2. SYNOPSIS

<table>
<tr><td>Name of Sponsor/Company:
Impax Pharmaceuticals, a Division of Impax Laboratories, Inc.</td><td rowspan="3">Individual Study Table Referring to Part of the Dossier
Volume:
Page:</td><td rowspan="3">(For National Authority Use Only)</td></tr>
<tr><td>Name of Finished Product:
IPX066</td></tr>
<tr><td>Name of Active Ingredient:
Carbidopa-Levodopa</td></tr>
<tr><td colspan="3">Title of Study: A Study to Evaluate the Safety and Efficacy of IPX066 in Advanced Parkinson’s Disease</td></tr>
<tr><td colspan="3">Principal Investigator: Robert A. Hauser, MD, Parkinson's Disease and Movement Disorders Center, University of South Florida, Tampa, FL
Investigators: 68 investigators</td></tr>
<tr><td colspan="3">Study center(s): A total of 68 centers in North America and Europe: 35 centers in the United States, 3 in Canada, 3 in France, 5 in Germany, 7 in Poland, 3 in Romania, 5 in Spain and 7 in Ukraine</td></tr>
<tr><td colspan="3">Publications (reference): Hauser RA, Nausieda P, Ondo W, Espay AJ, Hsu A, O’Connell M, Kell S, Gupta S. Double-blind, Controlled Trial of IPX066, a Novel Carbidopa-Levodopa Extended-Release Formulation, in Advanced Parkinson’s Disease (ADVANCE-PD Trial). 15th International Congress of Parkinson’s Disease and Movement Disorders, June, 2011, Toronto, Canada.</td></tr>
<tr><td colspan="2">Studied period (years):
Date first subject enrolled: 29 September 2009
Date last subject completed: 19 January 2011</td><td>Phase of development:
3</td></tr>
<tr><td colspan="3">Objectives: To evaluate the safety and efficacy of IPX066 in the treatment of advanced Parkinson’s Disease (PD) subjects in comparison to immediate-release (IR) carbidopa-levodopa (CD-LD).</td></tr>
<tr><td colspan="3">Methodology: This Phase 3 study was a randomized, double-blind, double-dummy, active-control, parallel-group study planned to compare the efficacy and safety of IPX066 to that of IR CD-LD in subjects with advanced PD patients with insufficient control of motor symptoms or motor fluctuations. Qualified subjects must have been maintained on a stable standard LD regimen with a total daily LD dose of at least 400 mg and a daily dosing frequency of at least four times, and experiencing at least 2.5 hours of “off” time per day during waking hours. Subjects entered a 3-week IR CD-LD treatment period to allow for dose adjustment of their IR CD-LD regimen, followed by a 6-week dose conversion to IPX066. Subjects were then equally randomized in a blinded fashion into one of two parallel treatment arms of either IPX066 or IR CD-LD. Following randomization, subjects entered a 13-week double-blind treatment period using the dosing regimen established at the end of Week 3 (Visit 2) for IR CD-LD and at the end of Week 9 (Visit 5) for IPX066.</td></tr>
<tr><td colspan="3">Number of patients (planned and analyzed):
Planned: Approximately 420 enrolled subjects, to have at least 350 randomized subjects.
Actual: 471 subjects were enrolled and 393 subjects were randomized.</td></tr>
</table>

Diagnosis and main criteria for inclusion:
Key inclusion criteria included: idiopathic PD per United Kingdom Parkinson's Disease Society Brain Bank Diagnostic Criteria; Hoehn and Yahr Staging I-IV in the "on" state; ≥30 years old at PD diagnosis, currently treated with stable levodopa (LD) regimen (LD ≥400 mg LD/day, dosed ≥ 4 times/day and stable for ≥4 weeks at Screening); able to differentiate "on" state from "off" state with 75% concordance rate during training; averaging ≥2.5 hours "off" time at Visits 1 and ≥1 hour "off" each day based on 3 days of diary; able to properly complete diary, had predictable "off" periods ("yes" to Question #36 on the Unified Parkinson's Disease Rating Scale [UPDRS]).

