Levodopa Cyclops® for treatment of OFF episodes in Parkinson's Disease

PureIMS offers **Levodopa Cyclops®** for licensing; a levodopa pre-filled dry powder inhaler for the treatment of Parkinson's Disease patients suffering from OFF episodes.
PureIMS is a clinical-stage pharmaceutical company focused on developing and commercializing innovative inhaled therapies for the treatment of systemic and respiratory diseases with significant unmet medical needs.

Levodopa

Levodopa has been used as maintenance treatment for Parkinson's disease (PD) for over 50 years and remains the most effective therapy available. However, OFF episodes continue to present a serious burden and remain a substantial unmet medical need.
Patients with OFF episodes need rescue therapy to be able to participate in daily activities. Rescue therapies augment maintenance therapies and are intended to provide rapid and predictable relief.

Major unmet medical needs in PD patients:

- OFF episodes in mid- and late-stage PD patients.
- No immediate relief nor easy-to-use treatment modalities available.

Levodopa Cyclops®

Cyclops®:

Cyclops® is a **credit card-size, easy-to-use, pre-filled, DPI** that PureIMS offers for high-dose drugs and emergency applications. For the treatment of OFF episodes Cyclops® versions for single-use or dual-use are available.

This patent-protected DPI can be produced cost-effectively because of its simple, yet sophisticated design. Upon inhalation it uses the patient's breath to disperse the dry powder into small particles appropriately sized for deep lung deposition and, if required, rapid absorption of the drug into the systemic circulation.
The Cyclops® attributes enable its **easy, hygienic and effective use** on a worldwide scale.
A Cyclops® application for the treatment of pulmonary *Pseudomonas aeruginosa* infections is on the market under a *named patient program* and is reimbursed.

Levodopa Cyclops®:

Levodopa Cyclops® offers Parkinson's disease patients with OFF episodes a rescue therapy enabling them to comfortably resume their daily activities.

Levodopa Cyclops® has clear advantages over Inbrija®:

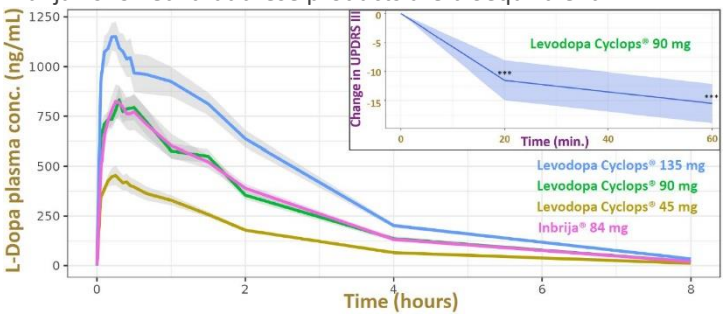
Easier handling and therefore much quicker to prime during OFF episodes (better compliance) ● less cough as side effect ● offering better pricing possibilities, generating a larger market share and higher reimbursement rates.

Levodopa Cyclops® also has important advantages compared to subcutaneous and sublingual apomorphine:

Apomorphine causes nausea and vomiting, necessitating regular use of anti-emetics ● sublingual apomorphine therapy induces serious tolerability issues in the oral cavity.

Clinical studies:

Studies showed that PD patients in an OFF episode can readily use Levodopa Cyclops®. Single doses up to and including 135 mg were well tolerated and therapeutic plasma concentrations were reached within minutes, with less variability and substantially faster than oral levodopa. All are prerequisites for rapid and predictable OFF episode relief.
A Phase II PoC study showed a significant and clinically meaningful improvement of MDS-UPDRS Part III motor score within 20 minutes and a head-to-head comparison with Inbrija® showed that these products are bioequivalent.



Regulatory:

FDA previously confirmed applicability of the 505(b)(2) registration route, and the above PK data indicate that a bioequivalence-based route is feasible. This route supports dossier submissions within 2.5 years or shorter (US). Also for Europe strategies for abbreviated registration routes have been developed.

Manufacturing and IP Protection

PureIMS has a GMP manufacturing facility licensed to produce Cyclops® IMPs. Cyclops® for single use is IP-protected until at least 2035. Patents for dual and multiple use Cyclops® versions have been filed mid-2023.

Contact

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