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 the major EU countries.[2]

Colistin can be administered by inhalation or infusion, but available inhalers are very burdensome, as is parenteral administration. This reduces adherence to therapy.

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 shows excellent *in vitro* and *in vivo* performance. Colistin Cyclops® has strong advantages over other authorized products (Table 1). This significant benefit is supported by EMA and FDA **orphan drug designations (ODD)**.

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]
Environmental AB exposure	160 mg	140 mg	35-55 mg

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. Cyclops® efficiency dramatically reduces environmental antibiotic exposure.

Real-world experience

To date well over **140,000 doses of Colistin Cyclops®** have been prescribed to patients following extemporaneous production. Some patients have chronically used Colistin Cyclops® to great satisfaction for **10+ years**. It is **reimbursed by all payers**. Installed annual production capacity: **1.5–2.5M units**.

Development program: accelerated regulatory pathways

EMA and FDA granted **ODD** 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), shortening timelines (36 months), and lower overall development risk. PureIMS plans to initiate a similar process with the FDA.

Commercial opportunity

Peak EU+US sales of Colistin Cyclops® in CF are conservatively estimated at ~€66M with 85-95% gross margins. Additional territories (e.g. Asia, MENA, CIS) and expansion into **non-CF bronchiectasis, PCD and COPD** could increase the **commercial opportunity beyond €1B**.

Contact

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