	8.6	0.0	-29	17
Standing	1	65	76.3	9.4	78.0	50	93	65	-0.7	10.3	0.0	-41	15
Standing	3	65	78.0	8.2	80.0	60	102	64	0.3	8.7	0.0	-31	19
V9, Wk 20 (M)													
Supine	3	60	74.0	9.2	75.0	50	110	60	0.2	8.2	0.0	-33	20
Standing	1	60	77.9	9.4	80.0	50	100	60	0.7	9.1	2.0	-39	14
Standing	3	60	78.0	10.4	79.0	51	100	59	0.3	9.0	0.0	-33	20

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)													
V10, Wk 24 (M)													
Supine	3	60	74.0	9.0	73.0	56	99	60	0.3	6.7	1.0	-28	11
Standing	1	60	78.0	8.8	78.5	52	102	60	0.7	9.5	2.0	-35	18
Standing	3	60	77.8	9.0	79.5	52	95	59	0.2	9.3	2.0	-29	20
Early Termination Visit													
Supine	3	57	74.5	8.4	75.0	59	92	57	1.7	8.1	3.0	-18	21
Standing	1	57	79.1	9.1	79.0	57	97	56	2.8	10.2	2.5	-16	32
Standing	3	57	79.6	8.8	80.0	61	101	55	1.8	8.5	0.0	-12	29
Last Visit													
Supine	3	120	74.3	8.7	74.0	56	99	120	0.8	7.7	1.0	-28	21
Standing	1	120	78.8	9.1	79.0	52	102	119	1.9	9.8	2.0	-35	32
Standing	3	120	78.8	8.9	80.0	52	101	117	1.0	8.9	2.0	-29	29

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
Min Post-BL													
Supine	3	120	67.6	8.9	68.0	46	89	120	-5.9	8.7	-6.0	-33	17
Standing	1	120	71.6	9.5	73.0	47	89	119	-5.3	9.3	-5.0	-41	23
Standing	3	120	72.2	9.2	72.0	50	91	117	-5.6	7.9	-5.0	-33	11
Max Post-BL													
Supine	3	120	80.3	9.4	80.0	60	110	120	6.8	7.0	7.0	-14	28
Standing	1	120	85.2	9.6	85.0	60	126	119	8.1	7.5	8.0	-13	32
Standing	3	120	85.6	10.7	83.5	65	130	117	7.6	7.5	6.0	-8	30

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V1, Wk -4 (SCR)													
Supine	3	121	71.2	11.0	72.0	42	98						
Standing	1	117	78.4	12.9	77.0	35	120						
Standing	3	116	78.2	13.4	79.0	35	116						
V2, Wk 0 (BL)													
Supine	3	121	72.3	11.3	72.0	44	98						
Standing	1	117	79.4	13.2	80.0	40	118						
Standing	3	116	79.0	13.8	79.0	38	120						
V3, Wk 2 (T)													
Supine	3	118	73.1	12.9	73.0	46	99	118	0.8	9.0	0.0	-22	28
Standing	1	117	80.6	13.8	80.0	52	112	115	1.6	9.4	1.0	-22	25
Standing	3	118	80.6	14.0	80.5	52	110	114	1.9	10.1	2.0	-33	32

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V4, Wk 4 (T)													
Supine	3	114	73.2	12.0	72.0	42	99	114	0.9	8.9	0.0	-18	32
Standing	1	113	80.9	12.8	82.0	40	109	111	2.1	10.3	2.0	-26	38
Standing	3	114	81.4	12.5	82.0	40	112	110	2.9	11.5	1.5	-31	39
V5, Wk 6 (M)													
Supine	3	70	70.0	11.9	68.0	44	100	70	-1.6	9.0	-2.0	-22	23
Standing	1	70	78.3	14.4	79.0	40	113	68	-0.1	9.8	0.0	-33	24
Standing	3	70	77.9	14.0	77.0	41	119	67	-0.3	9.7	-1.0	-28	26
V6, Wk 8 (M)													
Supine	3	64	73.4	13.4	73.5	43	107	64	0.8	10.4	0.0	-28	34
Standing	1	63	81.0	15.2	79.0	38	116	61	2.6	10.3	2.0	-22	36
Standing	3	63	80.1	14.9	78.0	36	126	60	2.2	11.4	2.0	-29	32

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V7, Wk 12 (M)													
Supine	3	54	70.6	12.2	70.5	37	100	54	-1.3	9.4	-1.5	-19	33
Standing	1	54	78.5	16.5	78.0	38	125	52	1.6	11.6	0.0	-23	40
Standing	3	54	77.3	16.1	76.5	39	125	51	0.5	11.7	1.0	-23	36
V8, Wk 16 (M)													
Supine	3	48	70.7	10.5	71.0	40	91	48	-0.6	8.6	-1.0	-16	20
Standing	1	48	76.4	14.6	76.0	37	123	46	0.1	10.8	-1.5	-28	28
Standing	3	48	76.8	15.2	76.0	37	129	45	1.4	10.0	0.0	-23	28
V9, Wk 20 (M)													
Supine	3	37	70.4	10.6	70.0	48	94	37	-1.3	8.7	-2.0	-19	19
Standing	1	37	76.9	11.8	79.0	46	96	37	0.5	10.2	0.0	-19	31
Standing	3	37	77.1	12.4	78.0	47	100	36	1.6	11.8	1.0	-19	46

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V10, Wk 24 (M)													
Supine	3	37	71.5	13.2	72.0	38	100	37	-0.1	9.8	0.0	-21	25
Standing	1	37	77.6	14.5	79.0	40	102	37	1.2	11.1	2.0	-20	26
Standing	3	37	76.7	14.6	75.0	41	106	36	1.0	10.8	1.5	-20	24
Early Termination Visit													
Supine	3	78	74.7	11.9	75.5	47	108	78	2.1	8.5	1.0	-21	23
Standing	1	77	81.3	12.7	83.0	55	112	76	0.5	10.1	1.0	-42	21
Standing	3	78	82.7	13.3	82.0	59	124	76	1.8	9.5	2.0	-26	23
Last Visit													
Supine	3	121	73.8	12.1	75.0	38	108	121	1.5	9.0	1.0	-21	25
Standing	1	120	80.3	13.3	81.0	40	112	118	0.9	10.4	1.0	-42	26
Standing	3	121	80.8	14.0	80.0	41	124	117	1.8	9.9	2.0	-26	24

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
Min Post-BL													
Supine	3	121	66.4	11.0	66.0	37	93	121	-5.9	7.5	-6.0	-28	15
Standing	1	120	72.5	12.4	72.5	37	103	118	-6.6	9.2	-5.0	-42	17
Standing	3	121	73.2	12.4	72.0	36	110	117	-5.8	9.3	-4.0	-33	18
Max Post-BL													
Supine	3	121	80.6	11.9	82.0	49	108	121	8.3	8.8	7.0	-11	34
Standing	1	120	88.7	13.0	89.0	54	125	118	9.4	9.3	9.0	-17	40
Standing	3	121	88.7	13.2	90.0	53	129	117	9.8	9.7	8.0	-18	46

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V1, Wk -4 (SCR)													
Supine	3	121	73.3	11.9	71.0	48	136						
Standing	1	117	79.5	13.1	78.0	47	130						
Standing	3	115	80.4	14.1	77.0	53	130						
V2, Wk 0 (BL)													
Supine	3	121	73.3	11.1	73.0	45	120						
Standing	1	119	81.0	13.5	79.0	46	122						
Standing	3	117	80.7	13.9	79.0	49	120						
V3, Wk 2 (T)													
Supine	3	115	74.8	11.6	74.0	44	102	115	1.4	8.9	2.0	-39	25
Standing	1	112	81.4	13.8	80.5	50	125	112	0.6	10.3	1.0	-30	30
Standing	3	111	81.1	13.5	80.0	48	129	111	0.5	9.6	0.0	-40	30

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening,
SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V4, Wk 4 (T)													
Supine	3	111	74.0	10.9	72.0	51	102	111	0.8	9.2	2.0	-42	26
Standing	1	110	81.5	13.0	81.0	55	114	109	0.8	9.7	1.0	-27	20
Standing	3	110	80.8	12.7	80.0	58	119	108	0.3	9.1	0.0	-22	21
V5, Wk 6 (M)													
Supine	3	82	74.0	10.8	75.5	52	98	82	1.9	7.9	2.0	-26	20
Standing	1	82	80.7	11.6	80.5	59	111	82	0.7	10.1	1.0	-28	29
Standing	3	82	80.9	12.6	80.0	60	119	80	1.3	10.0	0.0	-38	27
V6, Wk 8 (M)													
Supine	3	75	73.7	9.2	73.0	53	90	75	2.3	6.8	3.0	-19	20
Standing	1	75	81.3	13.2	80.0	59	123	75	1.6	8.6	1.0	-26	25
Standing	3	75	80.5	13.3	80.0	60	123	73	0.9	8.8	1.0	-26	24