Test product, dose and mode of administration, batch number:
The test product in this study was IPX066, an extended-release CD-LD (1:4 ratio) capsule formulation to be taken orally. Doses of IPX066 were individually titrated during the open label Dose-Conversion period based on efficacy and tolerability to maximize clinical benefit. Subjects randomized to IPX066 during the double-blind Maintenance period received IPX066 (plus placebo matching IR CD-LD).

IPX066 was provided in 4 dosing strengths with the following lot numbers:

- IPX066 23.75–95 mg CD-LD capsules (IPX066 95 mg): RB09030-120, RB09042-120, RB10003-120, RB10010-120
- IPX066 36.25–145 mg CD-LD capsules (IPX066 145 mg): RB09029-120, RB09029A-120, RB09041-120, RB10004-120
- IPX066 48.75–195 mg CD-LD capsules (IPX066 195 mg): RB09028-120, RB09028A-120, RB09040-120
- IPX066 61.25–245 mg CD-LD capsules (IPX066 245 mg): RB09027-120Placebo capsules were provided during the double-blind period for the 4 dosing strengths of IPX066, with the following lot numbers:
- IPX066 95 mg: RB09025-120
- IPX066 145 mg: RB09023-120
- IPX066 195 mg: RB09021-120
- IPX066 245 mg: RB09024-120

Duration of treatment: This 22-week study included three treatment periods: open label IR CD-LD Dose Adjustment (3 weeks); open label IPX06 Dose Conversion (6 weeks); and double-blind IPX066 or IR CD-LD Maintenance (13 weeks).

Reference therapy, dose and mode of administration, batch number:
IR CD-LD was the reference therapy in this study. Doses of IPX066 were individually titrated during the open label Dose-Conversion period based on efficacy and tolerability to maximize clinical benefit. Subjects randomized to IR CD-LD during the double-blind Maintenance period received IR CD-LD (plus placebo matching IPX066).

IR CD-LD (Sinemet Plus, Nacom) was provided in 25-100 mg capsules, with the following lot numbers: RB09031-200, RB09047-200, RB10009-200.

Placebo capsules were provided during the double-blind period for the 4 dosing strengths of IPX066 and the IR CD-LD, with the following lot numbers: IR CD-LD: RB09037-200A, RB09037A-200.

Criteria for evaluation:

Efficacy:

Primary efficacy:

- Baseline-adjusted "off" time (derived from the PD Diary) as a percentage of waking hours at the end of study (EOS).

Secondary efficacy:

- Responder analysis: Proportion of subjects with at least 1 hour improvement in "off" time from Baseline (primary responder analysis), as well as 0.5, 1.5, 2, and 3 hour improvements
- Baseline-adjusted "off" time as a percentage of waking hours at Visits 6, 7 and 8
- Baseline-adjusted total "off" time at EOS and Visits 6, 7 and 8
- Baseline-adjusted total "on" time with no troublesome dyskinesia (defined as "on" time with no or non-troublesome dyskinesia) at EOS and Visits 6, 7 and 8
- Baseline-adjusted total "on" time with troublesome dyskinesia at EOS and Visits 6, 7 and 8
- Baseline-adjusted UPDRS Parts II + III, Parts I + II + III, Total UPDRS Part I, UPDRS Parts II, III and IV, as well as Part II assessed for the "off" state, at EOS and Visits 6, 7 and 8
- Patient Global Impression (PGI) and Clinical Global Impression (CGI) at EOS, examined as continuous variables and as percentage of subjects improved

Exploratory efficacy:

- Morning effectiveness: the percentage of subjects "on" immediately after morning awakening, the time from awakening to first "on" episode, and the duration of the first "on" episode after morning awakening
- Reduction in fluctuations: the number of fluctuations experienced on a daily basis, with a fluctuation defined as any change from "off" to "on" state or from "on" to "off" state

Quality of life, sleep, disability and functional ability:

- Baseline-adjusted Parkinson's Disease Questionnaire-39 (PDQ-39) and subscores at EOS
- Baseline-adjusted Scales for Outcomes in Parkinson's Disease-Sleep Scale (SCOPA-S) and subscores at EOS
- Baseline-adjusted Modified Rankin Scale (mRS) at EOS
- Baseline-adjusted Measure of Health Status from EuroQoL Group (EQ-5D) at EOS
- Baseline-adjusted Health Survey Questionnaire (SF-36 v2 Acute), subscales and summary scores at EOS

Safety:

- Treatment-emergent adverse events (AEs), actively solicited and collected as reported by the subject throughout the study.

