Subject ID:	50381001
Age, race, sex, actual treatment group:	48 years, BLACK OR AFRICAN AMERICAN, Female, Placebo
Medical history: (MedDRA Preferred Term)	女性不妊手術, 上腕骨骨折, 骨折観血的整復, 扁桃摘出, 扁桃炎, 甲状腺腫瘤, 甲状腺機能亢進症, 嚥下障害
Current medical conditions: (MedDRA Preferred Term)	薬物過敏症, 鉄欠乏性貧血, ざ瘡, 脂質異常症, 背部痛, 四肢痛, 動悸, 心電図異常, 血小板数増加
Concomitant medications:	IRON(01), LEVOTHYROXINE(02), CLINDAMYCIN(03), MIDAZOLAM(04), FAMOTIDINE(05), HYDROMORPHONE(06), PROMETHAZINE(07), MORPHINE(08), VICODIN(09), FLEBOBAG RING LACT(10)
Date of first dose/last dose of study drug (Study Day):	19 SEP 2017 / 18 DEC 2017 (Study Day 91)
Other events: (MedDRA Preferred Term)	甲状腺機能低下症

Serious adverse events (Investigator term/MedDRA preferred term):	Multi-nodular Goiter / 甲状腺腫
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	07 NOV 2017 (Study Day 50, Period 1) / 08 NOV 2017 (Study Day 51, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 04, 05, 06, 07, 08, 10, 11
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	cyst formation / 嚢胞
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	07 NOV 2017 (Study Day 50, Period 1) / 08 NOV 2017 (Study Day 51, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 03, 04, 05, 06, 07, 09, 10
Relationship of event:	NOT RELATED

Subject ID:	51051014
Age, race, sex, actual treatment group:	80 years, JAPANESE, Male, Placebo → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	痔核
Concomitant medications:	LOXOPROFEN(01), REBAMIPIDE(02), MAGNESIUM OXIDE(03), SENNOSIDE A+B(04), NERIPROCT(05), MS ONSHIPPU(06), LOXOPROFEN(07), MS ONSHIPPU(08)
Date of first dose/last dose of study drug (Study Day):	29 SEP 2017 / 18 SEP 2018 (Study Day 355)
Other events: (MedDRA Preferred Term)	転倒

Serious adverse events (Investigator term/MedDRA preferred term):	Rib fracture / 肋骨骨折
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	04 APR 2018 (Study Day 188, Period 2) / 28 APR 2018 (Study Day 212, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05
Relationship of event:	NOT RELATED

Subject ID:	51071007
Age, race, sex, actual treatment group:	58 years, JAPANESE, Female, Placebo → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	閉経, 脂質異常症, 高血圧
Concomitant medications:	OLMESARTAN(01), NICARDIPINE(02), ROSUVASTATIN(03), PARACETAMOL(04), PARACETAMOL(05), ULTRACET(06)
Date of first dose/last dose of study drug (Study Day):	03 JUL 2017 / 26 JUN 2018 (Study Day 359)
Other events: (MedDRA Preferred Term)	処置による疼痛

Serious adverse events (Investigator term/MedDRA preferred term):	Left gonarthrosis / 変形性関節症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	23 APR 2018 (Study Day 295, Period 2) / 31 MAY 2018 (Study Day 333, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	Left medial meniscus injury / 半月板損傷
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	23 APR 2018 (Study Day 295, Period 2) / 31 MAY 2018 (Study Day 333, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03
Relationship of event:	NOT RELATED

Subject ID:	51171004
Age, race, sex, actual treatment group:	66 years, JAPANESE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	背部痛, 閉経, 乳房腫瘤, 頚腕症候群, 子宮平滑筋腫, 子宮頚部上皮異形成, アレルギー性皮膚炎, 肝斑
Concomitant medications:	TRANEXAMIC ACID(01), CINAL(02), LOXOPROFEN(03), RESTAMIN CORTIZON(04), NEO-MEDROL EYE-EAR(05), INFLUENZA VACCINE(06), VALISONE-G(07), ZOLPIDEM(08), CEFCAPENE(09), LANSOPRAZOLE(10), CEFAZOLIN(11), TRIAZOLAM(12)
Date of first dose/last dose of study drug (Study Day):	02 AUG 2017 / 23 JUL 2018 (Study Day 356)
Other events: (MedDRA Preferred Term)	転倒

Serious adverse events (Investigator term/MedDRA preferred term):	Right ankle fracture / 足関節部骨折
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	22 FEB 2018 (Study Day 205, Period 2) / 07 AUG 2018 (Study Day 371, Follow-up/off-study)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07
Relationship of event:	NOT RELATED

Subject ID:	52071003
Age, race, sex, actual treatment group:	68 years, OTHER ASIAN, Female, Placebo → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	意識消失
Current medical conditions: (MedDRA Preferred Term)	糖尿病, 閉経, 高脂血症, 傾眠
Concomitant medications:	GLIMEPIRIDE(01), RISTFOR(02), ZETITOR(03), CLOPIDOGREL(04), MIRABEGRON(05), ALBIS(06), LANSOPRAZOLE(07), ACECLOFENAC(08)
Date of first dose/last dose of study drug (Study Day):	24 NOV 2017 / 21 NOV 2018 (Study Day 363)
Other events: (MedDRA Preferred Term)	夜間頻尿

Serious adverse events (Investigator term/MedDRA preferred term):	Chest pain (non-cardiac) / 非心臓性胸痛
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	05 AUG 2018 (Study Day 255, Period 2) / 09 AUG 2018 (Study Day 259, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06
Relationship of event:	NOT RELATED

Subject ID:	53041002
Age, race, sex, actual treatment group:	51 years, WHITE, Female, Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	接触皮膚炎, 靭帯手術, 閉経後, 外耳炎, インフルエンザ, 大腸ポリープ, 皮膚凍結療法, 上気道感染, 非心臓性胸痛
Current medical conditions: (MedDRA Preferred Term)	うつ病, 頭痛, 疲労, 変形性関節症, 季節性アレルギー, 甲状腺機能低下症, 脱毛症
Concomitant medications:	LEVOTHYROXINE(01), LEVOTHYROXINE(02), MAGNESIUM(03), PAROXETINE(04), PARACETAMOL(05), TRAMADOL(06), IBUPROFEN W/PARACETAMOL(07), PIMAFUCORT /00191101/(08), CETIRIZINE(09), DICLOFENAC(10), TRAMADOL(11), IODINE(12), IBUPROFEN W/PARACETAMOL(13), DICLOFENAC(14), AUGMENTIN /00756801/(15), FUSIDIC ACID(16), CEFALEXIN(17), PARACETAMOL(18), TRAMADOL(19), IBUPROFEN(20), FLUCLOXACILLIN(21), DEXAMETHASONE(22), DOCETAXEL(23), CYCLOPHOSPHAMIDE(24), PEGFILGRASTIM(25), PARACETAMOL(26), DOMPERIDONE(27), RANITIDINE(28), CODEINE(29), FLUCONAZOLE(30), OXYCODONE(31), FLUCONAZOLE(34), ENOXAPARIN(35), ZOPICLONE(36), ZOPICLONE(37), OMEPRAZOLE(40), LOPERAMIDE(41), LEVOTHYROXINE(42)
Date of first dose/last dose of study drug (Study Day):	20 SEP 2017 / 18 MAR 2018 (Study Day 180)
Other events: (MedDRA Preferred Term)	転倒, 挫傷, 熱傷, 寝汗, 悪心, 動物による引っかき傷, ウイルス性上気道感染, 筋骨格痛, 皮膚潰瘍

Serious adverse events (Investigator term/MedDRA preferred term):	Breast Cancer (Ductal Carcinoma in situ Left Breast) / 乳管内増殖性病変
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	26 FEB 2018 (Study Day 160, Period 1) / 07 AUG 2018 (Study Day 322, Follow-up/off-study)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG WITHDRAWN
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 16
Relationship of event:	NOT RELATED

Subject ID:	55061007
Age, race, sex, actual treatment group:	69 years, WHITE, Male, Placebo → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	股関節形成, 膝関節形成
Current medical conditions: (MedDRA Preferred Term)	高血圧, 高コレステロール血症, 変形性関節症
Concomitant medications:	ATORVASTATIN(01), AMLODIPINE(02), ENALAPRIL(03), ACETYLSALICYLIC ACID(04), CEFALEXIN(05), CIPROFLOXACIN(06), CEFALEXIN(07), ZOPICLONE(08), CEFALEXIN(09), PIP/TAZO(10), ENOXAPARIN(11), PARACETAMOL(12), TEMAZEPAM(13)
Date of first dose/last dose of study drug (Study Day):	27 JUN 2017 / 26 JUN 2018 (Study Day 365)
Other events: (MedDRA Preferred Term)	限局性感染, 変形性関節症, 筋骨格系胸痛, 企図的過量投与

Serious adverse events (Investigator term/MedDRA preferred term):	Erysipelas / 丹毒
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	17 MAY 2018 (Study Day 325, Period 2) / 10 AUG 2018 (Study Day 410, Follow-up/off-study)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06
Relationship of event:	NOT RELATED

