SYNOPSIS

Name of Sponsor/Company	Janssen-Cilag Asia-Pacific Medical Affairs *
	Johnson & Johnson Pte Ltd
Name of Finished Product	INVEGA SUSTENNA
Name of Active Ingredient(s)	JNJ-16977831-AAA (Paliperidone Palmitate)

*The legal entity acting as the sponsor for studies of Janssen-Cilag Asia-Pacific Medical Affairs may vary. The term "sponsor" is used throughout the protocol to represent these various legal entities; the sponsor is identified on the Contact Information page that accompanies the protocol..

Status: Final

Date: 21 February 2014

Prepared by: Janssen-Cilag Asia-Pacific Medical Affairs, Johnson & Johnson Pte Ltd

Protocol No.: R092670-SCH-3009.

Title of Study: Safety, Tolerability, and Treatment Response of Paliperidone Palmitate in Subjects with Schizophrenia When Switching from Oral Antipsychotics.

NCT No.: NCT01051531.

Clinical Registry No.: CR016522.

Coordinating Principal Investigator(s): Chang Yoon Kim, MD, PhD – Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea

Study Center(s): 48 sites in 8 countries (10 sites in Australia, 6 sites in China, 2 sites in Hong Kong, 10 sites in Korea, 9 sites in Malaysia, 2 sites in Philippines, 6 sites in Taiwan and 3 sites in Thailand).

Publication (Reference): Not applicable.

Study Period: Initiated on 15 April 2010 /completed on 17 May 2013.

Phase of Development: 3b.

Objectives: The primary objective of the study was to explore safety, tolerability and treatment response as measured by PANSS of paliperidone palmitate once-monthly injections compared to different previous oral antipsychotic medications in subjects with schizophrenia. Enrollment was limited to recently diagnosed subjects with schizophrenia, defined as having received the diagnosis of schizophrenia within 5 years prior to screening.

The secondary objectives of the study were to construct (homogeneous) groups of subjects based on their clinical characteristics, eg, previous medication, elapsed time after diagnosis, premorbid function, and develop guidance for the switch from oral antipsychotics and examine safety and tolerability of paliperidone palmitate in an Asia Pacific population over 18 months in subjects with schizophrenia on clinically important domains.

Methodology: This study was a non-randomized, single-arm, open-label, multicenter study to explore the safety, tolerability and treatment response in subjects with schizophrenia who were switched from an oral antipsychotic medication to once-monthly injections of paliperidone palmitate. The study consists of an

up-to-7-day screening period, an 18-month open-label treatment period, and an end-of-study /early-withdrawal visit.

Enrollment was limited to those who were recently diagnosed with schizophrenia, which was defined as having received the diagnosis of schizophrenia within 5 years before screening. The study duration was 18 months. A pharmacogenomic blood sample was collected from subjects who consented separately to the pharmacogenomic component of the study (where local regulations permitted). Subject participation in pharmacogenomic research was optional and was not offered to subjects who participate in the study at sites in Malaysia, Thailand, Hong Kong, China, Australia and New Zealand, or the Philippines.

Number of Subjects (planned and analyzed):

Data Sets Analyzed

	Paliperidone palmitate
Planned	587
Enrolled subjects [a]	
Site 061002 included	585
Site 061002 excluded	560
ITT /safety population [b]	
Site 061002 included	545
Site 061002 excluded	521 (100.0)
Healthcare utilization analysis set [c]	474 (91.0)
Mirror analysis set [d]	474 (91.0)
Pharmacogenomic analysis set [e]	54 (10.4)
PP population [f]	397 (76.2)
Subjects excluded from PP population	124 (23.8)
Reasons for exclusion from PP Population [g]	
Entered the study but entry criteria not met	18 (14.5)
Received excluded concomitant treatment	60 (48.4)
Received the wrong treatment or incorrect dose	11 (8.9)
Treatment compliance <70%	33 (26.6)
Other	23 (18.5)

DNA = deoxyribonucleic acid; ITT = intent-to-treat; PP = per-protocol.
Note: Percentages are based on number of subjects in ITT population.
[a] Enrolled subjects consists of all subjects who had signed informed consent.
[b] ITT Population consists of all subjects who received at least one injection of paliperidone palmitate. In this study, the ITT and safety populations contained the same subjects.
[c] Healthcare utilization set consists of all ITT subjects who participated in healthcare utilization data collection. Subjects from site 061002 were excluded.
[d] Mirror analysis set consists of all the healthcare utilization subjects with retrospective data (including hospitalization, emergency room visits and outpatient visits) available for the 12 months prior to day 1.
[e] Pharmacogenomic set consists of all ITT subjects who signed the DNA informed consent. Subjects from site 061002 were excluded.
[f] PP population consists of subjects in the ITT Population who did not had any major protocol deviations and had at least 70% study treatment compliance.
[g] Subjects may have more than one reason for exclusion. Percentages are based on number subjects excluded from PP population.

