PureIMS has global rights to Epinephrine Cyclops™, an epinephrine pre-filled dry powder inhaler for the first-aid treatment of persons at risk of anaphylaxis. PureIMS is a clinical-stage pharmaceutical and medication systems company focused on developing and commercializing innovative inhaled therapies for the treatment of systemic and respiratory diseases with significant unmet medical needs.

PUREIMS

Epinephrine

For over a century epinephrine has been used to treat severe allergic reactions and anaphylaxis, and to date it remains the most effective therapy available. The current emergency treatment to prevent anaphylaxis is intramuscular epinephrine injection by means of an autoinjector.

Persons suffering from a severe allergic reaction need emergency treatment to quickly counteract and stall progression of anaphylactic symptoms. This considerably improves their recovery and minimises the risk of anaphylactic shock and even death. Anyone who has ever had a severe allergic reaction should therefore at all times carry with them epinephrine emergency treatment.

Major unmet medical needs in persons at risk of anaphylaxis:

- Persons are reluctant to use their autoinjector device, which puts them at risk of untimely treatment of anaphylaxis. Non-invasive administration of epinephrine will lower the barrier to use.
- Less than 50% of persons at risk of anaphylaxis can use their autoinjector device correctly. An easier-to-use device for epinephrine administration is therefore required.

Epinephrine Cyclops™

Cyclops™:

Cyclops™ is an easy-to-use, pre-filled, disposable DPI that for high-dose drugs and emergency applications.

This patent-protected dry powder inhaler (DPI) is cost-effective to produce 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 hygienic and effective use on a worldwide scale.

Epinephrine Cyclops™:

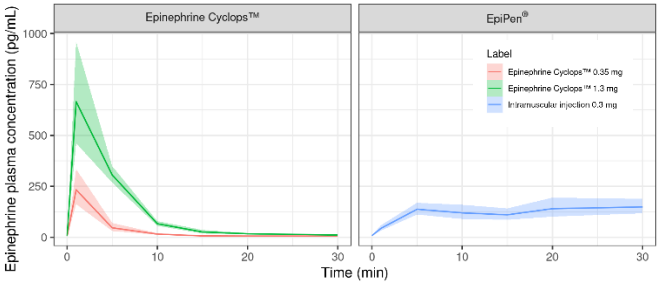
Epinephrine Cyclops™ carries a formulation of epinephrine and minimal excipients and has excellent *in vitro* and *in vivo* performance. Cyclops™ offers persons at risk of anaphylaxis a low barrier to use because it is non-invasive, easy and convenient to handle, has a fast onset of action and a short exposure which 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.

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 epinephrine. The exposure time is also shorter and less variable at all inhaled doses, which results in a plasma profile that approaches intravenous epinephrine.



Geometric mean plasma levels of epinephrine with standard error of the mean shaded.
Data are derived from 10 patients, with 3 receiving placebo inhaled formulation at each concentration.
Concentrations are baseline adjusted.

Phase 2 trials with Epinephrine Cyclops™ are in preparation.

Regulatory:

PureIMS is preparing for the hybrid registration route via a decentralized procedure which enables a fast EU marketing authorization of Epinephrine Cyclops™ within 3 years.

Manufacturing and IP Protection

PureIMS has a GMP manufacturing facility licensed for the production of Cyclops™ IMPs. Cyclops™ is IP-protected until 2034.

Contact

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