

Supplementary information

Study site information:

Argentina (5 sites), Australia (2 sites), Austria (1 site), Belgium (7 sites), Brazil (1 site), Bulgaria (4 sites), Canada (5 sites), China (15 sites), Czech Republic (7 sites), France (4 sites), Germany (5 sites), Greece (3 sites), Hungary (6 sites), Japan (43 sites), Mexico (4 sites), Poland (8 sites), Portugal (5 sites), Republic of Korea (4 sites), Romania (2 sites), Russia (19 sites), Slovakia (4 sites), Spain (10 sites), Sweden (1 site), Taiwan (4 sites), Ukraine (8 sites), and USA (24 sites).

Study IEC/IRB information:

The IEC/IRB list for the East Asian countries included in this post hoc study is as follows

Country	IEC/IRB Name and Address
China	Beijing Anding Hospital Ankanghutong Xicheng district, Beijing Beijing China
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	IEC of Shanghai Mental Health Center No 600 South Wan Ping Road Shanghai, 200030 China
	Guangzhou Brian Hospital 36 Fangcun Mingxin Road Guangzhou China N/A N/A Guangzhou, 510370 China
	The 3rd Affiliated Hospital of Sun Yatsen University No.600, Tianhe Road, Guangzhou Guangzhou, 510630 China

	IEC of the first affiliated hospital of Kunming Medical University No 2 Kunshi Rd Wuhua District Kunming, Yunnan, 650032 China
	IEC of Renmin Hospital of Wuhan University No 238 Jiefang Road Wuchang District Wuhan, Hubei, 430060 China
	The Institution of Beijing Huilongguan Hospital Huilongguan street, Changping District Beijing, 102200 China
	IEC of The Second People's Hospital, Hunan Province No 427 The Third Block Middle Furong Road Changsha, Hunan, 410007 China
	IEC of Xi'an Mental Health center 15 Yanyin Road Qujiang New District Xian, Shaanxi, 710061 China
	IEC of The First Affiliated of Fourth Military Medical University No 127 Changlexi Road Xian, Shaanxi, 710032 China
	Tianjin Anding Hospital No.39, Wujiayao Road, Hexi District, Tianjin Tianjin China
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	Nanjing Brain Hospital-IRB No. 264, Guangzhou Road Nanjing, 210029 China

	<p>The Institution of The mental health center of Hebei Province No.572 East Dongfeng Road Baoding, Hebei, 071000 China</p>
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Japan	<p>Kamitsuga General Hospital IRB 1-1033 Shimota-machi, Kanuma-City, Tochigi Kanuma, 322-0036 Japan</p>
	<p>Seiwakai Shoda Hospital IRB 1-16-32 Annaka, Annaka-City, Gunma Annaka, 379-0116 Japan</p>
	<p>Maebashi Hirosegawa Clinic IRB 2-10-9 Chiyoda-cho, Maebashi-City, Gunma Maebashi, 371-0022 Japan</p>
	<p>Shinozuka Hospital IRB 105-1 Shinozuka, Fujioka-City, Gunma Fujioka, 375-0017 Japan</p>
	<p>Kohnodai Hospital IRB, National Center for Global Health and Medicine 1-7-1 Kohnodai, Ichikawa-City, Chiba Ichikawa, 272-8516 Japan</p>
	<p>Sakayori Clinic IRB 2-26-3 Higashi-Oi, Shinagawa-ku, Tokyo Tokyo, 140-0011 Japan</p>
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	<p>Yamanashi Prefectural Kita Hospital IRB 3314-13, Kamijominamiwari, Asahi-machi, Nirasaki-City, Yamanashi Nirasaki, 407-0046 Japan</p>
	<p>Japanese Red Cross Society Azumino Hospital IRB 5685 Toyoshina, Azumino-City, Nagano Azumino Japan</p>
	<p>Aichi Medical Association IRB 4-14-28 Sakae, Naka-ku, Nagoya-City, Aichi Nagoya, 460-0008 Japan</p>
	<p>Fujita Health University Hospital IRB 1-98 Dengakugakubo Kutsukake-cho, Toyoake-City, Aichi Toyoake, 470-1192 Japan</p>
	<p>Hinaga general center for mental care IRB 5039 Hinaga, Yokkaichi-City, Mie Yokkaichi, 510-8575 Japan</p>
	<p>Osaka Medical College Hospital IRB 2-7 Daigaku-Machi, Takatsuki-City, Osaka Takatsuki, 569-8686 Japan</p>
	<p>Kansai Medical University Takii Hospital IRB 10-15 Fumizono-Cho, Moriguchi-City, Osaka Moriguchi, 570-8507 Japan</p>
	<p>Nakameguro Atlas Clinic IRB 1-26-1 Kamimeguro, Meguro-ku, Tokyo Tokyo, 153-0051 Japan</p>