Note: One of the sites in Australia (061002 [Investigator: D'Souza] who enrolled 25 subjects) was not compliant with good clinical practice (GCP). The reasons included (but were not limited to) discrepancies between electronic medical records, paper medical records and the electronic case report forms (eCRFs). In order to assess the impact of exclusion of data from site, a sensitivity analysis was performed with and without data from this site for the primary efficacy endpoint, the primary adverse events (AEs) (with system organ class) presentation, disposition, and demography.

Diagnosis and Main Criteria for Inclusion: Men and women from 18 to 50 years of age, (inclusive) and recently diagnosed with schizophrenia (within 5 years prior to screening) were enrolled in the study.

Test Product, Dose and Mode of Administration, Batch No.: INVEGA® (SUSTENNA™) contains paliperidone palmitate and is available as a sterile aqueous extended-release suspension for intramuscular injection in dose strengths of 50 milligram equivalents (mg eq), 75 mg eq, 100 mg eq, and 150 mg eq paliperidone. Study treatment was supplied in a pre-filled syringe.

Study treatment	Incoming Materials Description	Batch Identifier	Expiry Date
Paliperidone palmitate 50mg	R092670 100 mg eq /mL 0.5 mL long syringe /0.5mL fill	BEB9B	May 2013
		AJB6P	Oct 2012
		AAB7M	Jan 2012
		9JB7W	Sep 2011
		9CB6Z	Feb 2011
Paliperidone palmitate 75mg	R092670 100 mg eq /mL 1.0 mL long syringe /0.75 mL fill	BEB9C	May 2013
		AJB6Q	Oct 2012
		AFB6X	Jun 2012
		AJB6X	Oct 2012
		9HB5W	Jul 2011
Paliperidone palmitate 100mg	R092670 100 mg eq /mL 1.0 mL long syringe /0.5 mL fill	BCB8E	Mar 2013
		AKB6E	Nov 2012
		9HB5K	Jul 2011
Paliperidone palmitate 150mg	R092670 100 mg eq /mL 2.25 mL long syringe /1.5 mL fill	BFB7S	Jun 2013
		BDB7E	Apr 2013
		BCB8F	Mar 2013
		AKB6F	Nov 2012
		9JB7X	Sep 2011
		9CB71	Feb 2011

During the treatment period (after Day 8) subjects were eligible to receive 4 flexible doses of paliperidone palmitate (50, 75, 100, or 150 mg eq). The original protocol had a fixed dose (at 75 mg eq) from 3rd dose, but was amended at the request of several investigators to allow variable dosing.

On Day 1, all subjects received a paliperidone palmitate IM injection of 150 mg eq in the deltoid muscle. Subsequent injections of paliperidone palmitate were administered on Day 8 (±2 days, 100 mg eq) and on Day 38 (±7 days, 75 mg eq was recommended; however, other dose levels were allowed at the investigators' discretion). The investigator had to describe the reason in the medical record if a dose other than 75 mg eq. on Day 38 (±7 days) was selected. Thereafter subjects received paliperidone palmitate intramuscular (IM) injections, once-monthly (every 30±7 days). Four doses of paliperidone palmitate (50, 75, 100, or 150 mg eq.) will be available. Doses were to be adjusted in a stepwise fashion every 30 days per clinician's judgment for effectiveness and tolerability within the dose range of 50 to 150 mg eq.

Importantly, such a flexible dose administration schedule reflects the real-life treatment scenario in this indication.

Reference Therapy, Dose and Mode of Administration, Batch No.: Not applicable.

Duration of Treatment: 18 months.

Criteria for Evaluation:

Primary efficacy endpoint

- Change in Positive and Negative Syndrome Scale (for schizophrenia) (PANSS) total score at the end of treatment (Day 548) from baseline.