Subject ID:	56021035
Age, race, sex, actual treatment group:	38 years, WHITE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	女性不妊手術
Current medical conditions: (MedDRA Preferred Term)	–
Concomitant medications:	IBUPROFEN(01), PANTOPRAZOLE(02), METAMIZOLE(03), IRON(04), PENICILLIN NOS(05)
Date of first dose/last dose of study drug (Study Day):	15 AUG 2017 / 13 MAY 2018 (Study Day 272)
Other events: (MedDRA Preferred Term)	疲労, 背部痛, 鉄欠乏性貧血, 猩紅熱

Serious adverse events (Investigator term/MedDRA preferred term):	Hydrosalpinx / 卵管水腫
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	26 SEP 2017 (Study Day 43, Period 1) / 20 OCT 2017 (Study Day 67, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	–
Relationship of event:	NOT RELATED

Subject ID:	56051038
Age, race, sex, actual treatment group:	55 years, WHITE, Male, Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	季節性アレルギー, 変形性脊椎症, 高脂血症, 高血圧, 薬物不耐性, うつ病, 腎嚢胞, 腎機能障害
Concomitant medications:	CITALOPRAM(01), VALSARTAN(02), METOPROLOL(03), AMLODIPINE(04), LORATADINE(05), DOXYLAMINE;FOLIC ACID;PYRIDOXINE(06), LOPERAMIDE(07), DOXYLAMINE;FOLIC ACID;PYRIDOXINE(08), LOPERAMIDE(09), MYRTOL(10)
Date of first dose/last dose of study drug (Study Day):	02 AUG 2017 / 26 DEC 2017 (Study Day 147)
Other events: (MedDRA Preferred Term)	傾眠, 消化管感染, 胃腸炎, インフルエンザ, うつ病

Serious adverse events (Investigator term/MedDRA preferred term):	disturbance of vigilance / 注意力障害
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	19 OCT 2017 (Study Day 79, Period 1) / 20 OCT 2017 (Study Day 80, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09
Relationship of event:	RELATED

Subject ID:	56061008
Age, race, sex, actual treatment group:	75 years, WHITE, Female, Placebo → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	腎膿瘍, 手根管症候群, 狭窄性腱鞘炎
Current medical conditions: (MedDRA Preferred Term)	閉経後, 高血圧, 高コレステロール血症, 腹部膨満
Concomitant medications:	NEBIVOLOL(01), TELMISARTAN(02), PANTOPRAZOLE(03), METAMIZOLE(04), METAMIZOLE(05), METAMIZOLE(06)
Date of first dose/last dose of study drug (Study Day):	18 OCT 2017 / 16 OCT 2018 (Study Day 364)
Other events: (MedDRA Preferred Term)	気胸, 胸骨骨折, 肺挫傷, 傾眠

Serious adverse events (Investigator term/MedDRA preferred term):	anterior and posterior pelvic fracture / 骨盤骨折
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	27 NOV 2017 (Study Day 41, Period 1) / 24 JAN 2018 (Study Day 99, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 06
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	series of rib fractures both sides / 肋骨骨折
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	27 NOV 2017 (Study Day 41, Period 1) / 24 JAN 2018 (Study Day 99, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 06
Relationship of event:	NOT RELATED

Subject ID:	56061012
Age, race, sex, actual treatment group:	61 years, WHITE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	胃潰瘍, 血栓性静脈炎, 上顆炎, 軟骨疾患, 半月板除去, 骨病変部切除
Current medical conditions: (MedDRA Preferred Term)	卵巣嚢胞, 慢性胃炎, 甲状腺腫瘤, 閉経後, 高血圧, 高コレステロール血症, 腎嚢胞
Concomitant medications:	PANTOPRAZOLE(01), RAMIPRIL(02), PRAVASTATIN(03), ROXITHROMYCIN(04), ACETYLCYSTEINE(05), METRONIDAZOLE(06), CLARITHROMYCIN(07), PANTOPRAZOLE(08), PANTOPRAZOLE(09), IBUPROFEN(10), METAMIZOLE(11), RAMIPRIL(12)
Date of first dose/last dose of study drug (Study Day):	19 OCT 2017 / 17 OCT 2018 (Study Day 364)
Other events: (MedDRA Preferred Term)	気管支炎, 三叉神経痛, ヘリコバクター性胃炎, 挫傷, 手骨折

Serious adverse events (Investigator term/MedDRA preferred term):	multiple fragmentary base fracture P1 dig 5 right hand / 手骨折
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	18 MAY 2018 (Study Day 212, Period 2) / 04 JUN 2018 (Study Day 229, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED WITH SEQUELAE
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10
Relationship of event:	NOT RELATED

Subject ID:	58011011
Age, race, sex, actual treatment group:	25 years, WHITE, Female, Placebo → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	関節脱臼, 不安障害, うつ病
Concomitant medications:	VENLAFAXINE(01), IRON(02), CEFUROXIME(03), NUVARING(04), AMOXI-CLAVULANICO(05), KETOPROFEN(06), AUGMENTIN/00756801/(07), CYANOCOBALAMIN(08), IRON(09), IRON(10), PARACETAMOL(12)
Date of first dose/last dose of study drug (Study Day):	20 OCT 2017 / 28 OCT 2018 (Study Day 374)
Other events: (MedDRA Preferred Term)	鉄欠乏, 貧血, 咽頭炎, 末梢性浮腫, 皮膚感染, 頭痛, 尿中結晶陽性, 色素沈着障害

Serious adverse events (Investigator term/MedDRA preferred term):	Cyst of the lower jaw / 顎骨嚢胞
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	15 FEB 2018 (Study Day 119, Period 1) / 20 FEB 2018 (Study Day 124, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 10
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	Fistula of the lower jaw / 顎下瘻
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	15 FEB 2018 (Study Day 119, Period 1) / 20 FEB 2018 (Study Day 124, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 10
Relationship of event:	NOT RELATED

Subject ID:	58021004
Age, race, sex, actual treatment group:	50 years, WHITE, Male, Lemborexant 10 mg → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	関節鏡検査, 鼻中隔手術
Current medical conditions: (MedDRA Preferred Term)	外傷性関節症, 骨減少症, 前立腺腺腫
Concomitant medications:	COLECALCIFEROL(01), MENAQUINONE(02), TAMOXIFEN(03), CUCURBITA PEPO SEED W/EPILOBIUM PARVIFLORUM/L(04), DYNAMAG(05), POTASSIUM(06), TARAXACUM OFFICINALE(07), EPILOBIUM PARVIFLORUM(08), MIANSERIN(09), TAMOXIFEN(10), CIPROFLOXACIN(11), NADROPARIN(12), MELISSA OFFICINALIS(13), IBUPROFEN(14)
Date of first dose/last dose of study drug (Study Day):	21 SEP 2017 / 18 SEP 2018 (Study Day 363)
Other events: (MedDRA Preferred Term)	頭痛, 感覚鈍麻, 顔面痛, 胸部不快感

Serious adverse events (Investigator term/MedDRA preferred term):	Cystitis chronica / 膀胱炎
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	02 JAN 2018 (Study Day 104, Period 1) / 04 JAN 2018 (Study Day 106, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 10
Relationship of event:	NOT RELATED

Subject ID:	58021006
Age, race, sex, actual treatment group:	66 years, WHITE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	乳癌, 乳房切除
Current medical conditions: (MedDRA Preferred Term)	頭痛, 閉経後, 変形性脊椎症, 睡眠障害, 混合性不安抑うつ障害
Concomitant medications:	ESCITALOPRAM(01), IBUPROFEN(02), TRAZODONE(03), ESTAZOLAM(04), ZOPICLONE(05), NADROPARIN(06), MIDAZOLAM(07), METAMIZOLE(08), KETOPROFEN(09), CEFAZOLIN(10), AMIKACIN(11) , CIPROFLOXACIN(12), AUGMENTIN/00756801/(13), CIPROFLOXACIN(14), METRONIDAZOLE(15), SPIRONOLACTONE(16), PANTOPRAZOLE(17), FUROSEMIDE(18), CARVEDILOL(19), IRON(20), SODIUM CHLORIDE(21), DIGOXIN(22), THIOCODIN /01295801/(23), OXYGEN(24), ENOXAPARIN(25), METOCLOPRAMIDE(26), POTASSIUM(27), TRAMADOL(28), ULTRACET(29), SACCHAROMYCES BOULARDII(30), CEFOTAXIME(31), ALPRAZOLAM(32), NADROPARIN(35), AUGMENTIN/00756801/(36), METRONIDAZOLE(37), FUROSEMIDE(38), FUROSEMIDE(39), SODIUM CHLORIDE(40), NADROPARIN(41), DEXAMETHASONE(42), ULTRACET(43), PARACETAMOL(44), PANTOPRAZOLE(45), PANTOPRAZOLE(46), METRONIDAZOLE(47), PANTOPRAZOLE(48), ULTRACET(49), METRONIDAZOLE(50)
Date of first dose/last dose of study drug (Study Day):	17 OCT 2017 / 29 OCT 2018 (Study Day 378)
Other events: (MedDRA Preferred Term)	非心臓性胸痛, 僧帽弁閉鎖不全症, 胃炎, 呼吸不全, 鉄欠乏性貧血, 慢性心不全, 心房細動, クロストリジウム・ディフィシレ感染