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V7, Wk 12 (M)													
Supine	3	71	72.4	10.5	71.0	53	97	71	0.6	8.3	0.0	-18	19
Standing	1	71	80.4	12.4	79.0	58	113	71	0.1	11.3	0.0	-34	31
Standing	3	71	79.4	12.4	78.0	58	109	69	-0.6	11.3	2.0	-34	21
V8, Wk 16 (M)													
Supine	3	65	74.4	11.7	72.0	49	99	65	2.7	7.8	3.0	-18	22
Standing	1	65	81.1	13.0	80.0	57	115	65	0.8	9.8	0.0	-30	24
Standing	3	65	80.8	14.1	76.0	56	112	64	0.9	10.2	2.0	-33	20
V9, Wk 20 (M)													
Supine	3	60	72.6	9.7	72.5	50	98	60	1.3	8.5	1.5	-16	31
Standing	1	60	79.3	11.7	78.0	52	115	60	-0.4	10.0	0.0	-21	29
Standing	3	60	79.2	10.6	79.0	53	100	59	-0.1	9.6	1.0	-24	31

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V10, Wk 24 (M)													
Supine	3	60	70.7	9.2	70.0	54	96	60	-0.5	9.5	0.0	-40	21
Standing	1	60	77.1	11.7	75.5	59	111	60	-2.6	10.1	-3.5	-26	18
Standing	3	60	77.1	12.0	76.5	57	110	59	-2.2	10.4	-2.0	-34	19
Early Termination Visit													
Supine	3	57	78.4	13.1	79.0	58	126	57	3.4	9.5	4.0	-20	33
Standing	1	56	86.9	13.7	87.0	61	120	55	3.9	12.3	5.0	-20	30
Standing	3	56	86.8	13.3	88.0	60	122	54	3.7	11.1	3.5	-19	26
Last Visit													
Supine	3	120	74.1	12.0	72.5	54	126	120	0.9	10.4	1.5	-42	33
Standing	1	119	81.6	13.5	81.0	59	120	118	0.6	11.5	1.5	-26	30
Standing	3	119	81.5	13.4	82.0	57	122	116	0.7	11.0	1.0	-34	26

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
Min Post-BL													
Supine	3	120	68.2	10.7	67.0	44	107	120	-5.1	9.2	-4.0	-42	33
Standing	1	119	74.7	12.0	73.0	50	112	118	-6.3	10.6	-6.5	-34	30
Standing	3	119	74.5	11.6	75.0	48	107	116	-6.2	10.6	-6.0	-40	26
Max Post-BL													
Supine	3	120	82.3	11.3	81.0	60	126	120	9.1	8.5	8.0	-14	33
Standing	1	119	89.6	13.3	89.0	61	125	118	8.6	9.9	8.0	-20	31
Standing	3	119	89.5	12.6	89.0	67	129	116	8.8	8.5	8.0	-16	31

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=121)													
V1, Wk -4 (SCR)		121	72.75	22.19	70.00	21.1	154.3						
V2, Wk 0 (BL)		121	72.79	22.03	69.10	20.9	154.1						
V3, Wk 2 (T)		118	72.93	22.15	69.75	20.6	151.8	118	0.05	1.08	0.00	-3.0	3.5
V4, Wk 4 (T)		114	73.09	22.42	70.00	21.2	152.7	114	0.19	1.64	0.00	-5.0	5.0
V5, Wk 6 (M)		70	72.31	21.55	69.35	32.9	151.0	70	0.04	1.61	0.00	-6.0	3.5
V6, Wk 8 (M)		64	72.95	22.29	69.50	32.8	151.4	64	-0.01	1.88	0.00	-6.0	6.3
V7, Wk 12 (M)		54	71.78	20.16	71.40	34.0	122.5	54	0.34	2.65	0.10	-9.0	6.0
V8, Wk 16 (M)		48	72.51	20.81	73.00	34.0	124.0	48	0.46	2.70	0.25	-9.0	6.5
V9, Wk 20 (M)		37	73.46	20.87	76.00	33.8	112.0	37	0.38	3.57	0.90	-15.2	7.1

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=121)													
V10, Wk 24 (M)		37	73.63	21.20	78.00	33.6	114.0	37	0.55	3.81	0.70	-15.2	9.6
Early Termination Visit		79	73.01	22.75	68.90	20.8	151.2	79	0.21	1.88	0.00	-4.0	6.0
Last Visit		121	73.12	21.88	69.70	20.8	151.2	121	0.32	2.59	0.10	-15.2	9.6
Min Post-BL		121	71.92	21.61	69.00	20.6	151.0	121	-0.88	2.08	-0.50	-15.2	2.9
Max Post-BL		121	74.13	22.02	70.50	21.2	152.7	121	1.33	1.82	1.00	-4.0	9.6

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=121)													
V1, Wk -4 (SCR)		121	70.42	21.84	70.50	15.8	127.4						
V2, Wk 0 (BL)		121	70.46	21.99	70.50	16.2	127.4						
V3, Wk 2 (T)		115	70.78	22.57	71.40	16.1	132.8	115	0.36	1.21	0.00	-2.3	6.2
V4, Wk 4 (T)		112	71.18	22.98	71.50	16.0	135.2	112	0.61	1.68	0.05	-2.0	8.6
V5, Wk 6 (M)		82	71.45	21.52	72.70	20.0	130.2	82	0.63	1.86	0.05	-5.7	6.0
V6, Wk 8 (M)		75	72.33	21.83	75.00	20.0	129.5	75	0.78	1.90	0.30	-4.1	6.8
V7, Wk 12 (M)		71	71.10	21.34	72.90	21.0	127.0	71	0.88	2.33	0.60	-4.3	9.0
V8, Wk 16 (M)		64	71.65	21.97	72.75	21.0	131.0	64	1.29	2.75	0.85	-4.8	13.0
V9, Wk 20 (M)		60	72.97	21.34	75.50	23.0	129.0	60	1.40	3.15	1.00	-8.5	11.0

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)													
V10, Wk 24 (M)		60	72.93	21.14	75.00	23.0	129.0	60	1.36	3.40	0.90	-6.7	11.2
Early Termination Visit		58	68.60	23.51	65.50	16.0	133.3	58	0.50	1.91	0.35	-4.0	6.7
Last Visit		120	71.14	22.34	71.40	16.0	133.3	120	0.93	2.77	0.50	-6.7	11.2
Min Post-BL		120	69.66	21.95	70.25	16.0	132.8	120	-0.55	1.66	-0.10	-8.5	6.2
Max Post-BL		120	72.15	22.69	72.05	16.1	135.2	120	1.94	2.40	1.00	-1.4	13.0

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Height (cm)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V1, Wk -4 (SCR)		121	164.75	12.32	165.00	121.0	191.5						
V10, Wk 24 (M)		37	165.44	11.42	165.00	142.0	186.0	37	0.22	0.69	0.00	-1.0	2.5
Early Termination Visit		78	164.03	12.32	165.00	123.0	188.0	78	0.06	0.70	0.00	-2.0	2.5
Last Visit		116	164.72	12.21	165.00	123.0	191.5	116	0.11	0.69	0.00	-2.0	2.5
Min Post-BL		116	164.72	12.21	165.00	123.0	191.5	116	0.11	0.69	0.00	-2.0	2.5
Max Post-BL		116	164.72	12.21	165.00	123.0	191.5	116	0.11	0.69	0.00	-2.0	2.5

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Height (cm)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)													
V1, Wk -4 (SCR)		121	165.89	15.04	167.00	105.0	203.2						
V10, Wk 24 (M)		60	167.07	13.82	167.50	121.0	198.0	60	0.26	1.60	0.00	-5.2	7.1
Early Termination Visit		57	164.31	15.66	166.00	107.5	203.0	57	0.07	0.64	0.00	-2.0	2.5
Last Visit		117	165.72	14.75	167.00	107.5	203.0	117	0.17	1.23	0.00	-5.2	7.1
Min Post-BL		117	165.72	14.75	167.00	107.5	203.0	117	0.17	1.23	0.00	-5.2	7.1
Max Post-BL		117	165.72	14.75	167.00	107.5	203.0	117	0.17	1.23	0.00	-5.2	7.1

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Body Mass Index (kg/m²)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=121)													
V1, Wk -4 (SCR)		121	26.47	6.78	25.00	14.3	47.2						
V10, Wk 24 (M)		37	26.46	5.89	27.35	15.0	39.3	37	0.20	1.46	0.33	-6.1	3.2
Early Termination Visit		78	26.86	7.21	24.67	13.6	47.3	78	0.09	0.75	0.00	-1.7	2.3
Last Visit		116	26.69	6.78	25.65	13.6	47.3	116	0.12	1.03	0.03	-6.1	3.2
Min Post-BL		116	26.69	6.78	25.65	13.6	47.3	116	0.12	1.03	0.03	-6.1	3.2
Max Post-BL		116	26.70	6.77	25.65	13.6	47.3	116	0.13	1.02	0.06	-6.1	3.2

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-62　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Body Mass Index (kg/m^2)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=121)													
V1, Wk -4 (SCR)		121	25.09	6.21	24.16	14.3	50.0						
V10, Wk 24 (M)		60	25.74	6.14	25.06	14.4	53.4	60	0.41	1.46	0.35	-2.4	6.7
Early Termination Visit		57	24.95	7.07	22.32	13.9	50.6	57	0.25	0.75	0.17	-1.4	2.3
Last Visit		117	25.35	6.59	24.68	13.9	53.4	117	0.33	1.16	0.20	-2.4	6.7
Min Post-BL		117	25.35	6.59	24.68	13.9	53.4	117	0.33	1.17	0.20	-2.4	6.7
Max Post-BL		117	25.35	6.59	24.68	13.9	53.4	117	0.33	1.16	0.20	-2.4	6.7