- Clinical safety laboratory tests–Screening, Visits 5 and 8
- Vital signs including blood pressure, heart rate, temperature, and respiratory rate after supine for 5 minutes, as well as blood pressure and heart rate after standing for 2 minutes–Screening, Baseline, Visits 2, 3, 4, 5, 6, 7 and 8
- 12-Lead electrocardiogram (ECG)–Screening, Visit 8
- Modified Minnesota Impulsive Disorders Interview (m-MIDI) and scoring sheet–Screening, Visits 5, 6 and 8
- Physical examination–Screening, Visit 8
- Concomitant medications–throughout the study

Statistical methods:

Efficacy:
The efficacy analysis set for each study period (open label IR CD-LD Dose Adjustment, open label IPX066 Dose Conversion and double-blind Maintenance) included all subjects who entered that period (e.g., the efficacy analyses for the double-blind Maintenance period included all randomized subjects). Data from subjects who withdrew after randomization but before completing 13 weeks of double-blind treatment were included in the analyses at EOS, using a last observation carried forward (LOCF) approach, and were treated as non-responders in the responder analysis. An EOS measurement was defined as any measurement collected at Visit 8 or, if the subject terminated the trial after randomization and there was no Visit 8 measurement, the last blinded measurement collected within 3 days after the last dose.

Analysis for the primary efficacy measurement used a two-factor main effects Analysis of Covariance (ANCOVA) model with treatment and centers as factors and the percent of "off" time during waking hours at Baseline as a covariate. For continuous secondary endpoint variables, similar analyses were conducted. By definition, CGI and PGI encompass change, so no Baseline adjustment was necessary. Categorical variables were examined using Cochran-Mantel-Haenzel chi-squared techniques. Rather than adjusting significance levels, the issue of multiple comparisons was addressed by analyzing efficacy in a hierarchical manner.

Safety:
The Safety Analysis Set included all subjects who received at least one dose of study drug during the Dose-Adjustment period of the trial. Safety results were reported separately for each portion of the trial (open label IR CD-LD Dose Adjustment, open label IPX066 Dose Conversion, and double-blind Maintenance periods). Reported AEs were coded to standard terms using the Medical Dictionary for Regulatory Activities (MedDRA), version 12.1.

Treatment-emergent AEs were tabulated, as were laboratory test data, findings of physical examinations, vital signs, ECG results and concomitant medications. Treatment-emergent AEs were defined as AEs that started after the first dose of study treatment was administered or within 72 hours after the last dose of study treatment was administered; this was done because patients were likely to alter their dopaminergic medications soon after discontinuing study treatment. No hypothesis testing was performed on the safety data. For completeness, AEs that occurred at any time during the study are included in the posttext listings.

