

Parion Sciences Receives Positive Opinion from EMA Paediatric Committee on the Paediatric Investigation Plan for Idrevloride Inhalation Solution for Treatment of Primary Ciliary Dyskinesia

Durham, NC, April 5, 2023 Parion Sciences (Parion) today announced receipt of a positive opinion from the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) for the Paediatric Investigation Plan (PIP) for Idrevloride Inhalation Solution, an epithelial sodium channel (ENaC) inhibitor, currently in development for the treatment of primary ciliary dyskinesia (PCD).

This opinion is based on the clinical development plan leading to marketing authorization in Europe, including the completed “CLEAN PCD” Phase 2 study, which demonstrated significant improvement of lung function with Idrevloride Inhalation Solution, compared with hypertonic saline in people with PCD who were at least 12 years of age. As part of the PIP approval, Parion and the EMA agreed the clinical trial designs and endpoints necessary for EMA marketing authorization for the treatment of people with PCD.

For the registration of new medicines in Europe, biopharmaceutical companies are required to provide a PIP which outlines the strategy for investigation of a new medicinal product in the pediatric population. The positive PIP opinion from PDCO is an endorsement of the clinical program to evaluate the safety and efficacy of Idrevloride Inhalation Solution in people with PCD. Upon successful completion of the agreed PIP, Idrevloride Inhalation Solution would be eligible for up to an additional two years of marketing exclusivity in the EU, on top of the ten-year EU market exclusivity after market approval as result of its EU Orphan Drug Designation.

About Primary Ciliary Dyskinesia (PCD)

PCD is a rare genetic disease that affects the cilia that line the airways, sinuses, and reproductive tract and are responsible for moving mucus and other particles out of the lungs. In people with PCD, the loss of ability to clear mucus from the lungs by defective cilia leads to repeated lower respiratory tract infections that cause progressive loss of lung function. To date, there are no clinically proven therapies that improve mucus clearance from the lungs or lung function in people with PCD.

About ENaC Inhibitors and Idrevloride

Epithelial sodium channel (ENaC) inhibitors are designed to block the sodium channels on the airway surface. In respiratory diseases, such as chronic obstructive pulmonary disease, asthma, cystic fibrosis and primary ciliary dyskinesia, where there is a build-up of excessively concentrated mucus, models have demonstrated that blocking ENaC hydrates the mucus on the lung surface. Hydration of airway mucus restores airway clearance and improves lung function. Idrevloride is a novel, long acting ENaC Inhibitor that was well tolerated at the doses tested in multiple clinical trials in healthy volunteers and patients with muco-obstructive lung diseases, including primary ciliary dyskinesia. Further studies with Idrevloride Inhalation Solution in people with PCD are being planned.

About Parion Sciences

Parion Sciences is a development stage biopharmaceutical company dedicated to research, development, and commercialization of treatments to improve and extend the lives of patients with severe respiratory diseases. Parion has a diverse pipeline of pre-clinical and clinical candidates for the treatment of these diseases via distinctive mechanisms of action and approaches. Parion is at the forefront of ENaC development and is leveraging our scientific expertise in epithelial biology to expand our platforms and advance novel chemical compounds into people with muco-obstructive respiratory diseases such as chronic obstructive pulmonary disease, primary ciliary dyskinesia, bronchiectasis, severe asthma, and viral infections in the lung. Parion has received

support and grant funding from the National Institutes of Health and the Cystic Fibrosis Foundation.