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 drug 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 well over **115,000 doses of Colistin Cyclops®** have been prescribed to patients following extemporaneous production. Some patients have chronically used Colistin Cyclops® to great satisfaction for over **ten years**. It is **reimbursed by all payers** in the Netherlands.

Development program: accelerated regulatory pathways

EMA and FDA granted **Orphan Drug Designation** to Colistin Cyclops® for the treatment of CF. In 2025, Protocol Assistance from EMA led to agreement on a **PK-based hybrid development pathway**, significantly reducing development costs (<€4 million), shorten timelines, and lower overall development risk. PureIMS plans to initiate a similar process with the FDA.

Commercial opportunity

Peak EU+US sales of Colistin Cyclops® for the indication CF are conservatively estimated at around ~€66M with a potential gross margin of 85-95%. Spexis estimated peak EU+US+CA sales of €252.5M for ColiFin®. Further expansion into non-CF bronchiectasis, PCD and COPD increases the commercial opportunity, potentially exceeding $1B.

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References: 1. Sastre-Femenia et al., Lancet Reg Health Eur, 2023;34: 100736; 2. CF patient registry data 2021/2022 UK, FR, DE, NL; 3. Public assessment report ColiFin; 4. Schuster et al., Thorax. 2013 68(4):344-350; 5. Colistin Cyclops® Named Patient Program; 6. Colobreathe European public assessment report; 7. Lenney et al., J Cyst Fibr. 2011 10(1):9-14; 8. In vitro performance data PureIMS; 9. Spexis corporate presentation on ColiFin, Nov 2022.