BL=Baseline, ET=Early Termination, LCM=Lacosamide, M=Maintenance, Max=maximum, Min=minimum, SCR=Screening, SD=standard deviation, T=Titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V1, Wk -4 (SCR)													
Supine	3	19	112.1	13.3	110.0	90	141						
Standing	1	19	117.4	18.3	112.0	90	152						
Standing	3	19	118.3	17.1	120.0	96	156						
V2, Wk 0 (BL)													
Supine	3	19	112.4	13.7	107.0	91	142						
Standing	1	19	118.8	19.9	117.0	82	155						
Standing	3	19	118.2	16.2	113.0	98	151						
V3, Wk 2 (T)													
Supine	3	19	111.4	13.8	108.0	89	142	19	-0.9	8.2	-1.0	-12	16
Standing	1	19	116.6	18.2	117.0	75	147	19	-2.2	13.1	-5.0	-28	24
Standing	3	19	118.0	17.6	119.0	80	144	19	-0.2	11.6	-1.0	-30	23

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V4, Wk 4 (T)													
Supine	3	18	115.4	16.0	115.0	91	148	18	2.9	11.7	4.0	-19	22
Standing	1	18	124.1	14.1	120.5	101	147	18	4.5	14.1	1.5	-19	29
Standing	3	18	122.9	16.9	124.5	95	148	18	3.8	13.7	0.0	-12	40
V5, Wk 6 (M)													
Supine	3	9	110.8	15.0	112.0	91	141	9	-1.4	13.0	1.0	-17	15
Standing	1	9	120.1	17.0	114.0	103	161	9	3.8	16.9	4.0	-26	30
Standing	3	9	117.9	12.3	114.0	108	145	9	-2.2	9.6	-1.0	-16	10
V6, Wk 8 (M)													
Supine	3	5	110.4	12.5	108.0	100	132	5	0.2	8.8	3.0	-14	8
Standing	1	5	121.6	21.3	114.0	99	156	5	11.6	12.7	9.0	-4	31
Standing	3	5	122.0	19.6	111.0	105	148	5	7.0	7.4	7.0	-3	17

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V7, Wk 12 (M)													
Supine	3	4	114.3	17.1	108.0	102	139	4	2.0	8.0	0.5	-6	13
Standing	1	4	121.3	15.9	120.5	104	140	4	9.5	9.5	9.5	-2	21
Standing	3	4	125.5	27.4	118.5	103	162	4	7.0	4.2	7.5	2	11
V8, Wk 16 (M)													
Supine	3	3	105.0	6.1	108.0	98	109	3	-2.7	6.0	-2.0	-9	3
Standing	1	3	108.0	9.8	105.0	100	119	3	6.3	9.3	2.0	0	17
Standing	3	3	106.7	4.5	107.0	102	111	3	-1.0	7.8	3.0	-10	4
V9, Wk 20 (M)													
Supine	3	3	111.7	10.6	110.0	102	123	3	4.0	13.1	2.0	-8	18
Standing	1	3	120.3	14.4	126.0	104	131	3	18.7	8.7	21.0	9	26
Standing	3	3	109.3	4.7	111.0	104	113	3	1.7	8.4	6.0	-8	7

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V10, Wk 24 (M)													
Supine	3	3	106.7	5.5	107.0	101	112	3	-1.0	7.0	-4.0	-6	7
Standing	1	3	111.0	4.4	109.0	108	116	3	9.3	13.8	4.0	-1	25
Standing	3	3	112.7	6.4	110.0	108	120	3	5.0	6.6	4.0	-1	12
Early Termination Visit													
Supine	3	16	111.6	10.9	111.5	95	136	16	-1.7	13.0	2.0	-29	22
Standing	1	16	120.4	13.8	117.5	104	150	16	-1.6	13.9	-5.0	-23	22
Standing	3	16	117.8	16.1	113.0	102	152	16	-2.4	12.4	-3.5	-33	21
Last Visit													
Supine	3	19	110.8	10.2	110.0	95	136	19	-1.6	12.1	2.0	-29	22
Standing	1	19	118.9	13.2	115.0	104	150	19	0.1	14.1	-1.0	-23	25
Standing	3	19	116.9	15.0	113.0	102	152	19	-1.3	11.9	-1.0	-33	21

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
Min Post-BL													
Supine	3	19	104.8	10.9	104.0	89	126	19	-7.5	10.0	-9.0	-29	12
Standing	1	19	110.8	14.5	111.0	75	136	19	-8.1	11.2	-7.0	-28	12
Standing	3	19	111.2	15.7	112.0	80	144	19	-7.0	11.8	-6.0	-33	19
Max Post-BL													
Supine	3	19	120.3	13.4	120.0	96	148	19	7.9	10.1	10.0	-11	22
Standing	1	19	129.8	15.3	128.0	110	161	19	11.0	14.2	13.0	-15	31
Standing	3	19	128.9	16.5	127.0	102	162	19	10.7	10.7	11.0	-8	40

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
LCM (N=11)													
V1, Wk -4 (SCR)													
Supine	3	11	107.7	16.1	103.0	89	140						
Standing	1	11	115.0	24.9	115.0	83	168						
Standing	3	11	113.0	23.7	111.0	80	167						
V2, Wk 0 (BL)													
Supine	3	11	111.6	15.9	110.0	86	141						
Standing	1	11	113.5	19.2	111.0	88	157						
Standing	3	11	114.6	16.1	114.0	93	149						
V3, Wk 2 (T)													
Supine	3	11	111.6	19.0	108.0	84	150	11	0.0	9.9	3.0	-18	13
Standing	1	11	116.2	18.3	110.0	92	160	11	2.6	7.8	3.0	-8	15
Standing	3	11	113.6	20.1	112.0	82	159	11	-1.0	9.0	-2.0	-14	11

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V4, Wk 4 (T)													
Supine	3	11	113.5	16.8	115.0	90	146	11	1.8	13.7	5.0	-25	20
Standing	1	11	114.3	17.6	113.0	95	160	11	0.7	11.3	0.0	-19	25
Standing	3	11	116.3	16.1	111.0	98	156	11	1.6	10.5	-1.0	-18	24
V5, Wk 6 (M)													
Supine	3	11	116.1	17.3	109.0	94	153	11	4.5	10.3	1.0	-8	22
Standing	1	11	121.0	21.2	118.0	96	171	11	7.5	13.6	5.0	-10	42
Standing	3	11	115.3	17.5	116.0	93	153	11	0.6	12.5	1.0	-21	27
V6, Wk 8 (M)													
Supine	3	10	116.2	14.6	112.5	97	139	10	4.9	6.0	4.5	-2	12
Standing	1	10	121.6	20.7	117.5	97	164	10	7.8	9.6	6.0	-4	25
Standing	3	10	117.1	21.3	112.0	91	168	10	2.8	11.4	-2.5	-9	23

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V7, Wk 12 (M)													
Supine	3	10	108.4	11.1	108.0	94	129	10	-2.9	12.3	-1.5	-24	18
Standing	1	10	112.3	13.3	110.5	91	132	10	-1.5	12.6	0.5	-27	19
Standing	3	10	112.8	14.8	109.0	95	136	10	-1.5	11.1	-2.0	-19	14
V8, Wk 16 (M)													
Supine	3	9	112.9	12.9	115.0	96	132	9	1.4	8.6	-1.0	-9	14
Standing	1	9	116.8	15.7	110.0	97	146	9	2.7	11.4	8.0	-20	16
Standing	3	9	112.1	14.4	107.0	100	144	9	-2.2	8.0	-4.0	-18	9
V9, Wk 20 (M)													
Supine	3	9	111.8	13.6	118.0	86	125	9	0.3	13.3	-1.0	-16	26
Standing	1	9	112.2	20.5	118.0	70	135	9	-1.9	19.6	-5.0	-30	32
Standing	3	9	113.2	15.3	115.0	90	137	9	-1.1	13.8	-3.0	-23	22

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V10, Wk 24 (M)													
Supine	3	9	110.7	10.3	112.0	99	130	9	-0.8	11.7	0.0	-20	17
Standing	1	9	113.8	15.4	110.0	94	145	9	-0.3	18.2	2.0	-33	22
Standing	3	9	113.6	14.9	114.0	90	140	9	-0.8	18.6	-5.0	-32	35
Early Termination Visit													
Supine	3	2	116.0	4.2	116.0	113	119	2	3.5	0.7	3.5	3	4
Standing	1	2	110.0	0.0	110.0	110	110	2	-1.0	0.0	-1.0	-1	-1
Standing	3	2	109.0	2.8	109.0	107	111	2	-7.0	0.0	-7.0	-7	-7
Last Visit													
Supine	3	11	111.6	9.5	112.0	99	130	11	0.0	10.6	2.0	-20	17
Standing	1	11	113.1	13.9	110.0	94	145	11	-0.5	16.2	-1.0	-33	22
Standing	3	11	112.7	13.5	111.0	90	140	11	-1.9	16.9	-6.0	-32	35