Serious adverse events (Investigator term/MedDRA preferred term):	Breast cancer after left side mastectomy / 乳癌
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	27 JUN 2018 (Study Day 254, Period 2) / 30 JUN 2018 (Study Day 257, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization, Important medical events
Severity:	MILD
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 08, 09, 10, 11
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	Right side pleuropneumonia / 肺炎
Start date of adverse event (Study	25 SEP 2018 (Study Day 344, Period 2) / 28 OCT 2018 (Study Day

Day, Period)/outcome date of adverse event (Study Day, Period):	377, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 06, 07, 08, 09, 10, 11
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	Noninfectious inflammation of gastrointenstinal tract / 胃腸の炎症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	17 OCT 2018 (Study Day 366, Period 2) / 28 OCT 2018 (Study Day 377, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 49, 50
Relationship of event:	NOT RELATED

Subject ID:	58071021
Age, race, sex, actual treatment group:	72 years, WHITE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	薬物過敏症, 尿失禁, 胸椎骨折, 膀胱結石除去, 膀胱結石, 静脈瘤手術
Current medical conditions: (MedDRA Preferred Term)	閉経後, 甲状腺摘除, 近視, 高血圧, 末梢静脈疾患, 高脂血症, 耐糖能障害
Concomitant medications:	LERCANIDIPINE(01), BISOPROLOL FUMARATE W/PERINDOPRIL ARGININE(02), INDAPAMIDE(03), ATORVASTATIN(04), ACETYLCYSTEINE(05), ALTHAEA OFFICINALIS(06), PARACETAMOL(07), DABIGATRAN(08), METOPROLOL(09), PROPAFENONE(10)
Date of first dose/last dose of study drug (Study Day):	13 SEP 2017 / 04 SEP 2018 (Study Day 357)
Other events: (MedDRA Preferred Term)	上咽頭炎

Serious adverse events (Investigator term/MedDRA preferred term):	Atrial Fibrillation / 心房細動
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	12 MAY 2018 (Study Day 242, Period 2) / 14 MAY 2018 (Study Day 244, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Important medical events
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07
Relationship of event:	NOT RELATED

Subject ID:	59021005
Age, race, sex, actual treatment group:	53 years, WHITE, Female, Placebo → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	子宮摘出, 子宮平滑筋腫, 胆嚢切除
Current medical conditions: (MedDRA Preferred Term)	閉経後, 2 型糖尿病
Concomitant medications:	METFORMIN(01), CIPROFLOXACIN(02), IBUPROFEN(03), PARACETAMOL(04), DICLOFENAC(05), VIMOVO(06), INFLUENZA VACCINE(07), INSULIN(08), INSULIN DETEMIR(09), INSULIN LISPRO(10), METAMIZOLE(11), DUOCID/00892601/(12), RANITIDINE(13), ATORVASTATIN(14), KETOPROFEN(15), NEUROBION/00176001/(16), BETAHISTINE(17), NEBIVOLOL(18), ROSUVASTATIN(19), THIOCTIC ACID(20), ACETYLSALICYLIC ACID(21), ACETYLCYSTEINE(22), DICLOFENAC(23)
Date of first dose/last dose of study drug (Study Day):	06 JUL 2017 / 02 JUL 2018 (Study Day 362)
Other events: (MedDRA Preferred Term)	頭痛, 筋骨格系胸痛, 関節痛, 上気道感染, ビタミン B 群欠乏, 脂質異常症, 心筋症, 椎骨脳底動脈不全, 肥満, 変形性関節症, 糖尿病性ニューロパチー, 錯感覚

Serious adverse events (Investigator term/MedDRA preferred term):	diabetic neuropathy / 糖尿病性ニューロパチー
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	12 JUN 2018 (Study Day 342, Period 2) / 18 JUN 2018 (Study Day 348, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22, 23
Relationship of event:	NOT RELATED

Subject ID:	59021006
Age, race, sex, actual treatment group:	56 years, WHITE, Female, Lemborexant 10 mg → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	帯状疱疹
Current medical conditions: (MedDRA Preferred Term)	閉経後, 便秘, 2 型糖尿病, 糖尿病性ニューロパチー, 脂質異常症, 変形性脊椎症, 慢性胆嚢炎, 腎結石症
Concomitant medications:	INSULIN DETEMIR(01), INSULIN ASPART(02), SIMVASTATIN(03), FENOFIBRATE(04), NEUROBION /00176001/(05), PENTOXIFYLLINE(06), ACETYLSALICYLIC ACID(07), EXTRAVERAL(08), INSULIN DETEMIR(09), INSULIN ASPART(10), ACETYLSALICYLIC ACID(11), THIOCTIC ACID(12), SULODEXIDE(13), GABAPENTIN(14), NEBIVOLOL(15), DICLOFENAC(16), IBUPROFEN(17)
Date of first dose/last dose of study drug (Study Day):	21 JUL 2017 / 15 JUL 2018 (Study Day 360)
Other events: (MedDRA Preferred Term)	パニック発作, 糖尿病, 悪心, 食欲減退, 疲労, 錯感覚, ビタミン B 群欠乏, 心筋症, 関節痛

Serious adverse events (Investigator term/MedDRA preferred term):	diabetes mellitus type ii aggravated / 2 型糖尿病
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	15 JAN 2018 (Study Day 179, Period 1) / 19 JAN 2018 (Study Day 183, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15
Relationship of event:	NOT RELATED

Subject ID:	59021011
Age, race, sex, actual treatment group:	67 years, WHITE, Female, Lemborexant 10 mg → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	胆嚢切除
Current medical conditions: (MedDRA Preferred Term)	閉経後, 2型糖尿病, 糖尿病性血管障害, 脂質異常症, 高血圧, 糖尿病性ニューロパチー
Concomitant medications:	METFORMIN(01), GLICLAZIDE(02), NEBIVOLOL(03), ACETYLSALICYLIC ACID(04), NEUROBION /00176001/(05), THIOCTIC ACID(06), PENTOXIFYLLINE(07), FENOFIBRATE(08), SIMVASTATIN(09), PANTOPRAZOLE(10), SULODEXIDE(11), PHOSPHATIDYL CHOLINE W/SILYBUM MARIANUM(12), LIVER THERAPY(13), ARGININE(14), URSODEOXYCHOLIC ACID(15)
Date of first dose/last dose of study drug (Study Day):	26 JUL 2017 / 15 JUL 2018 (Study Day 355)
Other events: (MedDRA Preferred Term)	錯乱状態, ビタミンB群欠乏, 心筋症, 尿路感染, 白内障, 上腹部痛

Serious adverse events (Investigator term/MedDRA preferred term):	cholestasis / 胆汁うっ滞
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	11 JAN 2018 (Study Day 170, Period 1) / 19 JAN 2018 (Study Day 178, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	toxic liver disease / 肝毒性
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	11 JAN 2018 (Study Day 170, Period 1) / 19 JAN 2018 (Study Day 178, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse	01, 02, 03, 04, 05, 06, 07, 08, 09

event):	
Relationship of event:	NOT RELATED

Subject ID:	59021012
Age, race, sex, actual treatment group:	58 years, WHITE, Female, Lemborexant 10 mg → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	閉経後, 2 型糖尿病, 高血圧, 脂質異常症, 慢性閉塞性肺疾患, 糖尿病性血管障害, 糖尿病性ニューロパチー, 喉頭炎, 椎骨脳底動脈不全
Concomitant medications:	METFORMIN(01), GLICLAZIDE(02), PENTOXIFYLLINE(03), PERINDOPRIL(04), NEBIVOLOL(05), INDAPAMIDE(06), ATORVASTATIN(07), NSAIDS(08), IBUPROFEN(09), ACETYLCYSTEINE(10), FENSPIRIDE(11), INFLUENZA VACCINE(12), PARACETAMOL(13), DEXKETOPROFEN(14), TOLPERISONE(15), METAMIZOLE(16), DICLOFENAC(17), VIMOVO(18), AMOXI-CLAVULANICO(19), IBUPROFEN(20), PARACETAMOL(21)
Date of first dose/last dose of study drug (Study Day):	04 AUG 2017 / 05 AUG 2018 (Study Day 367)
Other events: (MedDRA Preferred Term)	筋力低下, 筋骨格痛, インフルエンザ, 関節痛, 変形性脊椎症, 歯膿瘍, 変形性関節症, 胸痛

Serious adverse events (Investigator term/MedDRA preferred term):	pseudomixomatous chronic laryngitis / 喉頭の炎症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	19 JUL 2018 (Study Day 350, Period 2) / 09 AUG 2018 (Study Day 371, Follow-up/off-study)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	NOT APPLICABLE
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21
Relationship of event:	NOT RELATED