	Nara Medical University Hospital IRB 840 Shijyo-cho, Kashihara-City, Nara Kashihara, 634-8522 Japan
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Table S1. Extent of exposure over time for patients in the East Asian subgroup treated with PP3M and PP1M in the double-blind phase (safety analysis set)

DB phase period	Total	DOSE, n (%)			
		n (%)	175 mg eq.	263 mg eq.	350 mg eq.
PP3M (n=170)	n (%)	175 mg eq.	263 mg eq.	350 mg eq.	525 mg eq.
Day 1	170 (100)	5 (3)	18 (11)	83 (49)	64 (38)
Week 8	1 (1)	0 (0)	0 (0)	1 (100)	0 (0)
Week 12	150 (88)	3 (2)	16 (11)	71 (47)	60 (40)
Week 24	140 (82)	3 (2)	14 (10)	68 (49)	55 (39)
Week 32	1 (1)	0 (0)	0 (0)	1 (100)	0 (0)
Week 36	130 (76)	3 (2)	10 (8)	64 (49)	53 (41)
PP1M (n=174)	n (%)	50 mg eq.	75 mg eq.	100 mg eq.	150 mg eq.
Day 1	174 (100)	6 (3)	19 (11)	77 (44)	72 (41)
Week 4	165 (95)	6 (4)	17 (10)	76 (46)	66 (40)
Week 8	160 (92)	6 (4)	17 (11)	75 (47)	62 (39)
Week 12	156 (90)	5 (3)	17 (11)	73 (47)	61 (39)
Week 16	151 (87)	5 (3)	17 (11)	71 (47)	58 (38)
Week 20	147 (84)	5 (3)	17 (12)	69 (47)	56 (38)
Week 24	139 (80)	5 (4)	17 (12)	63 (45)	54 (39)
Week 28	137 (79)	5 (4)	17 (12)	62 (45)	53 (39)
Week 32	135 (78)	5 (4)	17 (13)	60 (44)	53 (39)
Week 36	132 (76)	5 (4)	17 (13)	59 (45)	51 (39)
Week 40	129 (74)	5 (4)	17 (13)	58 (45)	49 (38)
Week 44	125 (72)	5 (4)	17 (14)	57 (46)	46 (37)

Notes: Within each dose level, the percentages are based on the number of patients who had an injection administered at this visit

Abbreviations: DB, double-blind; eq, equivalent; n, number of patients in a subset; PP1M, paliperidone palmitate once-monthly formulation; PP3M, paliperidone palmitate three-monthly formulation

Table S2. Extent of exposure over time for patients in the Chinese subgroup treated with PP3M and PP1M in the double-blind phase (safety analysis set)

DB phase period	Total n (%)	DOSE, n (%)			
		175 mg eq.	263 mg eq.	350 mg eq.	525 mg eq.
PP3M (n=104)					
Day 1	104 (100)	3 (3)	3 (3)	53 (51)	45 (43)
Week 8	1 (1)	0 (0)	0 (0)	1 (100)	0
Week 12	95 (91)	3 (3)	3 (3)	45 (47)	44 (46)
Week 24	90 (87)	3 (3)	2 (2)	44 (49)	41 (46)
Week 36	87 (84)	3 (3)	2 (2)	42 (48)	40 (46)
PP1M (n=106)		50 mg eq.	75 mg eq.	100 mg eq.	150 mg eq.
Day 1	106 (100)	0 (0)	4 (4)	52 (49)	50 (47)
Week 4	102 (96)	0 (0)	4 (4)	52 (51)	46 (45)
Week 8	101 (95)	0 (0)	4 (4)	52 (51)	45 (45)
Week 12	98 (92)	0 (0)	4 (4)	50 (51)	44 (45)
Week 16	96 (91)	0 (0)	4 (4)	50 (52)	42 (44)
Week 20	93 (88)	0 (0)	4 (4)	48 (52)	41 (44)
Week 24	89 (84)	0 (0)	4 (4)	45 (51)	40 (45)
Week 28	88 (83)	0 (0)	4 (5)	44 (50)	40 (45)
Week 32	87 (82)	0 (0)	4 (5)	43 (49)	40 (46)
Week 36	86 (81)	0 (0)	4 (5)	43 (50)	39 (45)
Week 40	84 (79)	0 (0)	4 (5)	42 (50)	38 (45)
Week 44	80 (75)	0 (0)	4 (5)	41 (51)	35 (44)