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
Min Post-BL													
Supine	3	11	101.9	10.3	102.0	84	121	11	-9.7	11.6	-12.0	-25	9
Standing	1	11	102.5	13.4	105.0	70	124	11	-11.1	13.8	-10.0	-33	8
Standing	3	11	103.4	11.7	103.0	82	120	11	-11.3	11.0	-10.0	-32	9
Max Post-BL													
Supine	3	11	121.8	15.3	119.0	100	153	11	10.2	8.3	11.0	-2	26
Standing	1	11	128.8	19.6	126.0	103	171	11	15.3	10.3	15.0	4	42
Standing	3	11	123.4	18.6	119.0	102	168	11	8.7	11.8	6.0	-5	35

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=19)													
V1, Wk -4 (SCR)													
Supine	3	19	69.5	11.6	67.0	53	92						
Standing	1	19	80.8	17.0	74.0	61	119						
Standing	3	19	82.2	16.4	83.0	58	115						
V2, Wk 0 (BL)													
Supine	3	19	66.5	12.7	65.0	39	91						
Standing	1	19	81.8	17.8	83.0	57	112						
Standing	3	19	80.2	13.6	77.0	58	102						
V3, Wk 2 (T)													
Supine	3	19	65.7	10.5	63.0	47	85	19	-0.8	10.5	-5.0	-23	17
Standing	1	19	79.6	15.6	80.0	53	112	19	-2.2	15.8	0.0	-49	20
Standing	3	19	76.7	15.4	75.0	43	102	19	-3.5	10.8	0.0	-28	17

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V4, Wk 4 (T)													
Supine	3	18	67.2	11.7	65.0	48	92	18	0.6	12.8	0.5	-22	25
Standing	1	18	80.6	16.2	77.0	55	114	18	-1.6	16.2	-2.5	-34	47
Standing	3	18	83.2	13.1	79.0	65	110	18	2.6	13.2	5.0	-21	32
V5, Wk 6 (M)													
Supine	3	9	69.1	10.8	69.0	49	89	9	5.3	8.1	6.0	-7	22
Standing	1	9	78.2	19.4	73.0	50	115	9	-1.4	12.9	3.0	-21	15
Standing	3	9	78.4	15.7	77.0	57	106	9	-1.7	10.4	2.0	-22	9
V6, Wk 8 (M)													
Supine	3	5	67.6	6.3	64.0	62	75	5	8.8	9.7	8.0	-2	24
Standing	1	5	75.0	19.1	71.0	61	108	5	2.6	10.0	1.0	-12	15
Standing	3	5	73.6	22.5	68.0	58	113	5	-0.2	10.1	2.0	-11	12

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V7, Wk 12 (M)													
Supine	3	4	60.8	15.7	57.0	46	83	4	3.3	10.5	2.5	-8	16
Standing	1	4	74.0	26.0	71.0	46	108	4	4.3	15.0	6.5	-16	20
Standing	3	4	72.3	28.9	65.5	45	113	4	0.0	15.6	5.5	-23	12
V8, Wk 16 (M)													
Supine	3	3	54.0	11.1	56.0	42	64	3	-0.3	3.5	0.0	-4	3
Standing	1	3	56.0	7.8	60.0	47	61	3	-3.7	9.9	1.0	-15	3
Standing	3	3	54.3	11.2	57.0	42	64	3	-8.3	15.4	-1.0	-26	2
V9, Wk 20 (M)													
Supine	3	3	61.7	8.1	58.0	56	71	3	7.3	11.5	7.0	-4	19
Standing	1	3	67.7	9.5	68.0	58	77	3	8.0	8.2	6.0	1	17
Standing	3	3	74.0	12.5	73.0	62	87	3	11.3	15.5	5.0	0	29

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V10, Wk 24 (M)													
Supine	3	3	59.7	4.9	62.0	54	63	3	5.3	16.6	3.0	-10	23
Standing	1	3	55.0	6.1	58.0	48	59	3	-4.7	8.1	-1.0	-14	1
Standing	3	3	62.0	2.0	62.0	60	64	3	-0.7	4.6	2.0	-6	2
Early Termination Visit													
Supine	3	16	66.8	7.8	70.0	53	79	16	-2.1	13.1	-1.5	-34	22
Standing	1	16	80.7	16.2	81.0	50	117	16	-5.3	11.1	-3.5	-29	14
Standing	3	16	83.4	13.7	82.0	62	119	16	-0.1	11.1	0.5	-18	20
Last Visit													
Supine	3	19	65.6	7.8	67.0	53	79	19	-0.9	13.5	0.0	-34	23
Standing	1	19	76.6	17.8	76.0	48	117	19	-5.2	10.5	-3.0	-29	14
Standing	3	19	80.0	14.8	78.0	60	119	19	-0.2	10.2	1.0	-18	20

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=19)													
Min Post-BL													
Supine	3	19	60.2	8.4	59.0	42	75	19	-6.3	11.8	-7.0	-34	8
Standing	1	19	71.1	14.6	71.0	46	98	19	-10.7	12.3	-9.0	-49	10
Standing	3	19	69.8	14.8	68.0	42	97	19	-10.4	10.5	-8.0	-28	2
Max Post-BL													
Supine	3	19	73.2	8.7	71.0	57	92	19	6.7	11.6	6.0	-12	25
Standing	1	19	87.7	15.2	82.0	68	117	19	5.9	15.7	6.0	-29	47
Standing	3	19	88.6	13.7	88.0	66	119	19	8.4	12.4	7.0	-15	32

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V1, Wk -4 (SCR)													
Supine	3	11	64.8	12.8	62.0	53	93						
Standing	1	11	79.6	18.0	77.0	57	125						
Standing	3	11	78.5	18.6	76.0	54	125						
V2, Wk 0 (BL)													
Supine	3	11	69.5	11.2	72.0	55	87						
Standing	1	11	80.5	16.2	79.0	60	121						
Standing	3	11	82.7	15.3	82.0	62	110						
V3, Wk 2 (T)													
Supine	3	11	70.3	14.7	66.0	50	95	11	0.8	7.2	0.0	-10	11
Standing	1	11	81.6	18.1	76.0	60	125	11	1.1	7.0	0.0	-10	16
Standing	3	11	83.8	18.9	79.0	62	124	11	1.1	9.3	3.0	-13	14

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V4, Wk 4 (T)													
Supine	3	11	68.9	10.9	68.0	50	85	11	-0.5	7.9	-1.0	-13	11
Standing	1	11	78.4	13.2	77.0	60	107	11	-2.2	6.4	-1.0	-14	6
Standing	3	11	80.6	16.4	81.0	60	120	11	-2.1	6.9	-2.0	-11	10
V5, Wk 6 (M)													
Supine	3	11	72.2	15.8	68.0	50	100	11	2.7	7.7	3.0	-10	13
Standing	1	11	82.2	19.8	76.0	60	126	11	1.6	10.0	2.0	-12	25
Standing	3	11	82.5	19.2	79.0	60	130	11	-0.3	8.6	0.0	-12	20
V6, Wk 8 (M)													
Supine	3	10	73.6	14.3	68.5	60	104	10	4.4	6.8	4.5	-4	17
Standing	1	10	82.6	14.4	80.5	63	116	10	1.9	7.1	1.5	-8	13
Standing	3	10	82.7	14.8	83.5	61	115	10	-0.1	7.9	0.5	-11	15

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V7, Wk 12 (M)													
Supine	3	10	63.9	9.6	62.5	50	78	10	-5.3	9.3	-6.0	-25	6
Standing	1	10	75.3	9.7	75.0	57	91	10	-5.4	13.7	-4.0	-38	10
Standing	3	10	75.9	8.8	74.0	68	91	10	-6.9	11.1	-4.0	-33	6
V8, Wk 16 (M)													
Supine	3	9	64.7	6.7	65.0	55	77	9	-5.2	14.8	5.0	-29	8
Standing	1	9	73.4	12.0	72.0	50	89	9	-8.0	18.8	-2.0	-41	13
Standing	3	9	78.3	8.5	76.0	67	93	9	-5.0	15.9	-1.0	-31	14
V9, Wk 20 (M)													
Supine	3	9	66.8	11.0	71.0	50	81	9	-3.1	8.9	-4.0	-16	9
Standing	1	9	75.9	11.9	80.0	50	90	9	-5.6	14.5	-4.0	-39	14
Standing	3	9	77.2	11.7	80.0	56	90	9	-6.1	12.5	-6.0	-30	15

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V10, Wk 24 (M)													
Supine	3	9	68.9	10.4	69.0	59	86	9	-1.0	8.2	0.0	-18	11
Standing	1	9	78.1	8.5	78.0	66	92	9	-3.3	15.7	-2.0	-35	18
Standing	3	9	76.9	9.3	75.0	66	95	9	-6.4	15.2	-11.0	-26	20
Early Termination Visit													
Supine	3	2	64.5	3.5	64.5	62	67	2	-3.0	9.9	-3.0	-10	4
Standing	1	2	80.5	6.4	80.5	76	85	2	4.0	2.8	4.0	2	6
Standing	3	2	72.5	2.1	72.5	71	74	2	-7.5	4.9	-7.5	-11	-4
Last Visit													
Supine	3	11	68.1	9.6	67.0	59	86	11	-1.4	8.0	0.0	-18	11
Standing	1	11	78.5	7.9	78.0	66	92	11	-2.0	14.4	0.0	-35	18
Standing	3	11	76.1	8.5	74.0	66	95	11	-6.6	13.7	-11.0	-26	20