SUMMARY – CONCLUSIONS

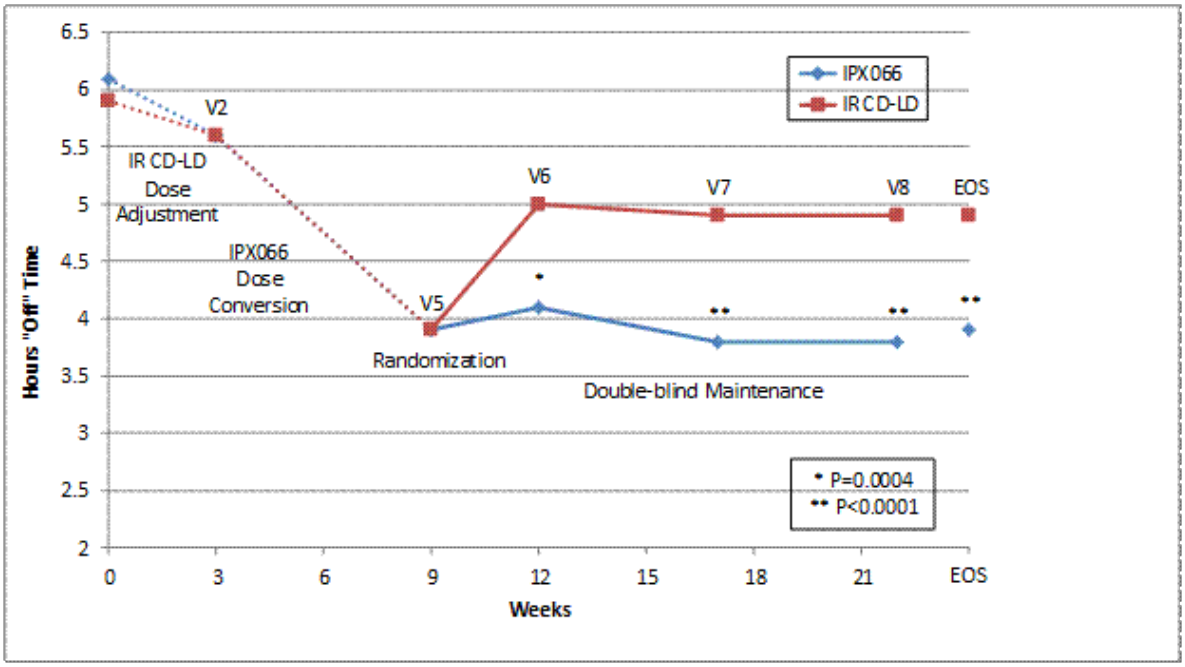
EFFICACY RESULTS:

Demographics:
The demographics of the two randomized treatment groups were similar. The mean age of all subjects enrolled in the study was 63.5 years (range 40-90 years), 62.0% of enrolled subjects were male, and the mean duration of PD at enrollment for randomized subjects was 7.42 years (range 0.5-29.0 years). For randomized subjects, the mean baseline Total UPDRS score was 39.28±15.50, with a combined Part II + Part III score of 32.37±14.81, baseline "off" time averaged 5.97±2.12 hours, and mean time "on" with troublesome dyskinesia was 0.36±0.96 hours. Compared with subjects who were randomized, dropouts during the open label Dose-Adjustment and Dose-Conversion periods tended to be older and female, taking higher total daily doses of IR CD-LD at Screening at higher frequencies and had longer durations of PD.

PD Diary:
The primary efficacy endpoint, baseline-adjusted off time as a percent of waking hours, demonstrated a significant improvement for IPX066 compared with IR CD-LD ($P<0.0001$), with improvement from 36.88% to 23.82% with IPX066 and from 35.99% to 29.79% with IR CD-LD. These differences represent a mean reduction of 35.4% in the percentage "off" time during waking hours with the IPX066 treatment compared to 17.2% with the IR CD-LD treatment.

Mean "off" time in subjects randomized to IPX066 (n = 201) decreased from 6.05 to 5.62 hours after open-label dose adjustment of IR CD-LD, and further decreased to 3.89 hours at the end of open-label dose conversion to IPX066, an improvement of 2.16 hours from Baseline (Figure 1). The mean "off" time in subjects randomized to IR CD-LD (n = 192) decreased from 5.89 to 5.64 hours after open-label dose adjustment of IR CD-LD, and further decreased to 3.87 hours at the end of open-label dose conversion to IPX066. At the end of the 13-week double blind Maintenance period, mean "off" time was 3.87 hours for IPX066 and 4.88 hours for IR CD-LD.

Figure 1: Mean "Off" Time by Visit for Randomized Subjects (N = 393) in Study IPX066-B09-02



Abbreviations: IR CD-LD = immediate-release carbidopa-levodopa; V = Visit; EOS = End of Study.
Number of values at each visit (IPX066/IR CD-LD): V1, V2, V5 = 201/192; V6 = 188/186, V7 = 188/183, V8 = 185/181, EOS = 201/192
Source: Table 14.2.1.1-3.