Secondary efficacy variables to support the findings of the primary efficacy analysis

- Change in Personal and Social Performance (PSP) scale score and evolution of ratio of mild degree of dysfunction (PSP total score of 71 to 100), varying degree of difficulty (31 to 70), and poor level of function (≤30) after switch to paliperidone palmitate
- Changes in PANSS total score and 5 PANSS symptom factors
- Symptom remission
- Overall score in global severity of illness (Clinical Global Impression−Schizophrenia, CGI-SCH scale)
- Medication Satisfaction Questionnaire (MSQ, 7-point categorical scale)
- Subject discontinuation, hospitalization, and institutionalization
- The rate of subject discontinuation during the study
- The rate of subjects hospitalized during the study
- The total number and mean duration of institutionalizations during the study.

Healthcare resource utilization

- Assessment of: Institutionalization days, total length of institutional stay, emergency and outpatient visits, employment and social support, mirror analysis.

Safety measures

- AEs [overall frequency, serious, related, significant, and special clinical interest], physical findings of body weight, laboratories*, Extrapyramidal Symptom Rating Scale-abbreviated [ESRS-A]).

* Laboratory evaluations were only performed at screening and Day 548 (end of treatment or early withdrawal) so no formal presentation of laboratory values was provided in the analysis. Clinically relevant laboratory and physical examination findings can be found in the AE data.

Statistical Methods:

The hypothesis used was
Null hypothesis: H0: $\Delta \geq -3$
vs
Alternative hypothesis: H1: $\Delta < -3$,
where Δ denotes change in PANSS total score.

Treatment response to paliperidone palmitate injection given once monthly was to be concluded if the upper limit of one-sided 95% confidence interval [CI] for the change from baseline in PANSS total score at Day 548 LOCF was less than -3 points.

Subgroup analyses of the primary efficacy variable included previous schizophrenia medications (first and second generation medications), elapsed time since diagnosis of schizophrenia, premorbid function, and presence of predominant negative symptoms.

RESULTS:

STUDY POPULATION:

Disposition

Overall, 510 (87.2%) subjects were enrolled from Asian countries: China (20.2%), Malaysia (20.2%), Korea (17.6%), Taiwan (11.3%), Thailand (9.6%), Philippines (5.1%), and in Hong Kong (3.2%). Overall, 75 (12.8%) subjects were enrolled from non-Asian countries (all in Australia).

Overall, 303 (58.2%) subjects in the ITT population (N=521) completed the study. Withdrawal of consent was the most frequently reported reason for early termination from the study (30.7%). This was followed by lack of efficacy (22.9%) and AEs (19.3%). Among subjects with a primary reason for withdrawal due to lack of efficacy, 66.0%withdrew without a schizophrenia-related AE, 52.0% had a study treatment related AE, 48.0% were without a study treatment related AE, and 34.0% had schizophrenia related AE. Subjects also withdrew due to being lost to follow-up (12.4%), protocol violation (5.0%), physician decision or "other reasons" (3.2% each), and noncompliance with study treatment (2.3%).

Baseline characteristics

The majority of subjects were male (65.5%), the median age of subjects was 27 years (range: 18 to 56 years), and the majority of subjects were Asian (92.5%) or White (6.0%).

The most frequent (Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition [DSM-IV] axis I) diagnosis of schizophrenia type was paranoid (74.3% of subjects); followed by undifferentiated (16.5%), disorganized (5.4%) and residual (3.8%). The median time since diagnosis was 1.79 years. Most subjects (68.9%) had received their diagnosis within 3 years prior to enrollment: 0 to 1 years (36.7%), 1 to 2 years (15.7%), 2 to 3 years (16.5%), 3 to 4 years (17.1%), and ≥4 years (14.0%).

Extent of Exposure

A mean (SD) of 13.9 (6.78) study treatment doses [95% CI: 13.34 to 14.51] were administered over 382.6 (202.07) days [95% CI: 365.2 to 400.01].