Subject ID:	59021015
Age, race, sex, actual treatment group:	55 years, WHITE, Male, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	虫垂切除, 上部消化管出血
Current medical conditions: (MedDRA Preferred Term)	高血圧, 2 型糖尿病, 顔面不全麻痺, 慢性閉塞性肺疾患, 副鼻腔炎
Concomitant medications:	METFORMIN(01), INSULIN(02), NEBIVOLOL(03), INDAPAMIDE(04), ACETYLSALICYLIC ACID(05), NEUROBION /00176001/(06), PENTOXIFYLLINE(07), PIRACETAM(08), PARACETAMOL(09), INSULIN(10), ACARBOSE(11), OSYROL-LASIX(12), AZOR/06230801/(13), ATORVASTATIN(14), PANTOPRAZOLE(16), PHOSPHOLIPIDS(17), METAMIZOLE(18), INFLUENZA VACCINE(19), IBUPROFEN(20), NETILMICIN(22), KANAMYCIN(23), RETINOL(24), LORATADINE(25), NETILMICIN(26), CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINA(27), IBUPROFEN(28), LORATADINE(29), NEPAFENAC(30), BRINZOLAMIDE(31)
Date of first dose/last dose of study drug (Study Day):	03 AUG 2017 / 05 AUG 2018 (Study Day 368)
Other events: (MedDRA Preferred Term)	胆石症, 良性前立腺肥大症, 膵腫大, 糖尿病網膜症, 白内障, 頭痛, 上気道感染, フロッピー眼瞼症候群, 非感染性結膜炎

Serious adverse events (Investigator term/MedDRA preferred term):	diabetic neuropathy / 糖尿病性ニューロパチー
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	09 OCT 2017 (Study Day 68, Period 1) / 13 OCT 2017 (Study Day 72, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED WITH SEQUELAE
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 16, 17
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	diabetic retinopathy / 糖尿病網膜症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	09 OCT 2017 (Study Day 68, Period 1) / 13 OCT 2017 (Study Day 72, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE

Outcome:	RECOVERED/RESOLVED WITH SEQUELAE
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 16, 17
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	left flaccid eyelid syndrome / フロッピー眼瞼症候群
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	29 MAY 2018 (Study Day 300, Period 2) / 17 JUL 2018 (Study Day 349, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20
Relationship of event:	NOT RELATED

Subject ID:	59021018
Age, race, sex, actual treatment group:	67 years, WHITE, Female, Placebo → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	閉経後, 狭心症, 高血圧, 頚動脈硬化症
Concomitant medications:	METOPROLOL(01), ACETYLSALICYLIC ACID(02), ARLEVERT(03), BETAHISTINE(04), CAPTOPRIL(05), TRIMETAZIDINE(06), CLOPIDOGREL(07), PANTOPRAZOLE(08), BETAHISTINE(09), POLYSACCHARIDE-IRON COMPLEX(10)
Date of first dose/last dose of study drug (Study Day):	22 AUG 2017 / 20 AUG 2018 (Study Day 364)
Other events: (MedDRA Preferred Term)	筋肉痛, 軟部組織腫脹, 浮動性めまい, 意識消失, 低色素性貧血

Serious adverse events (Investigator term/MedDRA preferred term):	extrasystolic arrhithmia / 期外収縮
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	06 JUN 2018 (Study Day 289, Period 2) / 23 JUN 2018 (Study Day 306, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04
Relationship of event:	NOT RELATED

Subject ID:	59021021
Age, race, sex, actual treatment group:	66 years, WHITE, Male, Lemborexant 10 mg → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	肺結核
Current medical conditions: (MedDRA Preferred Term)	高血圧, 慢性気管支炎, 慢性胆嚢炎, 慢性肝炎, 高コレステロール血症, 腎結石症, 変形性関節症, 慢性胃炎, 緑内障, 過敏性腸症候群, 心筋虚血, 肥満
Concomitant medications:	PARACETAMOL(01), ASCORBIC ACID(02), AMBAZONE(03), DESLORATADINE(04), GLYCOPYRRONIUM BROMIDE W/INDACATEROL MALEATE(05), GENTAMICIN(06), CEFTRIAXONE(07), BROMHEXINE(08), PARACETAMOL(09), ACETYLSALICYLIC ACID(11), METOPROLOL(12), RAMIPRIL(13), ATORVASTATIN(14), TICAGRELOR(15), PANTOPRAZOLE(16)
Date of first dose/last dose of study drug (Study Day):	24 AUG 2017 / 20 AUG 2018 (Study Day 362)
Other events: (MedDRA Preferred Term)	インフルエンザ, ウイルス性上気道感染

Serious adverse events (Investigator term/MedDRA preferred term):	COPD acutization / 慢性閉塞性肺疾患
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	02 NOV 2017 (Study Day 71, Period 1) / 14 NOV 2017 (Study Day 83, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	acute myocardial infarction / 急性心筋梗塞
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	10 JUN 2018 (Study Day 291, Period 2) / 18 JUN 2018 (Study Day 299, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED WITH SEQUELAE
Study drug action taken/other action taken:	DRUG INTERRUPTED

Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09
Relationship of event:	NOT RELATED

Subject ID:	59021036
Age, race, sex, actual treatment group:	65 years, WHITE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	閉経後, 高血圧, 慢性閉塞性肺疾患, 心筋虚血, 肥満, 胆嚢切除, 2 型糖尿病, 脂質異常症, 臍ヘルニア, 糖尿病性ニューロパチー, 対麻痺
Concomitant medications:	METOPROLOL(01), ACETYLSALICYLIC ACID(02), PENTAERITHRITYL TETRANITRATE(03), RISTFOR(04), GLIMEPIRIDE(05), GLIMEPIRIDE(06), DUOCID /00892601/(07), RANITIDINE(08), METAMIZOLE(09), SILYBUM MARIANUM(10), KETOPROFEN(11), TRIMETAZIDINE(12), ATORVASTATIN(13), PERINDOPRIL(14), INDAPAMIDE(15), FAMOTIDINE(16), PHOSPHOLIPIDS(17), ROWACHOL /06253701/(18)
Date of first dose/last dose of study drug (Study Day):	29 SEP 2017 / 18 SEP 2018 (Study Day 355)
Other events: (MedDRA Preferred Term)	脂肪肝, 胆嚢摘出術後症候群, 変形性関節症, 慢性胃炎

Serious adverse events (Investigator term/MedDRA preferred term):	angina pectoris / 狭心症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	13 MAR 2018 (Study Day 166, Period 1) / 19 MAR 2018 (Study Day 172, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 07, 08, 09, 10, 11, 16
Relationship of event:	NOT RELATED

Subject ID:	59021047
Age, race, sex, actual treatment group:	67 years, WHITE, Female, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	閉経後, 高血圧, 2 型糖尿病, 脂質異常症, 変形性脊椎症, 痛風, 心筋虚血, 狭心症, 混合性不安抑うつ障害, 左室不全, 腎炎, 聴力低下, 慢性副鼻腔炎, 回転性めまい
Concomitant medications:	INDAPAMIDE(01), AMLODIPINE(02), PERINDOPRIL(03), ATORVASTATIN(04), CLOPIDOGREL(05), PIROXICAM(06), NICERGOLINE(07), METAMIZOLE(08), BETAXOLOL(09), VIMOVO(11)
Date of first dose/last dose of study drug (Study Day):	16 OCT 2017 / 09 OCT 2018 (Study Day 359)
Other events: (MedDRA Preferred Term)	咽頭炎, 鼻炎, 頭痛, 血管運動性鼻炎, 狭心症, 頚部痛, 脂肪肝

Serious adverse events (Investigator term/MedDRA preferred term):	pericystic foreign body granulomatous inflammatory reaction / 炎症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	12 JUL 2018 (Study Day 270, Period 2) / 19 JUL 2018 (Study Day 277, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	traumatized epidermic cyst / 皮膚嚢腫
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	12 JUL 2018 (Study Day 270, Period 2) / 19 JUL 2018 (Study Day 277, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09
Relationship of event:	NOT RELATED

Subject ID:	59021050
Age, race, sex, actual treatment group:	69 years, WHITE, Male, Lemborexant 5 mg → Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	虫垂切除, 胆嚢切除, 白内障手術
Current medical conditions: (MedDRA Preferred Term)	高血圧, 脂質異常症, 痛風, 心房細動
Concomitant medications:	LERCANIDIPINE(01), RILMENIDINE(02), FUROSEMIDE(03), SPIRONOLACTONE(04), CANDESARTAN(05), ACENOCOUMAROL(06), ALLOPURINOL(07), ROSUVASTATIN(08), COLCHICINE(10), COLCHICINE(11), COLCHICINE(12), CEFUROXIME(13), COLCHICINE(14), COLCHICINE(15), COLCHICINE(16), ALLOPURINOL(17), AMLODIPINE(18), RAMIPRIL(19), INDAPAMIDE(20), PENTAERITHRITYL TETRANITRATE(21), FUROSEMIDE(22), SPIRONOLACTONE(23), COLCHICINE(24), COLCHICINE(25), COLCHICINE(26)
Date of first dose/last dose of study drug (Study Day):	23 OCT 2017 / 16 OCT 2018 (Study Day 359)
Other events: (MedDRA Preferred Term)	痛風, 歯感染

Serious adverse events (Investigator term/MedDRA preferred term):	arterial hypertension agravatted / 高血圧
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	16 MAR 2018 (Study Day 145, Period 1) / 20 MAR 2018 (Study Day 149, Period 1)
TEAE1/TEAE2	Yes / No
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23
Relationship of event:	NOT RELATED