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
Min Post-BL													
Supine	3	11	59.5	7.1	59.0	50	75	11	-9.9	10.4	-9.0	-29	4
Standing	1	11	67.6	11.0	72.0	50	80	11	-12.9	13.2	-10.0	-41	0
Standing	3	11	70.4	7.1	71.0	56	80	11	-12.4	9.6	-11.0	-33	-2
Max Post-BL													
Supine	3	11	76.5	14.0	71.0	62	104	11	7.1	6.4	8.0	-7	17
Standing	1	11	89.5	16.4	86.0	70	126	11	9.0	7.7	7.0	-2	25
Standing	3	11	89.1	18.5	83.0	68	130	11	6.4	9.2	5.0	-8	20

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V1, Wk -4 (SCR)													
Supine	3	19	66.4	14.4	66.0	42	98						
Standing	1	19	75.8	16.8	78.0	35	102						
Standing	3	19	75.8	16.2	79.0	35	103						
V2, Wk 0 (BL)													
Supine	3	19	65.2	13.4	69.0	44	93						
Standing	1	19	77.3	17.2	79.0	40	117						
Standing	3	19	75.8	14.8	79.0	38	100						
V3, Wk 2 (T)													
Supine	3	19	68.9	16.2	70.0	46	96	19	3.7	10.7	4.0	-18	24
Standing	1	19	83.8	15.5	83.0	55	111	19	6.5	10.4	8.0	-22	25
Standing	3	19	83.4	15.2	90.0	56	108	19	7.6	9.8	7.0	-7	32

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V4, Wk 4 (T)													
Supine	3	18	66.2	14.9	65.0	42	98	18	1.6	9.3	1.5	-17	18
Standing	1	18	77.8	15.7	79.5	40	102	18	1.3	10.8	5.0	-17	22
Standing	3	18	77.8	14.7	80.5	40	101	18	3.3	8.2	2.5	-15	19
V5, Wk 6 (M)													
Supine	3	9	68.8	9.5	68.0	55	86	9	7.9	7.1	7.0	-1	23
Standing	1	9	78.3	16.4	80.0	40	96	9	6.8	8.5	8.0	-7	23
Standing	3	9	77.7	15.9	80.0	41	94	9	5.6	6.1	8.0	-3	16
V6, Wk 8 (M)													
Supine	3	5	61.8	16.5	66.0	43	84	5	0.0	6.8	-3.0	-4	12
Standing	1	5	72.8	20.4	77.0	38	89	5	4.6	4.7	6.0	-2	10
Standing	3	5	72.4	21.4	76.0	36	92	5	4.2	4.4	4.0	-2	10

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V7, Wk 12 (M)													
Supine	3	4	59.0	14.9	65.0	37	69	4	-0.3	11.0	-3.0	-10	15
Standing	1	4	72.8	23.2	84.0	38	85	4	7.3	8.1	8.0	-2	15
Standing	3	4	71.5	22.3	80.5	39	86	4	7.8	6.7	8.0	1	14
V8, Wk 16 (M)													
Supine	3	3	54.0	12.5	58.0	40	64	3	-7.7	3.1	-7.0	-11	-5
Standing	1	3	59.3	19.4	69.0	37	72	3	-4.7	2.9	-3.0	-8	-3
Standing	3	3	59.7	19.9	68.0	37	74	3	-1.0	3.0	-1.0	-4	2
V9, Wk 20 (M)													
Supine	3	3	65.0	5.6	66.0	59	70	3	3.3	14.6	1.0	-10	19
Standing	1	3	75.3	8.4	71.0	70	85	3	11.3	20.6	13.0	-10	31
Standing	3	3	81.3	6.4	84.0	74	86	3	20.7	22.7	14.0	2	46

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V10, Wk 24 (M)													
Supine	3	3	62.3	21.1	74.0	38	75	3	0.7	8.4	5.0	-9	6
Standing	1	3	70.7	26.9	82.0	40	90	3	6.7	9.9	2.0	0	18
Standing	3	3	67.3	23.5	75.0	41	86	3	6.7	6.4	3.0	3	14
Early Termination Visit													
Supine	3	16	67.0	11.7	70.0	47	85	16	1.2	10.3	-0.5	-17	21
Standing	1	16	78.8	12.9	79.5	55	101	16	-1.0	14.3	1.0	-42	16
Standing	3	16	80.9	13.3	83.5	60	109	16	2.3	7.0	1.5	-15	12
Last Visit													
Supine	3	19	66.3	12.9	70.0	38	85	19	1.1	9.8	0.0	-17	21
Standing	1	19	77.5	15.1	80.0	40	101	19	0.2	13.8	2.0	-42	18
Standing	3	19	78.8	15.3	83.0	41	109	19	3.0	6.9	3.0	-15	14

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
Placebo (N=19)													
Min Post-BL													
Supine	3	19	61.1	13.1	60.0	37	85	19	-4.1	7.1	-5.0	-18	6
Standing	1	19	70.9	13.3	72.0	37	96	19	-6.4	10.7	-3.0	-42	8
Standing	3	19	73.5	14.4	75.0	36	92	19	-2.3	6.1	-1.0	-15	9
Max Post-BL													
Supine	3	19	75.4	12.9	73.0	49	98	19	10.2	9.3	13.0	-5	24
Standing	1	19	88.5	13.3	90.0	65	111	19	11.2	10.0	13.0	-17	31
Standing	3	19	88.3	13.7	90.0	62	109	19	12.5	10.2	11.0	-1	46

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V1, Wk -4 (SCR)													
Supine	3	11	68.7	10.7	65.0	55	88						
Standing	1	11	83.5	15.2	80.0	61	119						
Standing	3	11	88.0	16.6	85.0	67	119						
V2, Wk 0 (BL)													
Supine	3	11	72.6	13.3	68.0	55	102						
Standing	1	11	92.3	14.5	93.0	63	116						
Standing	3	11	90.2	17.1	84.0	68	115						
V3, Wk 2 (T)													
Supine	3	11	73.5	13.3	73.0	52	95	11	0.9	16.0	3.0	-39	20
Standing	1	11	90.4	17.0	88.0	68	125	11	-1.9	14.8	3.0	-30	18
Standing	3	11	91.3	16.6	87.0	71	129	11	1.1	16.1	4.0	-40	19

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V4, Wk 4 (T)													
Supine	3	11	70.0	8.2	70.0	57	82	11	-2.6	8.7	-3.0	-24	7
Standing	1	11	88.3	13.4	89.0	68	114	11	-4.0	14.7	-4.0	-26	20
Standing	3	11	91.9	12.5	90.0	76	119	11	1.7	10.9	4.0	-19	19
V5, Wk 6 (M)													
Supine	3	11	77.5	9.5	76.0	58	95	11	4.8	11.2	8.0	-26	14
Standing	1	11	90.5	10.0	93.0	73	104	11	-1.7	15.1	-1.0	-23	19
Standing	3	11	93.3	12.8	90.0	77	119	11	3.1	17.8	6.0	-38	25
V6, Wk 8 (M)													
Supine	3	10	77.8	8.5	80.0	61	87	10	8.1	6.2	7.5	-1	20
Standing	1	10	93.0	14.6	89.5	73	123	10	3.1	11.4	1.0	-14	25
Standing	3	10	88.9	15.5	84.5	72	123	10	1.2	14.6	5.0	-26	24

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V7, Wk 12 (M)													
Supine	3	10	68.7	8.9	67.5	54	82	10	-1.0	8.9	-1.5	-16	13
Standing	1	10	84.9	10.3	85.0	70	104	10	-5.0	13.8	-1.0	-30	11
Standing	3	10	85.2	9.9	82.0	72	103	10	-2.5	19.3	3.0	-34	21
V8, Wk 16 (M)													
Supine	3	9	70.2	11.8	68.0	55	90	9	0.0	8.2	2.0	-15	10
Standing	1	9	81.4	13.2	82.0	61	106	9	-9.3	10.1	-8.0	-30	6
Standing	3	9	85.3	14.0	83.0	61	104	9	-3.2	14.9	2.0	-33	13
V9, Wk 20 (M)													
Supine	3	9	68.1	8.9	70.0	56	81	9	-2.1	8.7	-5.0	-12	16
Standing	1	9	83.2	11.0	80.0	74	111	9	-7.6	11.0	-8.0	-21	11
Standing	3	9	83.1	6.4	82.0	72	93	9	-5.4	13.2	1.0	-24	9

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V10, Wk 24 (M)													
Supine	3	9	67.9	7.7	70.0	54	77	9	-2.3	8.1	-1.0	-12	9
Standing	1	9	83.1	7.3	84.0	68	92	9	-7.7	12.5	-8.0	-26	10
Standing	3	9	83.1	7.4	85.0	73	94	9	-5.4	18.7	2.0	-34	15
Early Termination Visit													
Supine	3	2	73.0	21.2	73.0	58	88	2	-10.5	4.9	-10.5	-14	-7
Standing	1	2	84.0	17.0	84.0	72	96	2	-15.0	7.1	-15.0	-20	-10
Standing	3	2	88.0	15.6	88.0	77	99	2	-9.5	9.2	-9.5	-16	-3
Last Visit													
Supine	3	11	68.8	9.8	70.0	54	88	11	-3.8	8.1	-7.0	-14	9
Standing	1	11	83.3	8.5	84.0	68	96	11	-9.0	11.8	-9.0	-26	10
Standing	3	11	84.0	8.5	85.0	73	99	11	-6.2	17.1	-3.0	-34	15

