Colistin Cyclops® for treating (chronic) *Pseudomonas aeruginosa* infections of the lungs

EMA & FDA ORPHAN DRUG DESIGNATION

PureIMS has global rights to **Colistin Cyclops®**, a colistin pre-filled dry powder inhaler for the treatment of pulmonary *Pseudomonas aeruginosa* 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.

Colistin

Colistimethate sodium (colistin) is:

- an **effective antibiotic against *Pseudomonas aeruginosa*** (Psa),
- that is the **least sensitive to antimicrobial resistance** of all antibiotics used to treat pulmonary Psa infections[1],
- and is, therefore, the **most widely used inhaled antibiotic** in CF in the major EU countries.[2]

Colistin 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.

Colistin Cyclops® provides the best answer to the disadvantages associated with other colistin administration routes and devices.

Cyclops®

Cyclops® is a **credit card-size, easy-to-use, pre-filled, single-use 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. The Cyclops® attributes enable its **easy, hygienic and effective use** on a worldwide scale.

Colistin Cyclops®

Colistin Cyclops® carries a **pure API formulation** and has excellent *in vitro* and *in vivo* performance. Colistin Cyclops® has clear advantages over other treatments such as nebulization and Colobreathe® (Table 1). This significant benefit is supported by the fact that EMA (and FDA) both granted Colistin Cyclops® **orphan designation status**.

Table 1: comparison of Colistin Cyclops® with other colistin inhalers.

	Nebulization	Colobreathe®	Colistin Cyclops®
Portability	Poor	Excellent	Excellent
Inhaler preparation steps	> 9	6	2
Duration of dose intake	10-15 min	< 1 min	<< 1 min
Incidence of cough	10%-46.7[3]	75.4%-89.8%[4]	9.1%-47.5%[5]
Estimated delivered dose	6-12%[6,7]	18-20%[6]	60%[8]

Colistin Cyclops® offers patients easier, faster and more convenient handling. Cleaning and disinfection of Cyclops® is not necessary. Colistin Cyclops® is **very well tolerated** because of effective powder dispersion, a medium-high resistance to air flow, and consequential efficient lung delivery. In addition, Colistin Cyclops® is pre-filled and does not require handling of capsules.

Real-world experience

To date over **100,000 doses of Colistin Cyclops®** have been prescribed to patients in a named patient program, following extemporaneous production. Some patients have chronically used Colistin Cyclops® to great satisfaction for over **nine years**. It is **reimbursed by all payers** in the Netherlands.

Development program: accelerated regulatory pathways

End of 2024 EMA and FDA designated Colistin Cyclops® orphan drug product for the treatment of cystic fibrosis. PureIMS discusses with both agencies possibilities for accelerated regulatory pathways.

Commercial opportunity

Peak EU+US sales of Colistin Cyclops® for the indication CF are conservatively estimated at around $162M with a potential gross margin of 85-95%. Further expansion into non-CF bronchiectasis and COPD increases the commercial opportunity, potentially exceeding $1B.

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