Subject ID:	59021077
Age, race, sex, actual treatment group:	66 years, WHITE, Female, Placebo → Lemborexant 10 mg
Medical history: (MedDRA Preferred Term)	子宮摘出, 子宮平滑筋腫
Current medical conditions: (MedDRA Preferred Term)	2 型糖尿病, 高血圧, 椎間板突出
Concomitant medications:	METFORMIN(01), INSULIN(02), INSULIN(03), DAPAGLIFLOZIN(04), INDAPAMIDE(05), INDAPAMIDE W/PERINDOPRIL(06), ACETYLSALICYLIC ACID(07), PROPRANOLOL(08), BISOPROLOL(09), AMOXI-CLAVULANICO(10), DROTAVERINE(11), METOCLOPRAMIDE(12), AMOXI-CLAVULANICO(13), ACHYRANTHES ASPERA;CALCIUM SILICATE;CYPERUS S(14), ANALGESICS(15), NADROPARIN(16), ULTRACET(17), GABAPENTIN(18), NEUROBION/00176001/(19), OSTEOCARE(20), ASCORBIC ACID(21)
Date of first dose/last dose of study drug (Study Day):	21 NOV 2017 / 11 NOV 2018 (Study Day 356)
Other events: (MedDRA Preferred Term)	左室肥大, 三尖弁閉鎖不全症, 僧帽弁閉鎖不全症, 大動脈弁閉鎖不全症

Serious adverse events (Investigator term/MedDRA preferred term):	nephrolithiasis / 腎結石症
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	16 JUL 2018 (Study Day 238, Period 2) / 15 AUG 2018 (Study Day 268, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	fall / 転倒
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	11 NOV 2018 (Study Day 356, Period 2) / 11 NOV 2018 (Study Day 356, Period 2)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	MODERATE
Outcome:	RECOVERED/RESOLVED

Study drug action taken/other action taken:	DRUG WITHDRAWN
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15
Relationship of event:	NOT RELATED

Serious adverse events (Investigator term/MedDRA preferred term):	bimalleolar fracture of right lower extremity / 足関節部骨折
Start date of adverse event (Study Day, Period)/outcome date of adverse event (Study Day, Period):	11 NOV 2018 (Study Day 356, Period 2) / 21 NOV 2018 (Study Day 366, Follow-up/off-study)
TEAE1/TEAE2	No / Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization, Persistent or significant disability or incapacity
Severity:	SEVERE
Outcome:	RECOVERED/RESOLVED WITH SEQUELAE
Study drug action taken/other action taken:	DRUG WITHDRAWN / WITHDRAWN FROM STUDY
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15
Relationship of event:	NOT RELATED

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MedDRA System Organ Class Preferred Term	Placebo (N=209) n (%)	Zolpidem ER 6.25 mg (N=263) n (%)	Lemborexant 5 mg (N=266) n (%)	Lemborexant 10 mg (N=268) n (%)	Lemborexant Total (N=534) n (%)
Subjects with any TEAE	53 (25.4)	93 (35.4)	74 (27.8)	82 (30.6)	156 (29.2)
血液およびリンパ系障害	1 (0.5)	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
内出血発生の増加傾向	1 (0.5)	0	1 (0.4)	0	1 (0.2)
白血球減少症	0	1 (0.4)	0	0	0
好中球減少症	0	0	0	1 (0.4)	1 (0.2)
心臓障害	2 (1.0)	4 (1.5)	2 (0.8)	9 (3.4)	11 (2.1)
狭心症	0	1 (0.4)	0	0	0
不整脈	0	0	1 (0.4)	2 (0.7)	3 (0.6)
上室性不整脈	0	0	0	1 (0.4)	1 (0.2)
心房細動	0	1 (0.4)	0	0	0
房室ブロック	1 (0.5)	0	0	0	0
冠動脈疾患	0	1 (0.4)	0	0	0

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心臓障害 (Cont.)					
期外収縮	0	0	0	1 (0.4)	1 (0.2)
結節性不整脈	0	0	0	1 (0.4)	1 (0.2)
動悸	1 (0.5)	0	0	1 (0.4)	1 (0.2)
洞性徐脈	0	0	0	1 (0.4)	1 (0.2)
上室性期外収縮	0	0	0	1 (0.4)	1 (0.2)
心室性期外収縮	0	1 (0.4)	1 (0.4)	3 (1.1)	4 (0.7)
耳および迷路障害	0	4 (1.5)	2 (0.8)	1 (0.4)	3 (0.6)
耳痛	0	1 (0.4)	0	0	0
耳垢分泌過多	0	1 (0.4)	0	1 (0.4)	1 (0.2)
耳鳴	0	0	1 (0.4)	0	1 (0.2)
回転性めまい	0	2 (0.8)	2 (0.8)	0	2 (0.4)
眼障害	2 (1.0)	1 (0.4)	0	1 (0.4)	1 (0.2)

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眼障害 (Cont.)					
複視	0	0	0	1 (0.4)	1 (0.2)
流涙増加	1 (0.5)	0	0	0	0
後嚢部混濁	0	1 (0.4)	0	0	0
霧視	1 (0.5)	0	0	0	0
胃腸障害	10 (4.8)	19 (7.2)	7 (2.6)	7 (2.6)	14 (2.6)
腹部不快感	0	2 (0.8)	0	0	0
腹部ヘルニア	0	0	1 (0.4)	0	1 (0.2)
腹痛	1 (0.5)	1 (0.4)	1 (0.4)	0	1 (0.2)
腹部硬直	1 (0.5)	0	0	0	0
便秘	1 (0.5)	4 (1.5)	0	1 (0.4)	1 (0.2)
下痢	5 (2.4)	5 (1.9)	1 (0.4)	3 (1.1)	4 (0.7)
口内乾燥	0	2 (0.8)	1 (0.4)	0	1 (0.2)
消化不良	2 (1.0)	2 (0.8)	0	1 (0.4)	1 (0.2)
胃炎	0	0	1 (0.4)	0	1 (0.2)

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胃腸障害 (Cont.)					
口腔腫脹	1 (0.5)	0	0	0	0
悪心	1 (0.5)	5 (1.9)	3 (1.1)	2 (0.7)	5 (0.9)
閉塞性膵炎	0	1 (0.4)	0	0	0
小腸閉塞	0	1 (0.4)	0	0	0
舌不快感	1 (0.5)	0	0	0	0
歯痛	0	1 (0.4)	0	0	0
嘔吐	1 (0.5)	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
一般・全身障害および投与部位の状態	2 (1.0)	8 (3.0)	5 (1.9)	4 (1.5)	9 (1.7)
胸痛	0	1 (0.4)	0	0	0
不快感	0	1 (0.4)	0	0	0
顔面痛	1 (0.5)	0	0	0	0
疲労	0	4 (1.5)	2 (0.8)	1 (0.4)	3 (0.6)
異常感	1 (0.5)	0	0	0	0
びくびく感	0	0	0	1 (0.4)	1 (0.2)

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一般・全身障害および投与部位の状態 (Cont.)					
歩行障害	0	1 (0.4)	0	0	0
宿酔	0	0	0	1 (0.4)	1 (0.2)
末梢性浮腫	0	1 (0.4)	2 (0.8)	0	2 (0.4)
発熱	0	0	1 (0.4)	0	1 (0.2)
不活発	0	0	0	1 (0.4)	1 (0.2)
肝胆道系障害	0	1 (0.4)	0	0	0
高ビリルビン血症	0	1 (0.4)	0	0	0
免疫系障害	0	2 (0.8)	0	0	0
食物アレルギー	0	1 (0.4)	0	0	0
過敏症	0	1 (0.4)	0	0	0

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感染症および寄生虫症	15 (7.2)	13 (4.9)	22 (8.3)	16 (6.0)	38 (7.1)
細菌性膣症	0	0	1 (0.4)	0	1 (0.2)
気管支炎	0	0	1 (0.4)	0	1 (0.2)
結膜炎	0	0	0	1 (0.4)	1 (0.2)
膀胱炎	2 (1.0)	1 (0.4)	1 (0.4)	0	1 (0.2)
感染性下痢	0	1 (0.4)	0	0	0
耳感染	0	1 (0.4)	0	0	0
胃腸炎	1 (0.5)	0	0	0	0
ウイルス性胃腸炎	0	0	1 (0.4)	0	1 (0.2)
ヘリコバクター性胃炎	0	0	1 (0.4)	0	1 (0.2)
麦粒腫	0	1 (0.4)	0	1 (0.4)	1 (0.2)
インフルエンザ	2 (1.0)	1 (0.4)	0	0	0
上咽頭炎	3 (1.4)	1 (0.4)	7 (2.6)	1 (0.4)	8 (1.5)
肺炎	0	1 (0.4)	0	0	0
膿尿	0	0	1 (0.4)	3 (1.1)	4 (0.7)

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感染症および寄生虫症 (Cont.)					
鼻炎	0	1 (0.4)	0	0	0
副鼻腔炎	1 (0.5)	0	0	1 (0.4)	1 (0.2)
歯感染	0	1 (0.4)	0	0	0
上気道感染	4 (1.9)	2 (0.8)	6 (2.3)	1 (0.4)	7 (1.3)
尿路感染	2 (1.0)	2 (0.8)	3 (1.1)	9 (3.4)	12 (2.2)
ウイルス性上気道感染	0	0	1 (0.4)	0	1 (0.2)
外陰腟真菌感染	1 (0.5)	0	0	0	0
傷害、中毒および処置合併症	3 (1.4)	6 (2.3)	5 (1.9)	6 (2.2)	11 (2.1)
偶発的過量投与	0	1 (0.4)	0	1 (0.4)	1 (0.2)
節足動物咬傷	0	0	0	2 (0.7)	2 (0.4)
第１度熱傷	1 (0.5)	0	0	0	0
挫傷	1 (0.5)	2 (0.8)	1 (0.4)	0	1 (0.2)
投薬欠落	0	1 (0.4)	0	0	0
転倒	0	0	4 (1.5)	0	4 (0.7)