The difference in "off" time was primarily related to an increase in time "on" without troublesome dyskinesia. The mean "on" time without troublesome dyskinesia increased 1.88 hours in the IPX066 group compared to an increase of 0.81 hours in IR CD-LD group (p=0.0002). The mean increase in "on" time with troublesome dyskinesia at EOS was similar (mean increase of 0.15 and 0.10 hours for IPX066 and IR CD-LD, respectively, p = 0.6047). There were no significant changes in time asleep.

In the responder analysis, the results were significant at each level of improvement ($P \leq 0.0034$). In the protocol-specified analysis of improvement by at least 1 hour, there were 127 (63.2%) responders in the IPX066 group compared to 87 (45.3%) responders in the IR CD-LD group ($P<0.0001$).

UPDRS:
For randomized subjects, the UPDRS Part II plus Part III at Baseline had a mean of approximately 32 units for each group, improved approximately 1 to 2 units during Dose Adjustment, and then further improved by about 4.5 to 5.5 units at the end of IPX066 Dose Conversion. This improvement was maintained through the double-blind portion of the trial for the IPX066 group (scores of approximately 26-27 units), while the IR CD-LD group values reverted, although not completely, back toward baseline (scores of approximately 29-30 units) by the first postrandomization time point, and the reversion toward Baseline continued for the remainder of the trial. The difference between IPX066 and IR CD-LD in UPDRS Part II plus Part III was significant at all postrandomization time points (EOS, $P<0.0001$; Visits 6, 7 and 8, all $P \leq 0.0019$).

The improvement in UPDRS Part II plus III is consistently seen in the other UPDRS measures defined

for this study: statistically significant (P<0.05) differences between treatments at EOS were seen for Parts I + II + III, Total UPDRS, Part I, Part II and Part III, and Part II also significantly improved in the "off" state. There was no significant difference (all P>0.082) between treatments at any time point for UPDRS Part IV.

PGI and CGI:
In both PGI and CGI at EOS, there was an overall significant difference between treatments (P<0.0001) in favor of IPX066. The mean PGI value for the IPX066 group at EOS was 4.9, compared with a mean of 4.1 for the IR CD-LD group. In the IPX066 group, 77 subjects (38.5%) reported their condition as much or very much improved, compared with 33 subjects (17.4%) in the IR CD-LD group. Conversely, 70 subjects (37.0%) in the IR CD-LD group rated their condition as worse (minimally, much, or very much worse), compared with 38 subjects (19.0%) in the IPX066 group. The CGI demonstrated a similar pattern of improvement with clinicians rating 40% of randomized subjects in the IPX066 group as much or very much better than Baseline, compared to 13.7% in the IR CD-LD group.

Exploratory:
Exploratory analyses of the PD Diary data showed that IPX066 provided a significant reduction in the number of fluctuations ("off" to "on" state or "on" to "off" state, P<0.0001). Without rescue levodopa, the percentage of awakenings in the "on" state and the time to the first "on" episode after awakening with IPX066 were not significantly different than with IR CD-LD. In addition, the IPX066 group had a significantly longer first "on" episode of the day after awakening, compared with IR CD-LD.

Quality of Life, Sleep, Disability and Functional Ability:
While in general, the quality of life and related measures (PDQ-39, SCOPA-S, mRS, EQ-5D and SF-36) were consistently numerically superior for IPX066 compared with IR CD-LD, only the differences in PDQ-39 (P=0.0345 for Total PDQ-39, P=0.0017 for Mobility subscore) and mRS (P=0.0061) were statistically significant at EOS.

Dosing:
In this study, the observed median total daily LD dose of IPX066 was approximately 1.8 times the dose of IR CD-LD (1365 mg vs. 750 mg), and IPX066 was dosed less frequently than IR CD-LD in this study: mean of 3.6 vs. 5.1 doses per day. Although levodopa concentrations were not measured in this study, by adjusting for reduced bioavailability of IPX066 (70% relative to IR CD-LD), the total daily systemic exposure of LD (AUC) with IPX066 treatment is estimated to be approximately 27% higher than that of IR CD-LD. However, the peak concentration of LD from IPX066 is estimated to be similar or slightly lower than that from IR CD-LD treatment.