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
Min Post-BL													
Supine	3	11	61.7	6.6	61.0	52	75	11	-10.9	10.3	-8.0	-39	-3
Standing	1	11	74.8	7.7	76.0	61	86	11	-17.5	10.1	-15.0	-30	-2
Standing	3	11	76.2	6.1	77.0	61	85	11	-14.0	16.7	-8.0	-40	8
Max Post-BL													
Supine	3	11	83.4	8.7	84.0	61	95	11	10.7	9.7	13.0	-14	20
Standing	1	11	99.1	12.4	96.0	83	125	11	6.8	13.4	8.0	-20	25
Standing	3	11	100.6	11.6	99.0	88	129	11	10.5	11.7	10.0	-16	25

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V1, Wk -4 (SCR)		19	60.66	14.52	59.80	21.1	95.6						
V2, Wk 0 (BL)		19	60.71	14.57	60.70	20.9	94.5						
V3, Wk 2 (T)		19	60.55	14.74	61.10	20.6	95.1	19	-0.16	0.97	-0.20	-1.7	2.0
V4, Wk 4 (T)		18	61.46	15.30	61.40	21.2	96.5	18	0.91	1.01	0.55	-0.3	3.5
V5, Wk 6 (M)		9	63.23	10.24	63.00	48.6	78.0	9	0.93	1.41	0.20	-0.6	3.5
V6, Wk 8 (M)		5	61.88	12.68	62.80	48.6	79.3	5	1.16	3.18	-0.50	-1.2	6.3
V7, Wk 12 (M)		4	64.85	13.05	66.10	48.2	79.0	4	1.88	3.00	1.30	-1.1	6.0
V8, Wk 16 (M)		3	66.13	15.26	69.40	49.5	79.5	3	3.27	3.15	3.10	0.2	6.5
V9, Wk 20 (M)		3	66.60	15.81	70.50	49.2	80.1	3	3.73	3.01	2.80	1.3	7.1

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V10, Wk 24 (M)		3	66.73	17.29	69.30	48.3	82.6	3	3.87	5.05	1.90	0.1	9.6
Early Termination Visit		16	60.31	15.09	60.75	20.8	94.0	16	0.00	0.82	0.05	-1.5	1.5
Last Visit		19	61.32	15.13	60.90	20.8	94.0	19	0.61	2.34	0.10	-1.5	9.6
Min Post-BL		19	60.24	14.59	60.90	20.6	94.0	19	-0.47	0.98	-0.70	-1.7	2.0
Max Post-BL		19	62.04	15.23	61.50	21.2	96.5	19	1.33	2.24	0.80	-1.4	9.6

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V1, Wk -4 (SCR)		11	62.01	19.78	53.20	40.2	108.0						
V2, Wk 0 (BL)		11	62.05	20.32	54.50	38.2	109.5						
V3, Wk 2 (T)		11	62.60	20.71	54.10	38.5	111.0	11	0.55	0.71	0.60	-0.7	1.5
V4, Wk 4 (T)		11	62.47	20.41	54.10	38.3	108.7	11	0.43	1.19	0.10	-0.8	3.1
V5, Wk 6 (M)		11	62.29	19.99	54.30	38.4	107.7	11	0.25	1.26	0.20	-1.8	2.1
V6, Wk 8 (M)		10	64.08	21.13	59.30	38.6	109.2	10	0.68	1.39	0.50	-1.5	3.6
V7, Wk 12 (M)		10	64.87	21.34	59.80	38.1	109.7	10	1.47	1.80	1.05	-0.1	5.6
V8, Wk 16 (M)		9	66.34	22.14	62.50	38.3	109.6	9	1.59	2.12	0.70	-0.5	6.3
V9, Wk 20 (M)		9	66.37	21.83	63.60	38.7	107.5	9	1.61	2.59	0.90	-2.0	6.6

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Weight (kg)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)													
V10, Wk 24 (M)		9	66.36	22.46	63.10	39.0	109.0	9	1.60	3.21	0.10	-0.9	9.1
Early Termination Visit		2	52.45	2.62	52.45	50.6	54.3	2	2.60	0.71	2.60	2.1	3.1
Last Visit		11	63.83	20.87	57.50	39.0	109.0	11	1.78	2.91	0.80	-0.9	9.1
Min Post-BL		11	61.74	20.13	53.80	38.1	107.5	11	-0.31	1.05	-0.10	-2.0	1.2
Max Post-BL		11	64.76	21.13	57.50	39.0	111.0	11	2.72	2.50	2.10	0.5	9.1

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Height (cm)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Placebo (N=19)													
V1, Wk -4 (SCR)		19	159.23	12.00	162.20	121.7	175.0						
V10, Wk 24 (M)		3	161.13	11.03	157.60	152.3	173.5	3	-0.27	0.38	-0.10	-0.7	0.0
Early Termination Visit		16	158.94	12.10	162.35	123.8	175.2	16	0.12	0.60	0.00	-0.7	2.1
Last Visit		19	159.29	11.67	162.00	123.8	175.2	19	0.06	0.58	0.00	-0.7	2.1
Min Post-BL		19	159.29	11.67	162.00	123.8	175.2	19	0.06	0.58	0.00	-0.7	2.1
Max Post-BL		19	159.29	11.67	162.00	123.8	175.2	19	0.06	0.58	0.00	-0.7	2.1

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Height (cm)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
LCM (N=11)													
V1, Wk -4 (SCR)		11	161.92	6.87	162.50	152.1	172.6						
V10, Wk 24 (M)		9	164.06	6.45	163.80	152.6	174.5	9	0.22	0.97	0.30	-1.6	1.9
Early Termination Visit		2	153.45	1.06	153.45	152.7	154.2	2	0.15	0.64	0.15	-0.3	0.6
Last Visit		11	162.13	7.19	162.60	152.6	174.5	11	0.21	0.89	0.30	-1.6	1.9
Min Post-BL		11	162.13	7.19	162.60	152.6	174.5	11	0.21	0.89	0.30	-1.6	1.9
Max Post-BL		11	162.13	7.19	162.60	152.6	174.5	11	0.21	0.89	0.30	-1.6	1.9

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Body Mass Index (kg/m^2)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
Placebo (N=19)													
V1, Wk -4 (SCR)		19	23.60	4.33	23.37	14.3	36.3						
V10, Wk 24 (M)		3	25.39	3.96	27.44	20.8	27.9	3	1.70	1.29	0.96	1.0	3.2
Early Termination Visit		16	23.53	4.63	23.41	13.6	35.8	16	-0.06	0.63	0.07	-1.7	0.8
Last Visit		19	23.82	4.48	23.42	13.6	35.8	19	0.22	0.98	0.28	-1.7	3.2
Min Post-BL		19	23.82	4.48	23.42	13.6	35.8	19	0.22	0.98	0.28	-1.7	3.2
Max Post-BL		19	23.82	4.48	23.42	13.6	35.8	19	0.22	0.98	0.28	-1.7	3.2

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

表 1.1-63　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 16.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Body Mass Index (kg/m²)

Treatment Group Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
LCM (N=11)													
V1, Wk -4 (SCR)		11	23.33	5.73	21.87	15.0	36.3						
V10, Wk 24 (M)		9	24.30	6.58	23.52	14.4	35.8	9	0.53	1.10	0.36	-0.7	2.5
Early Termination Visit		2	22.27	0.81	22.27	21.7	22.8	2	0.87	0.13	0.87	0.8	1.0
Last Visit		11	23.93	5.94	22.84	14.4	35.8	11	0.59	1.00	0.60	-0.7	2.5
Min Post-BL		11	23.93	5.94	22.84	14.4	35.8	11	0.59	1.00	0.60	-0.7	2.5
Max Post-BL		11	23.93	5.94	22.84	14.4	35.8	11	0.59	1.00	0.60	-0.7	2.5

BL=baseline, LCM=Lacosamide, M=maintenance, Max=maximum, Min=minimum, SCR=screening, SD=standard deviation, T=titration.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.