Notes: Within each dose level, the percentages are based on the number of patients who had an injection administered at this visit

Abbreviations: DB, double-blind; eq, equivalent; n, number of patients in a subset; PP1M, paliperidone palmitate once-monthly formulation; PP3M, paliperidone palmitate three-monthly formulation

Table S3. Extent of exposure over time for patients in the Japanese subgroup treated with PP3M and PP1M in the double-blind phase (safety analysis set)

DB phase period	Total n (%)	DOSE, n (%)			
		175 mg eq.	263 mg eq.	350 mg eq.	525 mg eq.
PP3M (n=52)	n (%)				
Day 1	52 (100)	2 (4)	13 (25)	25 (48)	12 (23)
Week 12	42 (81)	0 (0)	11 (26)	22 (52)	9 (21)
Week 24	39 (75)	0 (0)	11 (28)	20 (51)	8 (21)
Week 36	33 (63)	0 (0)	7 (21)	18 (55)	8 (24)
PP1M (n=56)	n (%)	50 mg eq.	75 mg eq.	100 mg eq.	150 mg eq.
Day 1	56 (100)	5 (9)	13 (23)	22 (39)	16 (29)
Week 4	52 (93)	5 (10)	11 (21)	21 (40)	15 (29)
Week 8	48 (86)	5 (10)	11 (23)	20 (42)	12 (25)
Week 12	47 (84)	4 (9)	11 (23)	20 (43)	12 (26)
Week 16	45 (80)	4 (9)	11 (24)	18 (40)	12 (27)
Week 20	44 (79)	4 (9)	11 (25)	18 (41)	11 (25)
Week 24	40 (71)	4 (10)	11 (28)	15 (38)	10 (25)
Week 28	39 (70)	4 (10)	11 (28)	15 (38)	9 (23)
Week 32	38 (68)	4 (11)	11 (29)	14 (37)	9 (24)
Week 36	36 (64)	4 (11)	11 (31)	13 (36)	8 (22)
Week 40	36 (64)	4 (11)	11 (31)	13 (36)	8 (22)
Week 44	36 (64)	4 (11)	11 (31)	13 (36)	8 (22)

Notes: Within each dose level, the percentages are based on the number of patients who had an injection administered at this visit

Abbreviations: DB, double-blind; eq, equivalent; n, number of patients in a subset; PP1M, paliperidone palmitate once-monthly formulation; PP3M, paliperidone palmitate three-monthly formulation

Table S4. Prior unique antipsychotic medication use in patients (Intent-to-treat open-label analysis set)

	OL phase (PPIM)			
	China (n=296)	Japan (n=175)	East Asia (n=510)	Global (N=1429)
Total number of patients with prior psychotropic medications, n (%)	248 (84)	175 (100)	459 (90)	1291 (90)
Atypical antipsychotics	222 (75)	164 (94)	422 (83)	1084 (76)
Risperidone	134 (45)	74 (42)	226 (44)	492 (34)
Paliperidone	39 (13)	74 (42)	132 (26)	304 (21)
Olanzapine	39 (13)	26 (15)	70 (14)	227 (16)
Quetiapine	33 (11)	13 (7)	54 (11)	156 (11)
Aripiprazole	25 (8)	30 (17)	63 (12)	141 (10)
Amisulpride	1 (<1)	0 (0)	4 (1)	25 (2)
Blonanserin	0 (0)	18 (10)	20 (4)	20 (1)
Ziprasidone	10 (3)	0 (0)	11 (2)	16 (1)
Clozapine	5 (2)	0 (0)	5 (1)	7 (<1)
Sertindole	0 (0)	0 (0)	0 (0)	5 (<1)
Asenapine	0 (0)	0 (0)	0 (0)	4 (<1)
Iloperidone	0 (0)	0 (0)	0 (0)	4 (<1)
Lurasidone	0 (0)	0 (0)	0 (0)	3 (<1)
Perospirone	3 (1)	0 (0)	3 (1)	3 (<1)
Levosulpiride	1 (<1)	0 (0)	1 (<1)	1 (<1)
Typical antipsychotics, n (%)	47 (16)	37 (21)	98 (19)	325 (23)
Haloperidol	23 (8)	10 (6)	45 (9)	160 (11)
Levomepromazine	0 (0)	4 (2)	4 (1)	48 (3)
Chlorpromazine	3 (1)	8 (5)	13 (3)	36 (3)
Chlorprothixene	0 (0)	0 (0)	0 (0)	33 (2)
Promethazine	5 (2)	12 (7)	17 (3)	33 (2)
Zuclopenthixol	0 (0)	0 (0)	0 (0)	30 (2)