The mean (SD) dose was 108.1 (24.23) mg eq [95% CI: 106.01 to 110.18]. The mean (SD) maintenance dose after Day 8 was 100.8 (28.33) mg eq [95% CI: 98.27 to 103.40]. Among the 218 subjects who discontinued from the study prematurely, the dose level at discontinuation was 100 mg eq for 35.3% of subjects, 150 mg eq for 33.5%, and 75 for 22.0%; with 8.7% of subjects receiving 50 mg eq and 0.5% receiving a non-protocol-specified dose of 175 mg eq.

EFFICACY RESULTS:

The primary efficacy analysis showed that the mean (SD) reduction from baseline in PANSS total score at the end of treatment (Day 548) was 11.3 (21.38) units. The associated one-sided 95% CI was [-inf. to -9.7]. This reduction represents a clinically meaningful improvement that was statistically significant $p<0.0001$ (one sample, one-sided t-test to test the hypothesis that the improvement from baseline was greater than or equal to 3 units). Effectiveness was concluded as the improvement from baseline was greater than or equal to 3 units.

Change from baseline in PANSS total score at Day 548 - LOCF

	Total (N=521)		
	PANSS total Score		
	Baseline	**Timepoint**	**Change from baseline[a]**
Baseline			
n		520	
Mean (SD)		64.1 (19.09)	
95% CI		62.5 to 65.7	
Median		62.0	
Range		30 to 124	
Day 548			
n	510	510	510
Mean (SD)	64.0 (19.02)	52.7 (20.50)	-11.3 (21.38)
Median	62.0	48.0	-8.5
Range	30 to 124	30 to 129	-88 to 75
One-sided 95% CI [b]			[-inf. to -9.7]
p-value [c]			<0.0001
95% CI	[62.3 to 65.6]	[50.9 to 54.5]	[-13.1 to -9.4]
p-value [d]			<0.0001

CI = confidence interval; inf. = infinity; ITT = intent-to-treat; LOCF = last observation carried forward; PANSS = Positive and Negative Symptom Scale (for schizophrenia); SD = standard deviation.

NOTE: Baseline was defined as Day 1. Subjects with at least one post baseline evaluation were summarized. Missing values were imputed by last non-missing post-baseline value (LOCF method). No imputation was done for missing baseline values.

[a] A reduction in PANSS total score from baseline represents an improvement.

[b] Treatment response for paliperidone palmitate injection given monthly once is concluded if upper limit of one-sided 95% CI for change from baseline in PANSS total score at Day 548 LOCF is less than -3 units.

[c] p-value is from one sided paired t-test for the null hypothesis that change is ≥ -3.

[d] p-value is from two-sided paired t-test for the null hypothesis that change = 0.

Cross-reference: Table 14.2.1.1.1; appendix 16.

Each of the 5 PANSS factor scores showed statistically significant reduction in symptoms. The percentage of subjects showing an improvement in PANSS total score from baseline reached 45.3% at Day 548. The percentage of subjects achieving responses for PANSS total score of a magnitude of ≥30% increased at each subsequent visit: 35.5% at Day 38, 66.8% at Day 188, 70.2% at Day 368 and 73.9% at Day 548. Also, 33.3% of subjects in the ITT population who were not in symptom remission at baseline were in symptom remission at Day 548; while 5.5% of subjects in the ITT population who were in symptom remission at baseline were not in symptom remission at Day 548. This finding towards symptom remission on treatment was statistically significant from Day 188 ($p<0.0001$).

The subgroup analysis of the primary efficacy variable indicated that the magnitude of improvement was greater among subjects with worse disease severity at baseline: PANSS baseline total score ≥70 (mean change: 23.1 compared with 4.7 among subjects with a score <70); subjects with baseline CGI-SCH overall severity score ≥5 (-26.2 compared with -8.5 among subjects with a score <5); among subjects with "poor premorbid function (PSP total score ≤30)" (26.7 compared with 12.9 for "varying premorbid function [PSP total score 31 to 70]" and -2.6 for "mild premorbid function [PSP total score of 71 to 100]"). Also the magnitude of improvement was greater among subjects with an elapsed time since first diagnosis <3 years (-12.1 compared with -9.5 among subjects with an elapsed time since diagnosis ≥3 years); among subjects with psychiatric hospitalization in last 2 years prior to baseline (-12.8 compared with -8.5 among subjects without hospitalization in last 2 years prior to baseline). The improvement among subjects was similar among subjects with and without predominant negative symptoms (-11.0 and -11.3, respectively).

