Turn a Patient with Parkinson’s Disease from an OFF State to Fully ON

**METHODS**

- **Background:** Parkinson’s disease (PD) patients suffer from ON/OFF episodes, including: wearing OFF, morning awareness, delayed/ON and sudden OFF

- **OFF episodes in PD have a significant negative impact on QoL.**

- **APL-130277 studied: single, sublingual/liquid film of apomorphine**

- **OBJECTIVE:**

  Evaluate if any differences exist in the efficacy of APL-130277 doses to turn a patient with PD from OFF to Fully ON based upon subgroup analyses.

- **METHODS**

  - **Open-label, single-arm, Phase 2 study**

  - **Pre-treatment with trimethobenzamide (anti-emetic) started 3 d prior to initiation of APL-130277 administered sublingually and allowed to dissolve over 2 mins

  - **APL-130277 administration:**

    - **Last dose of levodopa (LD) taken no later than 10 PM the night prior

    - **Atypical/secondary forms:**

    - **Patients:**

      - **PD (H&Y score 1-3 in ON state); no atypical/secondary forms

      - **Patients who had not turned ON with 25 mg**

        - **received 30 mg**

        - **Patients who had not turned ON with 15 mg**

          - **received 20 mg**

          - **Patients who had not turned ON with 10 mg**

            - **received 25 mg**

            - **If the patient did not turn ON within 3 hrs of dosing, the patient received 25 mg**

            - **If did not turn ON within 3 hrs of dosing, the patient received 15 mg**

            - **Patients who had not turned ON with 20 mg**

              - **received 25 mg**

              - **Patients who had not turned ON with 15 mg**

                - **received 20 mg**

                - **Patients who had not turned ON with 25 mg**

                  - **received the same dose**

                  - **Day 3:** patients who turned ON with either 20 or 25 mg received the same dose

                  - **>1 OFF episode/d and > 2 hrs of daily OFF time

- **RESULTS**

  - **Responders – includes 15 patients who turned Fully ON post APL-130277 treatment**

  - **Modified Intention to Treat (mITT) – includes 19 patients dosed**

  - **Adverse events (AEs):**

    - **Most common AEs were dizziness (36.8%), somnolence (31.6%) and nausea (21.1%)**

  - **Safety Assessments/Endpoints (Hauser R et al.  Movement Disorders.  2016 In Press)**

    - **Primary Efficacy Endpoint:**

      - (excludes 3 patients who were improperly instructed to swallow the strip and 1 patient who may not have received any form of apomorphine within 30 d of dosing Day 1)

      - **Per Protocol (PP) – includes 15 patients with no protocol dosing violations**

    - **CONCLUSIONS**

      - **APL-130277 converts patients with PD from OFF to Fully ON, regardless of patient demographics or disease characteristics**

      - **Phase 3 studies are ongoing to further evaluate efficacy and safety of APL-130277.**

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APL-130277 is currently an investigational product.