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傷害、中毒および処置合併症 (Cont.)					
手骨折	1 (0.5)	0	0	0	0
靭帯捻挫	0	0	0	1 (0.4)	1 (0.2)
肉離れ	0	0	0	2 (0.7)	2 (0.4)
処置後腫脹	0	1 (0.4)	0	0	0
外傷後頸部症候群	0	1 (0.4)	0	0	0
交通事故	0	1 (0.4)	0	0	0
皮膚擦過傷	0	1 (0.4)	0	0	0
臨床検査	6 (2.9)	7 (2.7)	3 (1.1)	12 (4.5)	15 (2.8)
アラニンアミノトランスフェラーゼ増加	1 (0.5)	2 (0.8)	0	1 (0.4)	1 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.5)	3 (1.1)	0	1 (0.4)	1 (0.2)
細菌検査陽性	0	1 (0.4)	0	1 (0.4)	1 (0.2)
血中アルカリホスファターゼ増加	1 (0.5)	1 (0.4)	0	0	0
血中コレステロール増加	0	0	0	1 (0.4)	1 (0.2)
血中クレアチン増加	0	0	0	1 (0.4)	1 (0.2)

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臨床検査 (Cont.)					
血中クレアチニン減少	0	0	0	1 (0.4)	1 (0.2)
血中クレアチニン増加	0	1 (0.4)	0	0	0
血中ブドウ糖減少	1 (0.5)	0	0	0	0
血中カリウム増加	1 (0.5)	1 (0.4)	0	1 (0.4)	1 (0.2)
血圧上昇	0	1 (0.4)	0	0	0
血中トリグリセリド増加	0	1 (0.4)	0	0	0
血中尿酸増加	1 (0.5)	1 (0.4)	0	2 (0.7)	2 (0.4)
尿中血陽性	1 (0.5)	0	0	0	0
尿中結晶陽性	0	0	0	1 (0.4)	1 (0.2)
心電図ＱＴ延長	1 (0.5)	0	1 (0.4)	1 (0.4)	2 (0.4)
心電図Ｔ波逆転	0	0	0	1 (0.4)	1 (0.2)
好酸球数増加	0	0	0	1 (0.4)	1 (0.2)
γ－グルタミルトランスフェラーゼ増加	0	2 (0.8)	1 (0.4)	1 (0.4)	2 (0.4)
心拍数増加	0	0	0	1 (0.4)	1 (0.2)
好中球数増加	0	0	0	1 (0.4)	1 (0.2)
尿沈渣陽性	0	0	0	1 (0.4)	1 (0.2)

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臨床検査 (Cont.)					
尿中ケトン体陽性	0	0	0	1 (0.4)	1 (0.2)
体重減少	0	1 (0.4)	0	0	0
体重増加	1 (0.5)	0	1 (0.4)	0	1 (0.2)
尿中白血球陽性	0	0	0	1 (0.4)	1 (0.2)
代謝および栄養障害	2 (1.0)	11 (4.2)	2 (0.8)	5 (1.9)	7 (1.3)
食欲減退	0	3 (1.1)	0	0	0
高カルシウム血症	0	1 (0.4)	0	0	0
高コレステロール血症	0	2 (0.8)	0	0	0
高血糖	0	1 (0.4)	0	0	0
高カリウム血症	0	1 (0.4)	2 (0.8)	2 (0.7)	4 (0.7)
高脂血症	0	0	0	1 (0.4)	1 (0.2)
高トリグリセリド血症	0	4 (1.5)	0	1 (0.4)	1 (0.2)
食欲亢進	2 (1.0)	0	0	1 (0.4)	1 (0.2)

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筋骨格系および結合組織障害	5 (2.4)	10 (3.8)	11 (4.1)	5 (1.9)	16 (3.0)
関節痛	0	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
背部痛	1 (0.5)	2 (0.8)	0	2 (0.7)	2 (0.4)
肋軟骨炎	1 (0.5)	0	0	0	0
側腹部痛	1 (0.5)	0	0	0	0
筋拘縮	0	0	1 (0.4)	0	1 (0.2)
筋痙縮	1 (0.5)	1 (0.4)	3 (1.1)	0	3 (0.6)
筋力低下	0	0	1 (0.4)	1 (0.4)	2 (0.4)
筋骨格不快感	1 (0.5)	0	0	0	0
筋骨格痛	0	2 (0.8)	0	0	0
筋肉痛	1 (0.5)	1 (0.4)	3 (1.1)	0	3 (0.6)
頚部痛	0	1 (0.4)	1 (0.4)	0	1 (0.2)
四肢痛	2 (1.0)	0	0	0	0
顎痛	0	1 (0.4)	0	0	0
仙腸骨炎	0	1 (0.4)	0	0	0

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筋骨格系および結合組織障害 (Cont.)					
変形性脊椎症	0	1 (0.4)	0	0	0
脊椎痛	1 (0.5)	0	0	0	0
滑液嚢腫	0	0	1 (0.4)	0	1 (0.2)
腱炎	0	0	0	1 (0.4)	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.5)	0	0	0	0
扁平上皮癌	1 (0.5)	0	0	0	0
神経系障害	20 (9.6)	33 (12 5)	30 (11.3)	36 (13.4)	66 (12.4)
平衡障害	0	0	0	1 (0.4)	1 (0.2)
認知障害	1 (0.5)	0	1 (0.4)	0	1 (0.2)
注意力障害	1 (0.5)	0	0	0	0
浮動性めまい	4 (1.9)	8 (3.0)	3 (1.1)	2 (0.7)	5 (0.9)
体位性めまい	0	1 (0.4)	1 (0.4)	0	1 (0.2)

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神経系障害 (Cont.)					
味覚異常	0	0	0	1 (0.4)	1 (0.2)
頭痛	13 (6.2)	14 (5.3)	17 (6.4)	13 (4.9)	30 (5.6)
感覚鈍麻	1 (0.5)	0	0	0	0
嗜眠	0	0	0	1 (0.4)	1 (0.2)
記憶障害	1 (0.5)	0	0	0	0
片頭痛	0	1 (0.4)	1 (0.4)	0	1 (0.2)
錯感覚	2 (1.0)	1 (0.4)	1 (0.4)	0	1 (0.2)
パーキンソン病	0	1 (0.4)	0	0	0
睡眠の質低下	0	1 (0.4)	0	1 (0.4)	1 (0.2)
失神寸前の状態	1 (0.5)	0	0	0	0
坐骨神経痛	0	1 (0.4)	0	1 (0.4)	1 (0.2)
鎮静	0	2 (0.8)	0	0	0
副鼻腔炎に伴う頭痛	0	0	1 (0.4)	1 (0.4)	2 (0.4)
睡眠時麻痺	0	0	1 (0.4)	3 (1.1)	4 (0.7)
傾眠	4 (1.9)	4 (1.5)	11 (4.1)	19 (7.1)	30 (5.6)
振戦	0	1 (0.4)	0	0	0

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精神障害	2 (1.0)	16 (6.1)	5 (1.9)	9 (3.4)	14 (2.6)
異常な夢	1 (0.5)	3 (1.1)	0	4 (1.5)	4 (0.7)
不安	0	5 (1.9)	2 (0.8)	0	2 (0.4)
錯乱状態	0	2 (0.8)	0	1 (0.4)	1 (0.2)
抑うつ気分	0	2 (0.8)	0	0	0
うつ病	0	3 (1.1)	0	0	0
失見当識	0	2 (0.8)	0	0	0
悲嘆反応	0	0	1 (0.4)	0	1 (0.2)
触覚性幻覚	0	0	0	1 (0.4)	1 (0.2)
不眠症	0	0	0	1 (0.4)	1 (0.2)
易刺激性	0	2 (0.8)	0	0	0
病的思考	0	1 (0.4)	0	0	0
悪夢	1 (0.5)	0	2 (0.8)	1 (0.4)	3 (0.6)
パニック発作	0	1 (0.4)	0	0	0
レム睡眠異常	0	0	0	1 (0.4)	1 (0.2)

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腎および尿路障害	0	2 (0.8)	1 (0.4)	2 (0.7)	3 (0.6)
糖尿	0	0	1 (0.4)	1 (0.4)	2 (0.4)
血尿	0	1 (0.4)	0	1 (0.4)	1 (0.2)
腎結石症	0	1 (0.4)	0	0	0
呼吸器、胸郭および縦隔障害	6 (2.9)	9 (3.4)	5 (1.9)	1 (0.4)	6 (1.1)
慢性気管支炎	0	0	1 (0.4)	0	1 (0.2)
咳嗽	2 (1.0)	4 (1.5)	1 (0.4)	1 (0.4)	2 (0.4)
呼吸困難	2 (1.0)	0	1 (0.4)	0	1 (0.2)
労作性呼吸困難	1 (0.5)	0	0	0	0
鼻出血	1 (0.5)	1 (0.4)	0	0	0
鼻部不快感	1 (0.5)	0	0	0	0
口腔咽頭痛	0	0	1 (0.4)	0	1 (0.2)
副鼻腔不快感	1 (0.5)	0	0	0	0