The overall severity index of the CGI-SCH showed a statistically significant improvement from baseline at Day 548. Such improvements were confirmed by subgroup analyses and were noted for each of the sub-indices. The MSQ score also showed a clinically and statistically significant improvement from baseline.

Overall, 41.8% of subjects prematurely withdrew from the study (22.9% of these subjects did so due to lack of efficacy). Overall, 12.1 [95% CI: 9.4 to 15.2] % of subjects were hospitalized during the study: 12.1% due to an AE, 8.8% for a psychiatric reasons, 0.8% for social reasons, and 2.9% for "other" reasons. Overall, 8.8% subjects were institutionalized (a subset of hospitalizations) for a psychiatric reason. The median time to first occurrence was 73.5 (95% CI: 54.0 to 108.0) days. Overall, 8.8% of subjects had full institutionalizations for psychiatric reasons. Most frequently subjects were institutionalized once (7.7% of subjects). The mean [95% CI] number of institutionalizations was 1.2 [1.0 to 1.3] and the length of stay was 36.6 [22.3 to 50.9] days. Among the 12.1% of subjects institutionalized for any reason, the median [95% CI] time to first institutionalization was 92.0 [68.0 to 146.0] days.

HEALTHCARE RESOURCE UTILIZATION:

A total of 474 /521 (91.0%) subjects were included in the healthcare resource utilization set. A total of 73 of the 474 subjects (15.4%) in the healthcare resource utilization set were being treated within a hospital setting when study treatment was started. Overall, within the healthcare resource utilization set, the incidence of cases of full institutionalization, emergency room and outpatient visits decreased as the duration of treatment increased.

For the mirror analysis set (N=474), the mean (SD) number of full institutionalized days per person year was 74.25 (125.168) days per person year during the 12-month retrospective period compared with 19.77 (64.440) days per person year ($p < 0.0001$) for the first 12 months of the prospective period and 18.93 (62.987) days per person year for the full 18-month prospective period ($p < 0.0001$, Table 39).

Also a sensitivity analysis excluding subjects with a schizophrenia history <1 year was performed as this was considered to render the two periods more comparable (as annualizing unduly exaggerates the duration of institutionalization during the retrospective period for subjects with a history of less than 1 year). For the mirror analysis set (excluding subjects with a schizophrenia history <1 year, N=176), the mean (SD) number of full institutionalized days per person year was 63.31 (122.409) days per person year during the 12-month retrospective period compared with 20.29 (65.762) days per person year ($p < 0.0001$) for the first 12 months of the prospective period and 19.16 (63.469) days per person year for the full 18-month prospective period ($p < 0.0001$, Table 39).

In the mirror analysis set, 178 (42.6%) subjects reported full institutionalization and 240 (50.6%) subjects did not report full institutionalization during the retrospective period. During the first 12 months of the prospective period, 111 (23.4%) subjects reported full institutionalization and 407 (85.9%) subjects did not report full institutionalization. Similar findings were seen when the full 18-month prospective period was considered (Table 14.4.5.4).

Emergency room and outpatient visits were summarized for the mirror analysis set; however, comparison between the prospective period and retrospective periods may be limited. For instance, it might be incorrect to assume that the subject's scheduled visit was solely for the purposes of study treatment administration and not combined with some activity that would otherwise have required an outpatient or emergency room visit for psychiatric purposes. This was not conceived when the CRF was developed and data were not captured concerning this possibility. Moreover, subjects might wait for a scheduled visit

when otherwise (outside of the study or the need to attend a clinical setting for a planned injection) they might have sought care in an emergency room or out-patient setting. For the mirror analysis set (N=474), when missing data were excluded, the mean (SD) number of emergency room visits per person year was 0.30 (0.961) visits per person year during the 12 month retrospective period, 0.55 (3.192) visits per person year for the first 12 months of the prospective period and 0.56 (3.196) visits per person year for the full 18-month prospective period. When missing data were imputed as zero, in the mirror analysis set, 78 (16.5%) subjects reported emergency room visits and 311 (65.6%) subjects did not report emergency room visits during the retrospective period. During the first 12 months of the prospective period, 21 (4.4%) subjects reported emergency room visits and 369 (77.8%) subjects did not report emergency room visits. For the mirror analysis set (N=474), when missing data were excluded, the mean (SD) number of outpatient visits per person year was 7.22 (9.737) visits per person year during the 12-month retrospective period, 8.40 (22.842) visits per person year for the first 12 months of the prospective period and 9.42 (23.104) visits per person year for the full 18-month prospective period. When missing data were imputed as zero, in the mirror analysis set, 300 (63.3%) subjects reported outpatient visits and 90 (19.0%) subjects did not report outpatient visits during the retrospective period. During the first 12 months of the prospective period, 209 (44.1%) subjects reported outpatient visits and 181 (38.2%) subjects did not report outpatient visits. Similar findings were seen when the full 18 month prospective period was considered.

