Background

OFF episodes in PD are a significant challenge for patients and their caregivers. International Congress of Parkinson’s Disease and Movement Disorders (ICP) guidelines recommend treatment for OFF episodes with apomorphine (APL) 

Methods

METHODS

• Open label, single arm, Phase 2 trial
• Last dose of levodopa (LD) taken earlier than 10 PM the night prior
• Patients presented to clinic at 4 AM, without taking any LD dose in the previous 4 hours
• APL at 25 mg was administered sublingually, and assessments were conducted 30 minutes post dose
• If the patient did not turn ON, 10 mg of LD (DDD) was given to verify the full ON response, lower than that which was observed with APL

Results

RESULTS

• Mean # of PD Medications, mean (range)
• Modified Hoehn and Yahr, [Screening Visit], mean (SD)
• UPDRS Part III, [OFF], mean (SD)
• UPDRS Part III, [Screening Visit], mean (SD)
• UPDRS Part III Change for Responders

Mean Dose: 18.4 mg

Figure 3: APL-30277 Dose Distribution at First Full ON (Responders)

Table 1: Demographics and Baseline Characteristics

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Figure 4: Pharmacokinetics/Pharmacodynamics: Mean Dose-Response

Figure 5: MDS-UPDRS Part III Change for Responders vs. Non-Responders

CONCLUSIONS

• On average, a minimum apomorphine concentration of 2.64 ng/mL was needed to turn on a patient Fully ON, lower than that which was previously reported.
• Plasma levels above this minimum efficacious concentration resulted in sustained improvements in motor function and ON time.
• Responders had large, clinically meaningful MDS-UPDRS Part III changes at all time-points while the non-responders had a similar motor improvement, but not enough to convert from OFF to Full ON.

Figure 6: Pharmacokinetics/Pharmacodynamics: Mean Apomorphine Plasma Concentration

ACKNOWLEDGEMENTS/DISCLOSURES

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Figure 2: Study Design

Figure 1: Apomorphine Sublingual Film (APL-30277)

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Figure 3: Responders, time and response to Duration of

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