Epinephrine Cyclops® for first-aid treatment of allergies with impending anaphylaxis

PureIMS has global rights to Epinephrine Cyclops®, an epinephrine pre-filled dry powder inhaler for the first-aid treatment of persons at risk of (severe) Type I allergic reactions and impending anaphylaxis. 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.

Epinephrine

For over a century epinephrine (EPI) has been used to treat allergic reactions and anaphylaxis, and to date it remains the most effective therapy available.

A (severe) allergic reaction requires emergency treatment to quickly counteract and stall progression of allergic symptoms to improve their recovery and minimise the risk of anaphylactic shock and even death.

Major unmet medical needs in persons at risk of (severe) Type I allergic reactions and impending anaphylaxis:

- Persons are reluctant to use an autoinjector device, which puts them at risk of untimely treatment potentially leading to anaphylaxis. Non-invasive inhalation of EPI will lower the barrier to use and is also more suitable to treat non-life threatening (but very burdensome) allergic reactions.
- Less than 50% of persons at risk of allergic reactions and anaphylaxis can use their autoinjector device correctly. An easier-to-use device for EPI administration is therefore required.

Epinephrine Cyclops®

Cyclops®:

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

A Cyclops® application for the treatment of CF is on the market under a *named patient program* and is reimbursed.

Epinephrine Cyclops®:

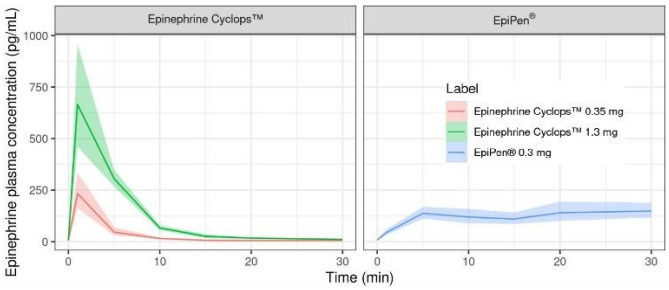
Epinephrine Cyclops® carries a **preservative- and antioxidant-free dry powder formulation** of EPI and has excellent *in vitro* and *in vivo* performance. It offers persons suffering from (severe) allergic reactions a low barrier to use because it is **non-invasive, easy and convenient to handle**, has a **fast onset of action** and a **short exposure** that allows for repeated treatment without dose stacking.

Epinephrine Cyclops® may also provide direct and effective local treatment of symptoms in the airways and oropharyngeal region. This may especially prove to be beneficial in food allergy patients with asthma.

Clinical studies:

A Phase 1 clinical trial with Epinephrine Cyclops® has been conducted. Single doses of 0.35 up to 1.3 mg were **well tolerated** and **no adverse reactions** occurred. **No cough** was observed.

Inhaled doses result in a much **shorter and less variable time to maximum plasma concentration** than intramuscular EPI. The exposure time is also shorter and less variable at all inhaled doses, which results in a plasma profile that approaches intravenous EPI.



Phase 2 trials with Epinephrine Cyclops® are in preparation.

Regulatory:

PureIMS is pursuing the hybrid registration route via a decentralized procedure which enables a fast EU marketing authorization of Epinephrine Cyclops®.

Manufacturing and IP Protection

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

Contact

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