Sulpiride	18 (6)	0 (0)	20 (4)	21 (1)
Trifluoperazine	0 (0)	0 (0)	0	19 (1)
Levomepromazine maleate	0 (0)	11 (6)	11 (2)	12 (1)
Perphenazine	7 (2)	0 (0)	7 (1)	11 (1)
Perazine	0 (0)	0 (0)	0 (0)	6 (<1)
Cyamemazine	0 (0)	0 (0)	0 (0)	4 (<1)
Flupentixol	0 (0)	0 (0)	0 (0)	4 (<1)
Zotepine	0 (0)	3 (2)	4 (1)	4 (<1)
Clotiapine	0 (0)	0 (0)	0 (0)	3 (<1)
Pimozide	0 (0)	0 (0)	0 (0)	3 (<1)
Prothipendyl	0 (0)	0 (0)	0 (0)	3 (<1)
Fluphenazine	0 (0)	0 (0)	0 (0)	2 (<1)
Nemonapride	0 (0)	2 (1)	2 (<1)	2 (<1)
Periciazine	0 (0)	2 (1)	2 (<1)	2 (<1)
Levomepromazine hydrochloride	0 (0)	1 (1)	1 (<1)	1 (<1)
Loxapine	0 (0)	0 (0)	0 (0)	1 (<1)
Melperone	0 (0)	0 (0)	0 (0)	1 (<1)
Thioridazine	0 (0)	0 (0)	0 (0)	1 (<1)
Tiotixene	0 (0)	0 (0)	0 (0)	1 (<1)
Depot antipsychotics, n (%)	11 (4)	56 (32)	70 (14)	210 (15)
Risperidone	4 (1)	41 (23)	47 (9)	94 (7)
Haloperidol decanoate	3 (1)	10 (6)	13 (3)	41 (3)
Paliperidone palmitate	1 (<1)	0 (0)	1 (<1)	23 (2)
Fluphenazine decanoate	1 (<1)	4 (2)	6 (1)	17 (1)
Zuclopenthixol	0 (0)	0 (0)	0 (0)	11 (1)
Flupentixol decanoate	0 (0)	0 (0)	0 (0)	9 (1)
Pipotiazine palmitate	2 (1)	0 (0)	2 (<1)	4 (<1)
Zuclopenthixol decanoate	0 (0)	0 (0)	0 (0)	4 (<1)
Fluphenazine	0 (0)	0 (0)	0 (0)	2 (<1)
Haloperidol	0 (0)	0 (0)	0 (0)	2 (<1)
Olanzapine	0 (0)	0 (0)	0 (0)	2 (<1)
Aripiprazole	0 (0)	0 (0)	0 (0)	1 (<1)

Bromperidol	0 (0)	1 (1)	1 (<1)	1 (<1)
Flupentixol	0 (0)	0 (0)	0 (0)	1 (<1)
Fluphenazine enantate	0 (0)	0 (0)	0 (0)	1 (<1)
Olanzapine embonate	0 (0)	0 (0)	0 (0)	1 (<1)

Notes: Percentages calculated with the number of patients in each group as denominator.

Abbreviations: OL, open-label; N, total number of patients; n, number of patients in a subset; PP1M, paliperidone palmitate 1-monthly formulation; PP3M, paliperidone palmitate 3-monthly formulation

Table S5. Concomitant benzodiazepine medication use in patients during the double-blind phase of the study (safety analysis set)

