PureIMS has global rights to Levodopa Cyclops™, 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 and medication systems 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 and easy-to-use treatment modalities available.

Levodopa Cyclops™

Cyclops™:

Cyclops™ is an easy-to-use, pre-filled, disposable DPI that PureIMS offers for high-dose drugs and emergency applications.

This patent-protected DPI is cost-effective to produce 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 circulation. Cyclops™ has several advantages over standard-of-care products across key therapeutic areas. The above-mentioned attributes enable its hygienic and effective use on a worldwide scale. One application (Colistin Cyclops™) is available on the market under compassionate use regimen and is reimbursed.

Levodopa Cyclops™:

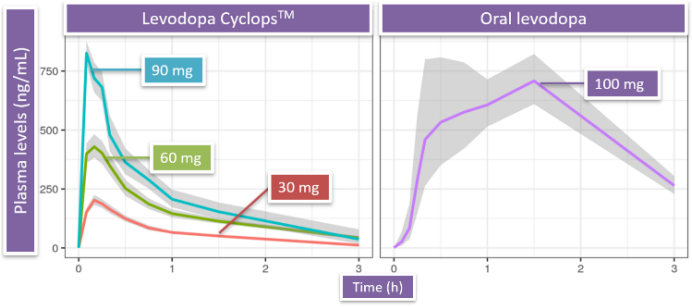
Levodopa Cyclops™ has clear advantages over Inbrija®: easier handling and therefore much quicker to prime during OFF-episodes (better compliance), a faster (< 20 minutes) and more consistent improvement of motor function, less cough as side effect and a higher drug load (98%). In addition, Levodopa Cyclops™ offers better pricing, 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. Additionally, sublingual apomorphine therapy induces serious tolerance issues in the oral cavity.

Clinical studies:

Studies showed that PD patients experiencing an OFF-episode can readily use Levodopa Cyclops™. Single doses of 30, 60 and 90 mg were well tolerated.

Inhaled doses resulted in a much shorter time to maximum plasma concentration and less variability than oral levodopa, both of which are prerequisites for rapid and predictable OFF-episode relief. A Phase II PoC study showed a significant ($P < 0.001$) and clinically meaningful change in MDS-UPDRS Part III motor score within 20 minutes.



Regulatory:

The FDA confirmed applicability of the 505(b)(2) regulatory pathway thus opening a fast development route to market authorization for Levodopa Cyclops™ within 3 years.

Manufacturing and IP Protection

PureIMS has a GMP manufacturing facility licensed for the production of Cyclops™ IMPs. Cyclops™ is IP-protected until 2034.

Contact

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