SAFETY RESULTS:

All Adverse Events:

- During the 13-week double-blind Maintenance period, the overall AE reporting rates were similar between the two groups (43.3% for IPX066, 39.6% for IR CD-LD). Adverse events reported by at least 2% of the IPX066 group during Maintenance (all ≤3.5%) were: insomnia, nausea, falls, dizziness, dyskinesia, diarrhea, weight decreased, oedema peripheral, upper respiratory tract infection, urinary tract infection and sleep disorder. For the IR CD-LD group, AEs reported by at least 2% of subjects during Maintenance (all ≤2.6%) were: depression, falls, peripheral oedema, upper respiratory tract infection,

urinary tract infection, sleep disorder, back pain, arthralgia and vomiting.

- During the 6-week IPX066 Dose-Conversion period, 45.8% of subjects reported an AE. Adverse events reported by at least 2% of subjects during Dose Conversion (all ≤5.6%) were: dyskinesia, nausea, headache, dizziness, "on/off" phenomenon, dry mouth, falls, anxiety and insomnia.
- During the 3-week IR CD-LD Dose-Adjustment period, 17.0% of enrolled subjects reported an AE. No AE was reported by more than 2% of subjects; the most frequently reported AE was headache (1.3%), followed by nausea, falls, back pain and somnolence (each reported by 0.8%).

Serious Adverse Events:

- Overall, more subjects reported serious adverse events (SAEs) during IPX066 treatments than during IR CD-LD treatments, but there was no consistent pattern or treatment-associated trend in any single SAE.
- During Maintenance, 13 SAEs were reported by a total of 11 subjects (5.5%) in the IPX066 group, only one of whom had SAEs (anxiety and acute psychosis) assessed as being related to study drug. In the IR CD-LD group, 5 subjects (2.6%) reported 8 SAEs, only one of whom had SAEs (atrial fibrillation, pneumonia and respiratory failure) judged by the Investigator to be related to therapy. No single SAE was reported by more than one subject during Maintenance.
- During the 6-week Dose Conversion, 22 SAEs were reported by 14 subjects (3.1%), including 2 deaths. Both deaths were reported as unrelated to study treatment (renal failure in a 74-year-old male with a history of nephrectomy and chronic pyelonephritis, and sudden death in a 70-year-old male with a history of aortic stenosis and hypertension). Except for gait disturbance, non-cardiac chest pain and dyskinesia, each SAE occurred in a single subject. Six subjects had SAEs that were classified as being related to study drug: 2 subjects with gait disturbance, 2 subjects with dyskinesia, 1 subject with overdose and 1 subject with acute psychosis.
- During the 3-week Dose-Adjustment period, 2 subjects (0.4%) reported SAEs, only one of which (hypertension) was considered by the Investigator to be related to study treatment.

Adverse Events Contributing to Withdrawal from Study:

- During double-blind Maintenance, a total of 6 subjects discontinued due to 7 AEs (3 subjects in each dose group, 1.5%), but none of these discontinuation AEs were reported by more than one subject: nausea, acute psychosis, and (in a single subject) anxiety and obsessive-compulsive disorder in the IPX066 group; and dyspepsia, subdural hematoma and delusion in the IR CD-LD group.
- During IPX066 Dose Conversion, 23 subjects (5.1%) discontinued due to AEs. The most common AEs leading to discontinuation during Dose Conversion (all <1%) appeared to be related to the dopaminergic effects of therapy or to PD itself: nausea, dizziness, dyskinesia, "on/off" phenomenon, anxiety and visual hallucinations.

- During IR CD-LD Dose Adjustment, 3 subjects (0.6%) discontinued due to 3 AEs: oedema peripheral, dyskinesia and cholelithiasis.

No clinically significant between-treatment-group differences, patterns of abnormal trends, or between-visit changes were observed for any of the hematology or blood chemistry parameters, vital signs or ECG results throughout the study.