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呼吸器、胸郭および縦隔障害 (Cont.)					
副鼻腔うっ血	0	1 (0.4)	1 (0.4)	0	1 (0.2)
頻呼吸	0	1 (0.4)	0	0	0
咽喉刺激感	0	2 (0.8)	0	0	0
上気道うっ血	1 (0.5)	0	0	0	0
上気道咳症候群	1 (0.5)	0	0	0	0
皮膚および皮下組織障害	3 (1.4)	4 (1.5)	3 (1.1)	2 (0.7)	5 (0.9)
接触皮膚炎	0	0	1 (0.4)	0	1 (0.2)
斑状出血	0	1 (0.4)	0	0	0
寝汗	1 (0.5)	0	0	1 (0.4)	1 (0.2)
丘疹	1 (0.5)	0	0	0	0
そう痒症	1 (0.5)	0	1 (0.4)	1 (0.4)	2 (0.4)
発疹	0	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
斑状丘疹状皮疹	0	1 (0.4)	0	0	0
顔面腫脹	0	1 (0.4)	0	0	0

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皮膚および皮下組織障害 (Cont.)					
蕁麻疹	0	0	1 (0.4)	0	1 (0.2)
外科および内科処置	0	1 (0.4)	0	0	0
抜歯	0	1 (0.4)	0	0	0
血管障害	3 (1.4)	3 (1.1)	1 (0.4)	1 (0.4)	2 (0.4)
拡張期高血圧	1 (0.5)	0	0	0	0
潮紅	0	1 (0.4)	0	0	0
高血圧	1 (0.5)	0	0	1 (0.4)	1 (0.2)
高血圧クリーゼ	0	1 (0.4)	0	0	0
末梢血管障害	0	1 (0.4)	0	0	0
側頭動脈炎	0	0	1 (0.4)	0	1 (0.2)
血管炎	1 (0.5)	0	0	0	0

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Subjects with any treatment-related TEAE	16 (7.7)	40 (15 2)	30 (11.3)	39 (14.6)	69 (12.9)
血液およびリンパ系障害	0	1 (0.4)	0	0	0
白血球減少症	0	1 (0.4)	0	0	0
心臓障害	1 (0.5)	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
不整脈	0	0	0	1 (0.4)	1 (0.2)
心房細動	0	1 (0.4)	0	0	0
房室ブロック	1 (0.5)	0	0	0	0
心室性期外収縮	0	0	1 (0.4)	0	1 (0.2)
耳および迷路障害	0	1 (0.4)	1 (0.4)	0	1 (0.2)
回転性めまい	0	1 (0.4)	1 (0.4)	0	1 (0.2)

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胃腸障害	3 (1.4)	8 (3.0)	1 (0.4)	2 (0.7)	3 (0.6)
腹部不快感	0	1 (0.4)	0	0	0
便秘	1 (0.5)	2 (0.8)	0	0	0
下痢	1 (0.5)	1 (0.4)	0	1 (0.4)	1 (0.2)
口内乾燥	0	2 (0.8)	1 (0.4)	0	1 (0.2)
消化不良	1 (0.5)	0	0	0	0
口腔腫脹	1 (0.5)	0	0	0	0
悪心	0	3 (1.1)	0	1 (0.4)	1 (0.2)
舌不快感	1 (0.5)	0	0	0	0
嘔吐	0	0	0	1 (0.4)	1 (0.2)
一般・全身障害および投与部位の状態	0	4 (1.5)	2 (0.8)	3 (1.1)	5 (0.9)
不快感	0	1 (0.4)	0	0	0
疲労	0	2 (0.8)	1 (0.4)	0	1 (0.2)

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一般・全身障害および投与部位の状態 (Cont.)					
びくびく感	0	0	0	1 (0.4)	1 (0.2)
歩行障害	0	1 (0.4)	0	0	0
宿酔	0	0	0	1 (0.4)	1 (0.2)
末梢性浮腫	0	0	1 (0.4)	0	1 (0.2)
不活発	0	0	0	1 (0.4)	1 (0.2)
免疫系障害	0	1 (0.4)	0	0	0
過敏症	0	1 (0.4)	0	0	0
感染症および寄生虫症	0	0	0	2 (0.7)	2 (0.4)
結膜炎	0	0	0	1 (0.4)	1 (0.2)
膿尿	0	0	0	1 (0.4)	1 (0.2)

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傷害、中毒および処置合併症	0	1 (0.4)	0	1 (0.4)	1 (0.2)
偶発的過量投与	0	1 (0.4)	0	1 (0.4)	1 (0.2)
臨床検査	2 (1.0)	2 (0.8)	0	4 (1.5)	4 (0.7)
アラニンアミノトランスフェラーゼ増加	1 (0.5)	1 (0.4)	0	1 (0.4)	1 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.5)	1 (0.4)	0	1 (0.4)	1 (0.2)
血中アルカリホスファターゼ増加	1 (0.5)	0	0	0	0
血中カリウム増加	0	1 (0.4)	0	0	0
心電図ＱＴ延長	1 (0.5)	0	0	1 (0.4)	1 (0.2)
心電図Ｔ波逆転	0	0	0	1 (0.4)	1 (0.2)
γ－グルタミルトランスフェラーゼ増加	0	1 (0.4)	0	0	0
心拍数増加	0	0	0	1 (0.4)	1 (0.2)

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MedDRA System Organ Class Preferred Term	Placebo (N=209) n (%)	Zolpidem ER 6.25 mg (N=263) n (%)	Lemborexant 5 mg (N=266) n (%)	Lemborexant 10 mg (N=268) n (%)	Lemborexant Total (N=534) n (%)
代謝および栄養障害	1 (0.5)	4 (1.5)	0	1 (0.4)	1 (0.2)
食欲減退	0	2 (0.8)	0	0	0
高カルシウム血症	0	1 (0.4)	0	0	0
高カリウム血症	0	1 (0.4)	0	0	0
食欲亢進	1 (0.5)	0	0	1 (0.4)	1 (0.2)
筋骨格系および結合組織障害	0	0	1 (0.4)	1 (0.4)	2 (0.4)
筋痙縮	0	0	1 (0.4)	0	1 (0.2)
筋力低下	0	0	0	1 (0.4)	1 (0.2)
神経系障害	9 (4.3)	21 (8.0)	22 (8.3)	28 (10.4)	50 (9.4)
平衡障害	0	0	0	1 (0.4)	1 (0.2)
認知障害	1 (0.5)	0	1 (0.4)	0	1 (0.2)

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MedDRA Version 20.1

付録 2.7.6-14
SOC/PT 別の副作用発現率
外国 304 試験
安全性解析対象集団

MedDRA System Organ Class Preferred Term	Placebo (N=209) n (%)	Zolpidem ER 6.25 mg (N=263) n (%)	Lemborexant 5 mg (N=266) n (%)	Lemborexant 10 mg (N=268) n (%)	Lemborexant Total (N=534) n (%)
神経系障害 (Cont.)					
注意力障害	1 (0.5)	0	0	0	0
浮動性めまい	3 (1.4)	7 (2.7)	2 (0.8)	1 (0.4)	3 (0.6)
体位性めまい	0	1 (0.4)	1 (0.4)	0	1 (0.2)
頭痛	4 (1.9)	6 (2.3)	9 (3.4)	8 (3.0)	17 (3.2)
嗜眠	0	0	0	1 (0.4)	1 (0.2)
片頭痛	0	0	1 (0.4)	0	1 (0.2)
錯感覚	1 (0.5)	1 (0.4)	0	0	0
睡眠の質低下	0	1 (0.4)	0	1 (0.4)	1 (0.2)
鎮静	0	2 (0.8)	0	0	0
睡眠時麻痺	0	0	1 (0.4)	3 (1.1)	4 (0.7)
傾眠	3 (1.4)	4 (1.5)	10 (3.8)	17 (6.3)	27 (5.1)
振戦	0	1 (0.4)	0	0	0
精神障害	1 (0.5)	9 (3.4)	3 (1.1)	6 (2.2)	9 (1.7)
異常な夢	1 (0.5)	2 (0.8)	0	3 (1.1)	3 (0.6)

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SOC/PT 別の副作用発現率
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精神障害 (Cont.)					
不安	0	3 (1.1)	1 (0.4)	0	1 (0.2)
錯乱状態	0	2 (0.8)	0	0	0
抑うつ気分	0	1 (0.4)	0	0	0
うつ病	0	1 (0.4)	0	0	0
失見当識	0	1 (0.4)	0	0	0
触覚性幻覚	0	0	0	1 (0.4)	1 (0.2)
不眠症	0	0	0	1 (0.4)	1 (0.2)
病的思考	0	1 (0.4)	0	0	0
悪夢	0	0	2 (0.8)	0	2 (0.4)
レム睡眠異常	0	0	0	1 (0.4)	1 (0.2)
呼吸器、胸郭および縦隔障害	2 (1.0)	1 (0.4)	2 (0.8)	0	2 (0.4)
咳嗽	0	0	1 (0.4)	0	1 (0.2)
呼吸困難	1 (0.5)	0	1 (0.4)	0	1 (0.2)
労作性呼吸困難	1 (0.5)	0	0	0	0

