In Parkinson's disease, adverse events (AEs) and upper respiratory tract infections (URIs) are common side effects of treatment. The levodopa (LD) drug Inbrija is an inhaled levodopa formulation designed to reduce the need for oral LD therapy. This study compares the safety and efficacy of Inbrija with placebo in patients with Parkinson's disease (PD) and OFF periods.

The Study Design

- **Study Type:** Pivotal phase 3 double-blind, placebo-controlled study
- **Study Name:** SPAN-PD Efficacy and Safety Study
- **Study Duration:** 12 months
- **Study Population:** PD patients with OFF periods
- **Inclusion Criteria:**
  - Treatment Options
  - Parkinson's Disease and OFF Periods
  - SPAN-PD Efficacy and Safety Study
- **Endpoints:**
  - Safety and Tolerability of Inbrija
  - Change in Unified Parkinson's Disease Rating Scale (UPDRS) Part III (motor) score

The study was conducted in a clinical trial setting, with subjects randomized to receive Inbrija 60 mg or 84 mg or placebo. The primary endpoint was change in UPDRS Part III score at week 12, measured both by clinic visit and by PD diary.

### Results

- **Safety Profile:**
  - Drug-related adverse events (AEs) were reported in 94.2% of the Inbrija groups and 87.4% of the placebo group.
  - The most common AEs were generally assessed as mild or moderate in intensity.
  - Drug-related cough was the most common AE, seen in 14.8% of the Inbrija 84 mg group and 1.8% of the placebo group.

- **Pharmacokinetic Evaluation:**
  - Levodopa plasma concentration variability among subjects was low, suggesting consistent delivery of the drug.

- **Pulmonary Function:**
  - Declines in pulmonary function observed over 12 months were relatively small, with no consistent, notable changes in chronic pulmonary safety as assessed by spirometry.

### Conclusion

Inbrija does not replace regular oral levodopa therapy but can be used as an adjunct to oral levodopa to reduce OFF periods. It is well-tolerated, with a safety profile similar to placebo, and provides a convenient, portable treatment option for patients with PD.

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**Table 1: Key In Vitro Clinical Trials**

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<th>Study Type</th>
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<th>Study Population</th>
<th>Major Selection Criteria</th>
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