CONCLUSIONS:

- IPX066 was statistically significantly superior over IR CD-LD:
  - in reducing "off" time with a corresponding increase in "on" time without troublesome dyskinesia.
  - in improving PGI and CGI.
  - in improving UPDRS Parts II+III, as well as individual Parts I, II and III
- The "on" time with troublesome dyskinesia and time asleep were not statistically significantly different between the two treatments.
- Subjects showed statistically significant improvement in Modified Rankin Scale and PDQ-39 (Total Score and Mobility subscore) with IPX066 compared with IR CD-LD. There were no statistically significant changes in SCOPA-S, EQ-5D or SF-36.
- In this study, IPX066 was dosed less frequently than IR CD-LD (mean of 3.6 vs. 5.1 doses/day).
- All Adverse Events:
  - During the 13-week direct comparison of the two treatments under double-blind conditions, the overall AE reporting rates were similar between the two groups (43.3% for IPX066, 39.6% for IR CD-LD). Adverse events reported by at least 2% of the IPX066 group during Maintenance (all ≤3.5%) were: insomnia, nausea, falls, dizziness, dyskinesia, diarrhea, weight decreased, oedema peripheral, upper respiratory tract infection, urinary tract infection and sleep disorder. For the IR CD-LD group, AEs reported by at least 2% of subjects during Maintenance (all ≤2.6%) were: depression, falls, peripheral oedema, upper respiratory tract infection, urinary tract infection, sleep disorder, back pain, arthralgia and vomiting.
  - During the 6-week IPX066 Dose-Conversion period, 45.8% of subjects reported an AE. Adverse events reported by at least 2% of subjects during Dose Conversion (all ≤5.6%) were: dyskinesia, nausea, headache, dizziness, "on/off" phenomenon, dry mouth, falls, anxiety and insomnia.
  - During the 3-week IR CD-LD Dose-Adjustment period, 17.0% of enrolled subjects reported an AE. No AE was reported by more than 2% of subjects; the most frequently reported AE was headache (1.3%), followed by nausea, falls, back pain and somnolence (each reported by 0.8%).
- Serious Adverse Events:
  - Overall, more subjects reported SAEs during IPX066 treatments than during IR CD-

LD treatments, but there was no consistent pattern or treatment-associated trend in any single SAE.

  - During Maintenance, 13 SAEs were reported by a total of 11 subjects (5.5%) in the IPX066 group and 8 SAEs were reported by 5 subjects (2.6%) in the IR CD-LD group. No single SAE was reported by more than one subject during Maintenance.
  - During IPX066 Dose Conversion, 22 SAEs were reported by 14 subjects (3.1%), including 2 deaths. Both deaths were reported as unrelated to study treatment (renal failure in a 74-year-old male with a history of nephrectomy and chronic pyelonephritis, and sudden death in a 70-year-old male with a history of aortic stenosis and hypertension). Each SAE (except for gait disturbance, non-cardiac chest pain and dyskinesia) occurred in a single subject.
  - During IR CD-LD Dose Adjustment, 2 subjects (0.4%) reported 3 SAEs.

- Adverse Events Contributing to Withdrawal from Study:
  - A total of 6 subjects discontinued due to AEs during double-blind Maintenance (3 subjects in each dose group, 1.5%), but none of these discontinuation AEs were reported by more than one subject: nausea, acute psychosis, and (in a single subject) anxiety and obsessive-compulsive disorder in the IPX066 group; and dyspepsia, subdural hematoma and delusion in the IR CD-LD group.
  - During IPX066 Dose Conversion, 23 subjects (5.1%) discontinued due to AEs. The most common AEs leading to discontinuation during Dose Conversion (all <1%) appeared to be related to the dopaminergic effects of therapy: nausea, dizziness, dyskinesia, “on/off” phenomenon, anxiety and visual hallucinations.
  - During IR CD-LD Dose Adjustment, 3 subjects (0.6%) discontinued due to AEs: oedema peripheral, dyskinesia and cholelithiasis.
- No clinically significant between-treatment-group differences, patterns of abnormal trends, or between-visit changes were observed for hematology or blood chemistry parameters, vital signs or ECG results throughout the study.
- The results of this study were clinically important to these subjects with advanced PD. Significantly more IPX066 subjects rated themselves much or very much improved.

In this study, IPX066 demonstrated statistically and clinically significant improvement over IR CD-LD therapy.

Date of the report: 23 November 2011