	PP3M				PP1M			
	China (n=104)	Japan (n=52)	East Asia (n=170)	Global (N=504)	China (n=106)	Japan (n=56)	East Asia (n=174)	Global (N=512)
Total number of patients with any benzodiazepines, n (%)	17 (16)	22 (42)	49 (29)	120 (24)	15 (14)	27 (48)	46 (26)	122 (24)
Lorazepam	9 (9)	19 (37)	37 (22)	66 (13)	8 (8)	25 (45)	35 (20)	70 (14)
Clonazepam	4 (4)	1 (2)	6 (4)	33 (7)	2 (2)	1 (2)	5 (3)	31 (6)
Diazepam	3 (3)	2 (4)	8 (5)	23 (5)	2 (2)	1 (2)	4 (2)	16 (3)
Alprazolam	1 (1)	0 (0)	1 (1)	3 (1)	1 (1)	0 (0)	1 (1)	3 (1)
Brotizolam	0 (0)	5 (10)	5 (3)	5 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Flunitrazepam	0 (0)	1 (2)	1 (1)	1 (<1)	0 (0)	4 (7)	4 (2)	4 (1)
Estazolam	1 (1)	0 (0)	1 (1)	1 (<1)	1 (1)	0 (0)	3 (2)	3 (1)
Nitrazepam	1 (1)	0 (0)	1 (1)	1 (<1)	0 (0)	2 (4)	2 (1)	3 (1)
Bromazepam	0 (0)	0 (0)	0 (0)	1 (<1)	0 (0)	0 (0)	0 (0)	2 (<1)
Midazolam	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	2 (1)	3 (1)
Quazepam	0 (0)	2 (4)	2 (1)	2 (<1)	0 (0)	1 (2)	1 (1)	1 (<1)
Temazepam	0 (0)	0 (0)	1 (1)	3 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Etizolam	0 (0)	1 (2)	1 (1)	1 (<1)	0 (0)	1 (2)	1 (1)	1 (<1)
Flurazepam	0 (0)	0 (0)	0 (0)	2 (<1)	0 (0)	0 (0)	0 (0)	0 (0)
Oxazepam	0 (0)	0 (0)	0 (0)	1 (<1)	0 (0)	0 (0)	0 (0)	1 (<1)
Phenazepam	0 (0)	0 (0)	0 (0)	1 (<1)	0 (0)	0 (0)	0 (0)	1 (<1)
Chlordiazepoxide	0 (0)	0 (0)	0 (0)	1 (<1)	0 (0)	0 (0)	0 (0)	0 (0)
Lormetazepam	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (<1)
Prazepam	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (<1)
Tetrazepam	0 (0)	0 (0)	0 (0)	1 (<1)	0 (0)	0 (0)	0 (0)	0 (0)
Triazolam	0 (0)	1 (2)	1 (1)	1 (<1)	0 (0)	0 (0)	0 (0)	0 (0)

Abbreviations: N, total number of patients; n, number of patients in a subset; PP1M, paliperidone palmitate once-monthly formulation; PP3M, paliperidone palmitate three-monthly formulation.

Table S6: Concomitant anti-Parkinson medication used in patients during open-label phase (intent-to-treat analysis set)

	PP1M			
	China (n=296)	Japan (n=175)	East Asia (n=510)	Global (N=1429)
Total number of patients with any anti-Parkinson medication in OL phase, n (%)	72 (24)	37 (21)	118 (23)	207 (14)
Trihexyphenidyl	72 (24)	11 (6)	86 (17)	98 (7)
Biperiden	0	27 (15)	29 (6)	77 (5)
Benzatropine	0	0	2 (<1)	29 (2)
Procyclidine	0	0	3 (1)	5 (<1)
Ropinirole	0	0	0	1 (<1)

Abbreviations: N, total number of patients; n, number of patients in a subset; OL, open-label; PP1M, paliperidone palmitate once-monthly formulation; PP3M, paliperidone palmitate three-monthly formulation

Table S7: Concomitant anti-Parkinson medication used in patients during double-blind phase (safety analysis set)

	PP1M				PP3M			
	China (n=106)	Japan (n=56)	East Asia (n=174)	Global (N=512)	China (n=104)	Japan (n=52)	East Asia (n=170)	Global (N=504)
Total number of patients with any anti-Parkinson medication in DB phase, n (%)	16 (15)	11 (20)	32 (18)	65 (13)	26 (25)	8 (15)	38 (22)	77 (15)
Biperiden	0	9 (16)	11 (6)	31 (6)	0	7 (13)	9 (5)	30 (6)
Trihexyphenidyl	15 (14)	3 (5)	19 (11)	24 (5)	26 (25)	0	28 (16)	36 (7)
Benzatropine	0	0	1 (1)	8 (2)	0	0	0	9 (2)
Amantadine	0	0	0	0	0	0	0	2 (<1)
Carbidopa	0	0	0	2 (<1)	0	0	0	0
Levodopa	0	0	0	2 (<1)	0	0	0	0
Procyclidine	0	0	1 (1)	2 (<1)	0	0	0	0
Anticholinergic agents	1 (1)	0	1 (1)	1 (<1)	0	0	0	0
Terguride	0	0	0	0	0	1 (2)	1 (1)	1 (<1)

Abbreviations: DB, double-blind; N, total number of patients; n, number of patients in a subset; PP1M, paliperidone palmitate once-monthly formulation; PP3M, paliperidone palmitate three-monthly formulation