PureIMS, a pharmaceutical company based in Roden - The Netherlands, has developed a proprietary, innovative platform for effective, safe and very convenient inhaled delivery of high-dose dry powders. This technology, called Cyclops™, is under a partnering/license arrangement available for pharma/biotech partners, thus supporting the development of a Cyclops™-based inhalation route for their drug of choice. PureIMS's Cyclops™-based internal pipeline programs are also available for partnered development & commercialization.

PUREIMS

Cyclops™

Device:

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

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 circulation. Cyclops™ has several advantages over standard-of-care products across key therapeutic areas.

The above-mentioned attributes enable its easy, hygienic and effective use on a worldwide scale.

A Cyclops™ application for the treatment of CF is on the market under a *named patient program* and is reimbursed.

Attributes:

Easy-to-use ● easy-to-carry around ● easy-to-actuate ● pre-filled ● disposable ● optimal performance with every dose ● hygienic ● no need for cleaning and disinfection ● moderate to high resistance inhaler ● effective dispersion principle ● less cough ● dry powder formulation inside ● long shelf-life ● no cold chain required ● good distribution properties also in developing regions of the world ● simple inhalation instruction ● cost effective production ● scalable

Upon delivery to the (small) airways for:

Local use: High pulmonary concentrations ● low systemic exposure ● fewer side-effects

Systemic use: Fast absorption ● fast onset of clinical effect ● elegant needle-free alternative for injectable drugs ● no influence of food intake ● no hepatic first-pass metabolism

Lead Program - Levodopa Cyclops™

Product:

Levodopa Cyclops™ offers Parkinson's disease patients with OFF-episodes a rescue therapy allowing them to participate in daily activities. Rescue therapies augment maintenance therapies and are intended to provide rapid and predictable relief.

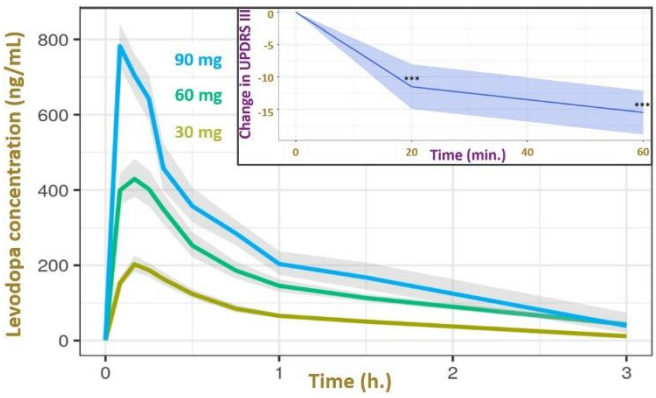
Levodopa Cyclops™ has clear advantages over Inbrija®: Easier handling and therefore much quicker to prime during OFF-episodes (better compliance) ● a faster and more consistent improvement of motor function ● less cough as side effect ● offers better pricing, generating a larger market share and higher 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 ● 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 and resulted in a much shorter time to maximum plasma concentration (< 10 min) 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 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 4 years.

Manufacturing and IP Protection

PureIMS has a GMP manufacturing facility licensed to produce Cyclops™ IMPs. Cyclops™ is IP-protected until at least 2035.

Contact

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