PureIMS has global rights to Amikacin Cyclops®, an amikacin pre-filled dry powder inhaler for the treatment of tuberculosis and non-tuberculous mycobacterial (NTM) infections. 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.

Amikacin

Amikacin is an approved drug for the treatment of tuberculosis (TB) and non-tuberculous mycobacterial (NTM) infections. Aminoglycosides such as amikacin are active antimicrobial agents with a concentration-dependent killing pattern and amikacin is most active against *Mycobacterium tuberculosis* (Mtb). Amikacin is not absorbed via the gastrointestinal tract, which makes its oral administration impossible. Amikacin has been on the market for decades and clinical studies with inhaled amikacin for the treatment of NTM-infections proved its safety, tolerability and efficacy.

TB is the world's most common infectious disease causing an increasing number of deaths each year. TB is very contagious and transmitted by Mtb containing droplets formed in the upper airways through coughing, sneezing or even talking. Reducing the contagiousness of TB would be a major step towards treatment of this disease and limiting its societal impact. Especially multidrug-resistant (MDR) TB is very difficult to treat. The current first- and second-line treatments for MDR-TB are inadequate and inefficient.

Aim:

Amikacin Cyclops® as an add-on therapy to oral treatment with other anti-TB drugs aims to significantly reduce the time to sputum conversion (i.e. airway sterilization). This shortens the time during which patients are contagious, and hence, limits the spread of the disease. Shorter requirement for isolated treatment furthermore reduces treatment costs and social impact for the patient.

Amikacin Cyclops®

Cyclops®:

Cyclops® is a **credit card-size, easy-to-use, pre-filled, disposable dry powder inhaler (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.

Amikacin Cyclops®:

Amikacin Cyclops® carries a powder formulation with a high drug load and has excellent *in vitro* performance.

Use of Amikacin Cyclops® will result in higher local amikacin concentrations than conventional infusion or intramuscular injection. This could more rapidly decrease contagiousness by sterilizing the upper airways of patients with 'open' (smear positive) TB. In addition, Cyclops® offers TB patients an easier and much more convenient administration than infusion or injection.

A fast reduction of contagiousness and new, less toxic drug regimens with shorter duration, will prevent long hospital admissions and thereby help to control healthcare costs. This is highly desirable especially in high burden settings in low and middle-resource countries. The affordability of Amikacin Cyclops® will lead to a high accessibility and potentially millions of lives saved.

Clinical studies:

An open-label Phase 1 clinical trial with Amikacin Cyclops® in TB patients was recently completed. The objective of this study was to document pharmacokinetics and local tolerability of Amikacin Cyclops® in drug-susceptible TB patients by administering 400, 700 and 1000 mg doses of dry powder amikacin. The pharmacokinetics of Amikacin Cyclops® are compared with a single 400 mg intravenous dose.

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

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