Parion Sciences P-1037 Inhalation Solution receives Orphan Drug Designation from the EMA for the Treatment of Primary Ciliary Dyskinesia

Durham, NC (November 17, 2020) – Parion Sciences, Inc. (Parion), a clinical-stage pharmaceutical company focused on treatments of unmet respiratory diseases, announced today, that on November 16, 2020, the European Commission has adopted the designation of P-1037 Inhalation Solution (P-1037 IS), a novel, epithelial sodium channel (ENaC) inhibitor, under evaluation as a potential treatment of primary ciliary dyskinesia (PCD), as an Orphan Drug. PCD is a serious disease that affects approximately 1 in 15,000 people worldwide. Primary ciliary dyskinesia is a disease that encompasses many inherited genetic disorders that impair cilia function and reduces the lung's ability to clear mucus. As a result, PCD patients experience lifelong respiratory disease with chronic, debilitating lung infections that can lead to respiratory failure.

The Orphan Drug Designation program in the EU provides orphan status to drugs and biologics that are intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating and the prevalence of the condition in the European Union must not be more than 5 in 10,000. In addition, no satisfactory method of diagnosis, prevention or treatment of the condition has been authorized. Orphan Drug Designation Sponsors who obtain orphan designation benefit from protocol assistance, a type of scientific advice specific for designated orphan medicines, and market exclusivity once the medicine is on the market. Fee reductions are also available depending on the status of the sponsor and the type of service required.

In addition, Parion had been previously granted Small & Medium Enterprise (SME) status by the European Medicine Agency (EMA). The EMA SME program is designed to promote innovation and the development of new medicinal products by smaller companies by providing financial incentives and administrative and procedural assistance associated with pre-marketing procedures, particularly in requesting and leveraging scientific advice, in submitting Marketing Authorization Applications (MAA) and regarding inspection procedures. The initiative also introduces incentives for post-authorization procedures.

About ENaC Inhibitors and P-1037 Inhalation Solution

Epithelial sodium channel (ENaC) inhibitors are designed to block the sodium channels on the airway surfaces. In respiratory diseases, such as chronic obstructive pulmonary disease, cystic fibrosis and primary ciliary dyskinesia, where there is a build-up of concentrated mucus, preclinical models have demonstrated that blocking ENaC hydrates the mucus on the lung surface. P-1037 IS, a novel, long acting ENaC Inhibitor delivered in a nebulized solution, was

well tolerated at the doses tested in multiple clinical trials in healthy volunteers and patients with muco-obstructive lung disease, including primary ciliary dyskinesia (PCD). Inhibiting the ENaC activity in PCD patients with P-1037 IS has been shown to improve airway mucus hydration and allow for more efficient mucus clearance in patients with PCD, thus leading to improved lung function. Further studies with P-1037 IS in PCD patients 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 muco-obstructive respiratory diseases such as severe asthma, cystic fibrosis, primary ciliary dyskinesia, bronchiectasis, chronic obstructive pulmonary disease, and viral infections in the lung. Parion has received support and grant funding from the National Institutes of Health and the Cystic Fibrosis Foundation.

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