SAFETY RESULTS:

Overall, 82.3% of subjects experienced a TEAE; with 67.2% experiencing a treatment-related TEAE (events were most frequently psychiatric and nervous disorders).

The relative contribution of TEAEs to the safety population was broadly similar among subjects who were tapering of their previous antipsychotics and those not using any antipsychotics concomitantly. TEAEs tended to be reported more frequently in the first 3 months for those subjects with antipsychotic use compared with subjects without antipsychotic use (47.6% compared with 20.3%). Overall, TEAEs were more frequent between Days 1 to 8 (39.3% of subjects) compared to Days 9 to 30 (27.1%).

Two (0.4%) subjects experienced a fatal TEAE (both considered to be not related to study treatment). A total of 14.6% of subjects reported SAEs and 12.7% of subjects had TEAE leading to discontinuation from treatment (events were most frequently within the SOC of psychiatric disorders). Treatment-related SAEs were reported for 8.1% of subjects.

Injection site pain, which was reported for 17.1% of subjects during the first week of treatment, decreased to a frequency of 1.3% of subjects from Days 9 to 30. The following injection site reactions were reported during the first week of treatment but were absent for the remainder of the first month of treatment: injection site swelling (1.2% of subjects), injection site oedema (0.4%), and injection site erythema, injection site haematoma, injection site irritation, and injection site nodule (each reported for single subjects [0.2%]). Injection site rash was reported for a single subject (0.2%) during the period from Days 9 to 30.

Prolactin-related TEAEs were reported for 11.9% of subjects. Such events were more frequent for women (25.6%) compared with men (4.7%). The most frequently reported prolactin-related TEAEs were amenorrhoea (11.1% of subjects) and menstrual disorder (5.6%) among women and sexual dysfunction among men (2.1%). Glucose-related TEAEs were infrequent (0.6%).

A total of 269 extrapyramidal symptom TEAEs were reported among 31.3% of subjects; most frequently akathisia (13.4%), tremor (6.3%), and restlessness (5.0%). The majority of extrapyramidal symptoms TEAEs were mild and severe extrapyramidal symptoms were infrequently reported (3 subjects) and restricted to akathisia (no event of akathisia was serious and only 3 [0.6%] subjects discontinued

treatment prematurely due to akathisia). The frequency of extrapyramidal symptom TEAEs was somewhat higher from Days 9 to 30 (5.6% of subjects receiving concomitant antipsychotics and 4.2% of subjects who were not receiving concomitant antipsychotics) compared to the first week of treatment (3.8% of subjects receiving concomitant antipsychotics and 2.7% of subjects who were not receiving concomitant antipsychotics). No subject had a serious extrapyramidal symptom TEAE during the first month of treatment. Treatment-emergent extrapyramidal symptoms led to study discontinuation for 5 subjects during Days 9 to 30 (such events were not reported during the first week of treatment).

A total of 388 TEAEs were reported among 115 of the 191 subjects on a maintenance dose level of 150 mg eq (60.2%, events were most frequently psychiatric and nervous disorders). Extrapyramidal symptom TEAEs were reported for 7.7% of subjects. Serious extrapyramidal symptom TEAEs and extrapyramidal symptom TEAE leading to study discontinuation were not reported for any subject on a maintenance dose of 150 mg eq.

Small but statistically significant changes in CGI-MS were noted for Parkinsonism and akathisia (each reduced by 0.1 units).

Clinically relevant vital sign abnormalities were observed, but these are not considered to raise any safety concerns. However, weight gain represented an important TEAE and a statistically significant mean increase in body weight at the end of treatment of 3.91 (95% CI: 2.9 to 4.9) kg was demonstrated. A ≥7% increase from baseline weight was reported for 41.8% of subjects at Day 548.

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