PureIMS has global rights to Tobramycin Cyclops™, a tobramycin pre-filled dry powder inhaler for the treatment of pulmonary Pseudomonas aeruginosa infections in cystic fibrosis. 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.

PUREIMS

Tobramycin

Tobramycin and colistin are effective antibiotics against *Pseudomonas aeruginosa* (Psa) and are, therefore, used to treat pulmonary Psa infections in cystic fibrosis (CF) and bronchiectasis (BE). Pulmonary Psa infection is associated with increased sputum production, more extensive bronchiectasis, more hospitalizations and reduced quality of life.

Tobramycin can be administered by inhalation or infusion, but the available inhalers are very burdensome to the patient, as is parenteral administration. This reduces patient adherence to therapy and ultimately therapeutic efficacy. Tobramycin Cyclops™ provides an answer to the problems associated with other tobramycin administration routes and devices.

In addition to Tobramycin Cyclops™ PureIMS also develops Colistin Cyclops™. This enables continuous alternating inhaled therapy between tobramycin and colistin from very similar easy-to-use inhalers for maximum patient friendliness.

Colistin Cyclops™

Cyclops™:

Cyclops™ is an easy-to-use, pre-filled, disposable dry-powder inhaler (DPI) that PureIMS develops 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.

Tobramycin Cyclops™:

Tobramycin Cyclops™ carries a formulation with a high drug load and has excellent *in vitro* performance. Tobramycin Cyclops™ has clear advantages compared to other treatments. It offers patients easier, faster and more convenient handling. Cleaning of the disposable Cyclops™ is not necessary.

Tobramycin Cyclops™ causes less side-effects (like coughing) compared to other inhalers, because of the lower, more efficient dose and higher resistance to air flow of Cyclops™. In addition, Tobramycin Cyclops™ is pre-filled and therefore does not require the sometimes complicated handling of capsules.

Clinical studies:

An open-label Phase 1 clinical trial with Tobramycin Cyclops™ has been conducted in BE patients. Single doses of 30, 60, 120 and 240 mg were well-tolerated and no serious adverse reactions occurred. Furthermore, hardly any cough was observed.
In addition, an open-label Phase 1 study with Tobramycin Cyclops™ in children with CF was completed very recently. Single doses of 30, 60 and 120 mg were investigated.

Regulatory:

Discussions with the EMA are ongoing to establish a clinical program for antibiotic drugs from Cyclops™. EMA endorses the necessity for new inhaled antibiotics.

Manufacturing and IP Protection

PureIMS has a GMP manufacturing facility licensed for the production of Cyclops™ IMPs. Cyclops™ is IP-protected until at least 2035.

Contact

www.pureims.com
Jeroen Tonnaer (CBDO)
T: +31 (0)50-205 3325
E: jtonnaer@pureims.com