Baseline Disease Severity Not Predictive of Sublingual Apomorphine (APL-130277) Dose Needed to Convert a PD Patient from the OFF to ON State

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BACKGROUND
- Up to 2/3rds of Parkinson’s disease (PD) patients suffer from OFF episodes including:
  - Wearing OFF
  - Morning akinesia
  - Delayed/no-ON and sudden OFF
- OFF episodes in PD have a significant negative impact on quality of life of patients
- APL-130277 is a soluble, sublingual film strip of apomorphine (Figure 1)

OBJECTIVE
Evaluate whether baseline PD disease severity predicted the effective dose of APL-130277

METHODS
- Open-label, single-arm, Phase 2 study
- Patients took their last dose of levodopa (LD) no later than 10 PM the night prior and presented to clinic in a.m. without taking usual morning dose of LD and other PD meds
- Baseline disease severity does not predict the effective dose needed to turn OFF episodes in PD have a significant negative impact on quality of life of patients
- APL-130277 was administered sublingually and allowed to dissolve over 2 minutes
- Patients could be dosed up to two times/day over 3 days
- Pre-treatment with trimethobenzamide (anti-emetic) was started 3 days prior to initiation of APL-130277 and was continued during its dosing
- MDS-UPDRS Part III and assessment of OFF/ON were conducted pre-dose and at 15, 30, 45, 60 and 90 mins after APL-130277 administration

RESULTS
- % of patients fully ON at each time point
- Change and % change in MDS-UPDRS Part III over time
- R² = 0.1277
- R² = 0.1338
- R² = 0.0544

CONCLUSIONS
- APL-130277 rapidly converts PD patients from the OFF to the ON state.
- Baseline disease severity does not predict the effective dose needed to turn an OFF patient ON.
- PD patients should be titrated starting with the lowest possible dose.

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APL-130277 is currently an investigational product.