Reference: Listing 9.1.1

1.1.4.3.4 子どもの行動チェックリスト及び実行機能に関する行動評価尺度

CBCL1½-5 版又は 6-18 版を用いた評価、及び BRIEF／BRIEF-P を用いた認知機能評価において、ラコサミド投与に起因すると考えられる臨床的に重要な徴候が認められた被験者はいなかった。

1.1.4.4 全集団のまとめ

全集団では 175 例（72.3%）に有害事象が認められ、投与群別ではプラセボ群 79 例（65.3%）及びラコサミド群 96 例（79.3%）であった。ほとんどの有害事象の重症度は軽度（プラセボ群 61.2%及びラコサミド群 62.8%）又は中等度（プラセボ群 19.0%及びラコサミド群 34.7%）であった。重篤な有害事象の発現率は 5.0%と低く、投与群別ではプラセボ群 3.3%及びラコサミド群 6.6%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 6.6%と低く、投与群別ではプラセボ群 4.1%及びラコサミド群 9.1%であった。治療期間中に新たな発作型を発現した被験者の割合は低く、プラセボ群とラコサミド群で同程度であった。Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作又はミオクロニー発作発現日数が増加した被験者は少なかった。臨床検査、バイタルサイン、神経学的検査、及びその他の評価項目の結果から、ラコサミド投与に起因すると考えられる臨床的に重要な徴候は認められなかった。

1.1.4.5 日本人集団のまとめ

日本人集団の安全性プロファイルは全集団と同様であった。日本人集団の有害事象の発現率は全集団と同程度であり、有害事象の重症度はすべて軽度であった。重篤な有害事象及び治験薬の投与中止に至った有害事象は認められなかった。治療期間中に新たな発作型を発現した被験者は認められず、Pospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作又はミオクロニー発作発現日数が増加した被験者は少なかった（ミオクロニー発作発現日数が増加した被験者がラコサミド群で 1 例）。臨床検査値、バイタルサイン、12 誘導心電図、及びその他の評価項目の結果は、全集団の結果と同様であり、安全性上の新たな懸念事項は認められなかった。

1.1.5 薬物動態

本治験の SS での第 5 回及び第 10 回来院時、並びに早期中止時の血漿中ラコサミド濃度を投与量別に表 1.1-64（全集団）及び表 1.1-65（日本人集団）に示した。

血漿中ラコサミド濃度は、実際に投与された用量を反映しており、その濃度は予測範囲内であった。

表 1.1-64　全集団の血漿中ラコサミド濃度：SS

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo Unknown

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo Unknown

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
N	14	4	12
n>=LOQ	0	0	0
Mean			
SD			
CV			
Median	BLQ	BLQ	BLQ
Min	BLQ	BLQ	BLQ
Max	BLQ	BLQ	BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 3 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ	BLQ	
N	1	1	
n>=LOQ	0	0	
Mean			
SD			
CV			
Median	BLQ	BLQ	
Min	BLQ	BLQ	
Max	BLQ	BLQ	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 4 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
N	2	2	2
n>=LOQ	0	0	0
Mean			
SD			
CV			
Median	BLQ	BLQ	BLQ
Min	BLQ	BLQ	BLQ
Max	BLQ	BLQ	BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 8 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ	BLQ	
N	2	1	
n>=LOQ	0	0	
Mean			
SD			
CV			
Median	BLQ	BLQ	
Min	BLQ	BLQ	
Max	BLQ	BLQ	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 12 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
N			1
n>=LOQ			0
Mean			
SD			
CV			
Median			BLQ
Min			BLQ
Max			BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 50 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
N			2
n>=LOQ			0
Mean			
SD			
CV			
Median			BLQ
Min			BLQ
Max			BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 100 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		
N	1		1
n>=LOQ	0		0
Mean			
SD			
CV			
Median	BLQ		BLQ
Min	BLQ		BLQ
Max	BLQ		BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 140 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]		BLQ	
N		1	
n>=LOQ		0	
Mean			
SD			
CV			
Median		BLQ	
Min		BLQ	
Max		BLQ	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 150 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
SP0982-[redacted]		BLQ	
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ		
SP0982-[redacted]		BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ	2.636645	
N	7	7	3
n>=LOQ	0	1	0
Mean			
SD			

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 150 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
CV			
Median	BLQ	BLQ	BLQ
Min	BLQ	BLQ	BLQ
Max	BLQ	2.636645	BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]			BLQ
SP0982-[redacted]		BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ		
SP0982-[redacted]			NV
SP0982-[redacted]			BLQ
SP0982-[redacted]			NV
SP0982-[redacted]	BLQ	10.579712	
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]		BLQ	
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]		BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: Placebo 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			NV
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ	BLQ	
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
N	32	17	35
n>=LOQ	0	1	0

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 200 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
Mean			
SD			
CV			
Median	BLQ	BLQ	BLQ
Min	BLQ	BLQ	BLQ
Max	BLQ	10.579712	BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 300 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		BLQ
N	1		1
n>=LOQ	0		0
Mean			
SD			
CV			
Median	BLQ		BLQ
Min	BLQ		BLQ
Max	BLQ		BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: Placebo 400 mg/day

Site-Subject Number	Visit, Week Number (Descriptor) V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		
SP0982-[redacted]	BLQ	1.241511	
SP0982-[redacted]	BLQ		
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		
SP0982-[redacted]			BLQ
SP0982-[redacted]			BLQ
N	4	1	4
n>=LOQ	0	1	0
Mean		1.2415110	
SD			
CV			
Median	BLQ	1.2415110	BLQ
Min	BLQ	1.241511	BLQ
Max	BLQ	1.241511	BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM Unknown

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	3.581234	4.747369	
SP0982-[redacted]	7.800472	6.905903	
SP0982-[redacted]	13.711212	7.372598	
SP0982-[redacted]	9.888661	9.738139	
SP0982-[redacted]			4.393188
SP0982-[redacted]			BLQ
SP0982-[redacted]			7.054580
SP0982-[redacted]	8.306843		
SP0982-[redacted]	6.066004	5.989011	
SP0982-[redacted]	5.380567		5.066212
SP0982-[redacted]	7.103077		9.775249
SP0982-[redacted]	7.632981		7.896657
SP0982-[redacted]			10.017819
SP0982-[redacted]	1.328980	NV	
SP0982-[redacted]		BLQ	
SP0982-[redacted]			4.917098

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM Unknown

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	7.215290		
SP0982-[redacted]			NV
SP0982-[redacted]		10.288473	
SP0982-[redacted]	13.752509		12.344542
SP0982-[redacted]	13.618529	14.524459	
SP0982-[redacted]	6.569819	4.076733	
N	14	9	9
n>=LOQ	14	8	8
Mean	7.9968699	7.0714094#	6.8294828#
SD	3.71284848	4.16342209	3.70459412
CV	46.4287720	58.8768353	54.2441389
Median	7.4241355	6.9059030	7.0545800
Min	1.328980	BLQ	BLQ
Max	13.752509	14.524459	12.344542

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM 3 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	11.768974	8.391925	
N	1	1	
n>=LOQ	1	1	
Mean	11.7689740	8.3919250	
SD			
CV			
Median	11.7689740	8.3919250	
Min	11.768974	8.391925	
Max	11.768974	8.391925	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 4 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	14.949291		13.954913
N	1		1
n>=LOQ	1		1
Mean	14.9492910		13.9549130
SD			
CV			
Median	14.9492910		13.9549130
Min	14.949291		13.954913
Max	14.949291		13.954913

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 6 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			0.401066
SP0982-[redacted]	0.512088	BLQ	
N	1	1	1
n>=LOQ	1	0	1
Mean	0.5120880		0.4010660
SD			
CV			
Median	0.5120880	BLQ	0.4010660
Min	0.512088	BLQ	0.401066
Max	0.512088	BLQ	0.401066

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 8 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	7.517048	14.489571	
SP0982-[redacted]	12.422343		15.960941
N	2	1	1
n>=LOQ	2	1	1
Mean	9.9696955	14.4895710	15.9609410
SD	3.46856736		
CV	34.7911063		
Median	9.9696955	14.4895710	15.9609410
Min	7.517048	14.489571	15.960941
Max	12.422343	14.489571	15.960941

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 10 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			19.864565
N			1
n>=LOQ			1
Mean			19.8645650
SD			
CV			
Median			19.8645650
Min			19.864565
Max			19.864565

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM 50 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			3.464857
SP0982-[redacted]			1.956136
SP0982-[redacted]			7.159338
N			3
n>=LOQ			3
Mean			4.1934437
SD			2.67702384
CV			63.8383166
Median			3.4648570
Min			1.956136
Max			7.159338

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM 100 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			4.118637
SP0982-[redacted]			4.554137
N			2
n>=LOQ			2
Mean			4.3363870
SD			0.30794500
CV			7.1014188
Median			4.3363870
Min			4.118637
Max			4.554137

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 150 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	2.437114		
SP0982-[redacted]		5.189477	
SP0982-[redacted]	6.889937		
SP0982-[redacted]	5.383676	5.443475	
SP0982-[redacted]	6.234193		
SP0982-[redacted]	10.105987	5.427901	
SP0982-[redacted]		3.470753	
SP0982-[redacted]		2.783240	
SP0982-[redacted]		10.895037	
SP0982-[redacted]			3.874967
SP0982-[redacted]			8.925780
SP0982-[redacted]			13.059576
SP0982-[redacted]	11.849014		
SP0982-[redacted]	3.444721	7.772084	
SP0982-[redacted]	11.952097	14.568676	
SP0982-[redacted]	16.132447		

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM 150 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	9.67		
SP0982-[redacted]			8.301831
N	10	8	4
n>=LOQ	10	8	4
Mean	8.4099186	6.9438304	8.5405385
SD	4.28182406	3.98991499	3.75919538
CV	50.9139774	57.4598568	44.0159057
Median	8.2799685	5.4356880	8.6138055
Min	2.437114	2.783240	3.874967
Max	16.132447	14.568676	13.059576

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	9.446106		
SP0982-[redacted]	9.847217	10.776810	
SP0982-[redacted]		11.723114	
SP0982-[redacted]			15.465722
SP0982-[redacted]			NV
SP0982-[redacted]	9.151397	NV	
SP0982-[redacted]			7.246370
SP0982-[redacted]		3.385707	
SP0982-[redacted]	12.126495	9.297097	
SP0982-[redacted]	9.970021		
SP0982-[redacted]		14.575138	
SP0982-[redacted]			BLQ
SP0982-[redacted]		8.300416	
SP0982-[redacted]			4.138619
SP0982-[redacted]	3.428503		
SP0982-[redacted]	2.291797		

