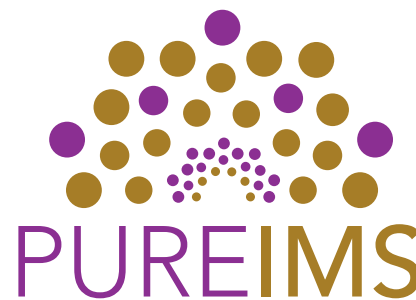


PureIMS has global rights to HCQ Cyclops™, a hydroxychloroquine (HCQ) pre-filled dry powder inhaler for intervention in SARS-CoV-2 and possible future coronavirus outbreaks. PureIMS is a clinical-stage pharmaceutical and medication systems company focused on developing and commercializing innovative therapies for the treatment of respiratory and systemic diseases with significant unmet medical needs.



HYDROXYCHLOROQUINE (HCQ)

HCQ is an approved drug for the treatment of malaria and several autoimmune diseases. It has been on the market for decades and clinical studies with inhaled HCQ for asthma treatment showed safety and tolerability. HCQ is also effective against many viruses, including SARS-CoV-2. In addition to the antiviral effects of HCQ, its immune modulating activity is expected to be an important aspect in the prevention of progression to severe COVID-19.

HCQ CYCLOPS™

CYCLOPS™:

Cyclops™ is an easy-to-use, pre-filled, disposable dry powder inhaler that has been developed for high-dose drugs and emergency applications.

This patent-protected inhaler 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. Cyclops™ has several advantages over standard-of-care products across key therapeutic areas. These attributes enable its hygienic and effective use on a worldwide scale.

HCQ CYCLOPS™:

HCQ Cyclops™ presents the promise of a more effective and safer alternative to oral HCQ. Pulmonary administration will result in much higher (therapeutic) HCQ concentrations in the lungs and much lower plasma concentrations, which increases antiviral efficacy while drastically lowering the occurrence of serious (e.g. cardiovascular) side-effects. The targeted lung delivery approach has similarly improved the safety and efficacy of corticosteroids, bronchodilators and antibiotics for use against asthma, COPD and cystic fibrosis.

Even with the development of vaccines, future coronavirus outbreaks will keep occurring, as with influenza. HCQ Cyclops™ will be a powerful therapy in the early stages of infection. It is a credit card sized portable, widely distributable, hygienic, easy-to-use tool and the non-invasive route of administration enables early intervention in any kind of outpatient setting.

PRE-CLINICAL STUDIES:

Pre-clinical data show that HCQ is effective against SARS-CoV-2 in primary lung epithelial cells. HCQ concentrations of 20 and 40 µM could reduce virus titers 48 hours post infection. Based on these facts we pursue an inhaled dose of 20 mg twice daily yielding high

enough tissue concentrations in the lungs to prevent SARS-CoV-2 entry and/or replication.

CLINICAL STUDIES:

An open-label Phase 1 clinical trial with HCQ Cyclops™ has been conducted. Single doses of 5, 10 and 20 mg were well tolerated and no serious adverse reactions occurred. Furthermore, hardly any cough was observed and the somewhat bitter taste of HCQ proved to be a surmountable discomfort. The inhaled doses did not lead to measurable plasma concentrations, which emphasizes the strong case for inhaled HCQ to prevent serious systemic side-effects often related to oral HCQ.

Phase 1b and a Phase 2a studies with HCQ Cyclops™ are in preparation.

MANUFACTURING AND IP PROTECTION

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



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