PureIMS initiates dose-finding study with Levodopa Cyclops™ dry powder inhaler

Roden, the Netherlands, August 23, 2023

Following a successful funding round in April of this year, PureIMS obtained ethical approval for a pharmacokinetic dose-finding study with its dry powder inhaler lead program Levodopa Cyclops™ and expects to have the study results before the end of 2023. Earlier clinical studies already demonstrated very rapid onset of action, a prerequisite for treating OFF-episodes in Parkinson's disease. Levodopa Cyclops™ is patient-friendly and very easy-to-use, a tremendous improvement in OFF-episode treatment. The results of this study will provide PureIMS a substantial step towards marketing authorization in the USA and further development in Europe.

The official study title is: "*A pilot open-label, randomized, crossover, comparative bioavailability study of levodopa administered via Levodopa Cyclops™ (test product) relative to Inbrija® (reference product) in healthy adult subjects*". The primary objective of this head-to-head comparison is to determine the dose at which comparative levodopa bioavailability will be reached with Levodopa Cyclops™ and reference listed drug Inbrija®.

The levodopa dose level resulting from this study will be used in a subsequent pivotal comparative bioavailability study, expected to complete the clinical package that will support marketing authorization in the USA following the 505(b)(2) regulatory pathway.

PureIMS owns the exclusive world-wide rights of Cyclops™, a dry powder inhaler for rapid and controlled drug delivery. The inhaler is easy-to-use, comfortable and pre-filled, ensuring high dose delivery and a fast onset-of-action. PureIMS has clinical stage in-house pipeline products - like Levodopa Cyclops™, Colistin Cyclops™ and Epinephrine Cyclops™ - that are open to partnering. Furthermore, the Cyclops™ platform is under a license arrangement available to pharma/biotech partners, thus supporting the development of a Cyclops™-based inhalation route for their vaccine or drug of choice. Recently the company closed such agreements with various parties.

Jaap Wieling, PureIMS' CEO commented,

> "*The entire team at PureIMS is very pleased with the actual start of this important clinical study. Patient studies have already proven the need for an improved levodopa dry powder inhaler and we are eager to continue the important development of Levodopa Cyclops™. Levodopa Cyclops™ truly has the potential of becoming the best treatment option for debilitating OFF-episodes in Parkinson's disease and to fulfill this unmet medical need*."

Please visit www.pureims.com for more information and for further inquiries, please contact:

Jaap Wieling, CEO
PureIMS bv
Ceintuurbaan Noord 152
9301NZ RODEN, the Netherlands
+31620335602 jwieling@pureims.com