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	5.033790	4.580063	
SP0982-[redacted]	4.088348	3.682596	
SP0982-[redacted]	7.244454	7.990452	
SP0982-[redacted]	11.171234	13.249493	
SP0982-[redacted]	1.590299	BLQ	
SP0982-[redacted]	12.746685	13.124853	
SP0982-[redacted]	11.841740		10.444667
SP0982-[redacted]	14.244931	10.205986	
SP0982-[redacted]			13.452241
SP0982-[redacted]			7.825286
SP0982-[redacted]	9.848870	NV	
SP0982-[redacted]	9.937821		
SP0982-[redacted]	11.866432		
SP0982-[redacted]			15.115401
SP0982-[redacted]	15.527821	2.990247	
SP0982-[redacted]	8.911127	7.939162	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set

Actual Dose: LCM 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	1.611491		1.656762
SP0982-[redacted]	9.961497	11.901084	
SP0982-[redacted]	9.350760	9.062467	
SP0982-[redacted]			14.625071
SP0982-[redacted]	5.808330		4.583489
SP0982-[redacted]	7.932290	8.100463	
SP0982-[redacted]	8.159929	6.678536	
SP0982-[redacted]	7.034569	6.337925	
SP0982-[redacted]	10.645537	7.698864	
SP0982-[redacted]	6.815763	8.995451	
SP0982-[redacted]	3.179768	7.148383	
SP0982-[redacted]	11.429517	5.883013	
SP0982-[redacted]	5.264859	4.913087	
SP0982-[redacted]			6.901733
SP0982-[redacted]			6.797044
SP0982-[redacted]	7.521423	5.511282	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			11.980018
SP0982-[redacted]	10.054829	9.952485	
SP0982-[redacted]	13.121870	14.267162	
SP0982-[redacted]	12.304749	13.242141	
SP0982-[redacted]	11.362723	14.888006	
SP0982-[redacted]	13.650267	7.392245	
SP0982-[redacted]	9.271422	8.674826	
SP0982-[redacted]			9.46
SP0982-[redacted]			14
SP0982-[redacted]			4.235724
SP0982-[redacted]	6.520985		
SP0982-[redacted]	9.652653		10.533179
N	41	32	18
n>=LOQ	41	31	17
Mean	8.8041541	8.5146423#	8.8034070#
SD	3.4947/8944	3.677/45989	4.7/4634639

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 200 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
CV	39.6947781	43.1898341	53.9148808
Median	9.4461060	8.2004395	8.6426430
Min	1.590299	BLQ	BLQ
Max	15.527821	14.888006	15.465722

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 300 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	6.802192		
SP0982-[redacted]		8.398539	
N	1	1	
n>=LOQ	1	1	
Mean	6.8021920	8.3985390	
SD			
CV			
Median	6.8021920	8.3985390	
Min	6.802192	8.398539	
Max	6.802192	8.398539	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-64　全集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1
Plasma Concentrations of Lacosamide
Analysis Set: Safety Set

Actual Dose: LCM 400 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	8.991625		
SP0982-[redacted]		13.077152	
N	1	1	
n>=LOQ	1	1	
Mean	8.9916250	13.0771520	
SD			
CV			
Median	8.9916250	13.0771520	
Min	8.991625	13.077152	
Max	8.991625	13.077152	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.
Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.
Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.
Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.
Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).
Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo Unknown

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		BLQ
SP0982-[redacted]			BLQ
SP0982-[redacted]	BLQ		BLQ
N	2		3
n>=LOQ	0		0
Mean			
SD			
CV			
Median	BLQ		BLQ
Min	BLQ		BLQ
Max	BLQ		BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo 3 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ	BLQ	
N	1	1	
n>=LOQ	0	0	
Mean			
SD			
CV			
Median	BLQ	BLQ	
Min	BLQ	BLQ	
Max	BLQ	BLQ	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo 4 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
N			1
n>=LOQ			0
Mean			
SD			
CV			
Median			BLQ
Min			BLQ
Max			BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1 Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo 200 mg/day

Site-Subject Number	Visit, Week Number (Descriptor)		
	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
SP0982-			BLQ
SP0982-	BLQ	BLQ	
SP0982-			BLQ
SP0982-	BLQ		BLQ
SP0982-			BLQ
SP0982-			BLQ
SP0982-			BLQ
SP0982-	BLQ		BLQ
SP0982-	BLQ		BLQ
SP0982-			BLQ
SP0982-	BLQ	BLQ	
N	5	2	10
n>=LOQ	0	0	0
Mean			
SD			

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo 200 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
CV			
Median	BLQ	BLQ	BLQ
Min	BLQ	BLQ	BLQ
Max	BLQ	BLQ	BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo 300 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	BLQ		BLQ
N	1		1
n>=LOQ	0		0
Mean			
SD			
CV			
Median	BLQ		BLQ
Min	BLQ		BLQ
Max	BLQ		BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: Placebo 400 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]			BLQ
N			1
n>=LOQ			0
Mean			
SD			
CV			
Median			BLQ
Min			BLQ
Max			BLQ

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: LCM 4 mg/kg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	14.949291		13.954913
N	1		1
n>=LOQ	1		1
Mean	14.9492910		13.9549130
SD			
CV			
Median	14.9492910		13.9549130
Min	14.949291		13.954913
Max	14.949291		13.954913

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: LCM 150 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	3.444721	7.772084	
SP0982-[redacted]	11.952097	14.568676	
SP0982-[redacted]	16.132447		
N	3	2	
n>=LOQ	3	2	
Mean	10.5097550	11.1703800	
SD	6.46566784	4.80591629	
CV	61.5206333	43.0237493	
Median	11.9520970	11.1703800	
Min	3.444721	7.772084	
Max	16.132447	14.568676	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: LCM 200 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]	7.521423	5.511282	
SP0982-[redacted]			11.980018
SP0982-[redacted]	10.054829	9.952485	
SP0982-[redacted]	13.121870	14.267162	
SP0982-[redacted]	12.304749	13.242141	
SP0982-[redacted]	11.362723	14.888006	
SP0982-[redacted]	13.650267	7.392245	
N	6	6	1
n>=LOQ	6	6	1
Mean	11.3359768	10.8755535	11.9800180
SD	2.26613102	3.87206462	
CV	19.9906109	35.6033798	
Median	11.8337360	11.5973130	11.9800180
Min	7.521423	5.511282	11.980018
Max	13.650267	14.888006	11.980018

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

表 1.1-65　日本人集団の血漿中ラコサミド濃度：SS（続き）

Table 21.1.1

Plasma Concentrations of Lacosamide

Analysis Set: Safety Set - Japanese

Actual Dose: LCM 300 mg/day

	Visit, Week Number (Descriptor)		
Site-Subject Number	V5, Wk 6 (T)	V10, Wk 24 (M)	Early Termination Visit
SP0982-[redacted]		8.393539	
N		1	
n>=LOQ		1	
Mean		8.3935390	
SD			
CV			
Median		8.3935390	
Min		8.393539	
Max		8.393539	

BLQ= Below Limit of Quantification, CV=Coefficient of Variation, LOQ=limit of quantification, M=Maintenance, Max=Maximum, Min=Minimum, NV=no value, SD=standard deviation, T=Titration.

Note: Values BLQ are replaced by value of 0 in calculations of means, SDs and CVs.

Note: Means, SDs and CVs are only calculated if at least 2/3 of the concentrations were quantified at the respective timepoint.

Note: Actual dose is defined as the most recent dose administrated prior to PK sampling.

Note: Where values below LOQ are included in the calculation of mean values, these mean values are marked (#).

Reference: Listing 5.4

1.1.6 結論

強直間代発作を有する 4 歳以上のてんかん患者に 1～3 剤の抗てんかん薬の併用療法としてラコサミドを経口投与した結果、プラセボと比較してラコサミドが有効であることが示され、本治験の主要目的を達成した。2 回目の強直間代発作の発現リスクは、プラセボ群と比較してラコサミド群で低く、統計学的に有意であった。強直間代発作を消失した被験者の割合でも統計学的に有意な差が認められた。また、小児被験者の結果は、成人被験者の結果と同様であった。

強直間代発作を消失した被験者の割合（KM 推定値を含む）、強直間代発作回数の変化率、強直間代発作回数の 50%及び 75%レスポンダーレートを評価した有効性の評価項目では、すべての評価時点でプラセボ群と比較してラコサミド群で一貫した改善が認められた。

欠神発作発現日数又は強直間代発作回数の増悪により発作リスクが増加する徴候は認められなかった。ミオクロニー発作発現日数の増悪は少数の被験者に認められた。

強直間代発作を有する 4 歳以上のてんかん患者に対してラコサミドはおおむね安全で良好な忍容性が示された。

全体的に、有効性及び安全性の結果は、強直間代発作を有する 4 歳以上のてんかん患者における併用療法としてのラコサミド投与が有効であることを支持するものであった。

日本人集団と全体集団の結果に大きな違いは認められなかった。日本人集団でもラコサミドの有効性及び良好な忍容性が示された。