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SOC/PT 別の副作用発現率
外国 304 試験
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MedDRA System Organ Class Preferred Term	Placebo (N=209) n (%)	Zolpidem ER 6.25 mg (N=263) n (%)	Lemborexant 5 mg (N=266) n (%)	Lemborexant 10 mg (N=268) n (%)	Lemborexant Total (N=534) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)					
咽喉刺激感	0	1 (0.4)	0	0	0
皮膚および皮下組織障害	2 (1.0)	2 (0.8)	0	1 (0.4)	1 (0.2)
寝汗	1 (0.5)	0	0	1 (0.4)	1 (0.2)
そう痒症	1 (0.5)	0	0	1 (0.4)	1 (0.2)
発疹	0	1 (0.4)	0	0	0
斑状丘疹状皮疹	0	1 (0.4)	0	0	0
血管障害	2 (1.0)	2 (0.8)	0	0	0
潮紅	0	1 (0.4)	0	0	0
高血圧	1 (0.5)	0	0	0	0
高血圧クリーゼ	0	1 (0.4)	0	0	0
血管炎	1 (0.5)	0	0	0	0

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MedDRA Version 20.1

付録 2.7.6-15　死亡又は重篤な有害事象の被験者ごとの叙述（外国 304 試験）

死亡又は重篤な有害事象が認められた被験者に関する叙述を以下に示した。

被験者識別コード	投与群	死亡に至った有害事象	死亡以外の重篤な有害事象
41021006	レンボレキサント 5 mg 群		X
44031056	レンボレキサント 5 mg 群		X
40251175	ゾルピデム ER 群		X
40341006	ゾルピデム ER 群		X
41011009	ゾルピデム ER 群		X
44051004	ゾルピデム ER 群		X

Subject ID:	41021006
Age, race, sex, actual treatment group:	56 years, White, Female, Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	クローン病, 関節痛, 乾癬, 閉経後
Concomitant medications (WHO Drug Name Preferred Term):	AZATHIOPRINE (01), FOLIC ACID (02), PROPRANOLOL (03)
Date of first dose/last dose of study drug (Duration of Exposure in Treatment Period):	21 APR 2017 / 23 MAY 2017 (33 days)
Other events: (MedDRA Preferred Term)	–

Serious adverse events (Investigator term/MedDRA preferred term):	GASTROENTERITIS OF VIRAL ORIGIN / ウイルス性胃腸炎
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	11 MAY 2017 (Study Day 21) / 13 MAY 2017 (Study Day 23)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of exiting hospitalization
Severity:	Moderate
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED / –
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03
Causality to study drug:	No

Subject ID:	44031056
Age, race, sex, actual treatment group:	59 years, White, Female, Lemborexant 5 mg
Medical history: (MedDRA Preferred Term)	胆石症, 肥満, 平滑筋腫, 腹壁形成, 胆嚢切除, 胃ステープリング, 子宮摘出
Current medical conditions: (MedDRA Preferred Term)	造影剤アレルギー, 骨粗鬆症, 湿疹, 高血圧
Concomitant medications (WHO Drug Name Preferred Term):	COLECALCIFEROL (01), CYANOCOBALAMIN (02), VALSARTAN (03), IBANDRONIC ACID (04)
Date of first dose/last dose of study drug (Duration of Exposure in Treatment Period):	25 AUG 2017 / 23 SEP 2017 (30 days)
Other events: (MedDRA Preferred Term)	–

Serious adverse events (Investigator term/MedDRA preferred term):	abdominal hernia / 腹部ヘルニア
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	25 SEP 2017 (Study Day 32) / 27 SEP 2017 (Study Day 34)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of exiting hospitalization
Severity:	Moderate
Outcome:	RECOVERED / RESOLVED
Study drug action taken/other action taken:	NOT APPLICABLE / –
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04
Causality to study drug:	No

Subject ID:	40251175
Age, race, sex, actual treatment group:	65 years, Black or African American, Female, Zolpidem ER 6.25 mg
Medical history: (MedDRA Preferred Term)	子宮摘出, ステント装着
Current medical conditions: (MedDRA Preferred Term)	血中コレステロール増加, 2 型糖尿病, 傾眠, 高血圧
Concomitant medications (WHO Drug Name Preferred Term):	INSULIN GLARGINE (01), LISINOPRIL (02), METOPROLOL (03)
Date of first dose/last dose of study drug (Duration of Exposure in Treatment Period):	17 OCT 2017 / 22 OCT 2017 (6 days)
Other events: (MedDRA Preferred Term)	–

Serious adverse events (Investigator term/MedDRA preferred term):	Peripheral Vascular Disease / 末梢血管障害
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	23 OCT 2017 (Study Day 7) / 29 OCT 2017 (Study Day 13)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	Severe
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG WITHDRAWN/WITHDRAWN FROM STUDY
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03
Causality to study drug:	No

Serious adverse events (Investigator term/MedDRA preferred term):	Coronary Artery Disease / 冠動脈疾患
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	24 OCT 2017 (Study Day 8) / 09 NOV 2017 (Study Day 24)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	Severe
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG WITHDRAWN/WITHDRAWN FROM STUDY
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03
Causality to study drug:	No

Serious adverse events	Healthcare Associated Pneumonia / 肺炎

(Investigator term/MedDRA preferred term):	
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	30 OCT 2017 (Study Day 14) / 09 NOV 2017 (Study Day 24)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of existing hospitalization
Severity:	Severe
Outcome:	RECOVERED/RESOLVED WITH SEQUELAE
Study drug action taken/other action taken:	DRUG WITHDRAWN/WITHDRAWN FROM STUDY
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03
Causality to study drug:	No

Subject ID:	40341006
Age, race, sex, actual treatment group:	81 years, Black or African American, Female, Zolpidem ER 6.25 mg
Medical history: (MedDRA Preferred Term)	子宮摘出
Current medical conditions: (MedDRA Preferred Term)	高脂血症, 喘鳴
Concomitant medications (WHO Drug Name Preferred Term):	ONDANSETRON (01), CIPROFLOXACIN (02), LOVASTATIN (03), MORPHINE (04), PARACETAMOL (05), TIOTROPIUM (06)
Date of first dose/last dose of study drug (Duration of Exposure in Treatment Period):	31 OCT 2016 / 29 NOV 2016 (30 days)
Other events: (MedDRA Preferred Term)	便秘, 腹痛, 悪心, 頭痛, 嘔吐, 食欲減退

Serious adverse events (Investigator term/MedDRA preferred term):	Small Bowel Obstruction / 小腸閉塞
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	16 NOV 2016 (Study Day 17) / 17 NOV 2016 (Study Day 18)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of exiting hospitalization
Severity:	Severe
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG INTERRUPTED/–
Concomitant medications (used until/on the start date of adverse event):	02, 03, 06
Causality to study drug:	No

Subject ID:	41011009
Age, race, sex, actual treatment group:	59 years, White, Female, Zolpidem ER 6.25 mg
Medical history: (MedDRA Preferred Term)	–
Current medical conditions: (MedDRA Preferred Term)	閉経後
Concomitant medications (WHO Drug Name Preferred Term):	–
Date of first dose/last dose of study drug (Duration of Exposure in Treatment Period):	16 OCT 2017 / 17 NOV 2017 (33 days)
Other events: (MedDRA Preferred Term)	–

Serious adverse events (Investigator term/MedDRA preferred term):	SEVERE LOW BACK PAIN / 背部痛
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	18 NOV 2017 (Study Day 34) / 04 DEC 2017 (Study Day 50)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of exiting hospitalization
Severity:	Severe
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DRUG WITHDRAWN/WITHDRAWN FROM STUDY
Concomitant medications (used until/on the start date of adverse event):	–
Causality to study drug:	No

Subject ID:	44051004
Age, race, sex, actual treatment group:	65 years, White, Female, Zolpidem ER 6.25 mg
Medical history: (MedDRA Preferred Term)	卵巣良性腫瘍, 良性乳房腫瘤除去, 子宮摘出, 乳房形成, 鼻中隔手術, 膀胱吊り上げ術
Current medical conditions: (MedDRA Preferred Term)	甲状腺機能低下症, 緑内障, 薬物過敏症, 傾眠, 高血圧
Concomitant medications (WHO Drug Name Preferred Term):	COLECALCIFEROL (01), TRI-NORMIN (02), LATANOPROST (03), LEVOTHYROXINE (04)
Date of first dose/last dose of study drug (Duration of Exposure in Treatment Period):	23 AUG 2017 / 19 SEP 2017 (28 days)
Other events: (MedDRA Preferred Term)	挫傷, 皮膚擦過傷

Serious adverse events (Investigator term/MedDRA preferred term):	right thoracic pain (of unknown origin) / 胸痛
Start date of adverse event (Study Day)/outcome date of adverse event (Study Day):	15 SEP 2017 (Study Day 24) / 16 SEP 2017 (Study Day 25)
TEAE	Yes
Serious criteria:	Requires inpatient hospitalization or prolongation of exiting hospitalization
Severity:	Severe
Outcome:	RECOVERED/RESOLVED
Study drug action taken/other action taken:	DOSE NOT CHANGED/–
Concomitant medications (used until/on the start date of adverse event):	01, 02, 03, 04
Causality to study drug:	No