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Parion Sciences Announces Publication of Phase 2 CLEAN-PCD Study in The Lancet Respiratory Medicine

- *Published Phase 2 Study findings demonstrate safety and efficacy of idrevloride in hypertonic saline for treatment of primary ciliary dyskinesia*
- *Abstract to be presented at 2023 European Respiratory Society Congress ALERT session*

Durham, NC (September 8, 2023) – Parion Sciences Inc. today announced publication in The Lancet Respiratory Medicine of positive results of the Phase 2 study of idrevloride in hypertonic saline in people with primary ciliary dyskinesia (PCD). In the CLEAN-PCD study, idrevloride in hypertonic saline was safe and associated with significant improvement in lung function over 28 days in people with primary ciliary dyskinesia compared with hypertonic saline alone.

“The CLEAN-PCD clinical trial is of particular importance in many regards: it is the largest study so far; the first transcontinental, multinational multicenter study; and the first study among people with PCD involving dedicated commitment from a pharmaceutical industry partner. For the first time, it demonstrates a safe pharmaceutical intervention improving lung function – a prerequisite for holding the progression of PCD-associated lung disease. It delineates a milestone in PCD research and may serve as a role model for many more trials to come in the near future” said Felix Ringshausen, MD.

The CLEAN-PCD study was a multinational, randomized, double-blind, placebo-controlled crossover trial in adults and adolescents with primary ciliary dyskinesia aged 12 years or older. Results of the study underscore the potential of Idrevloride Inhalation Solution to be a safe and effective nebulized treatment for people living with primary ciliary dyskinesia.

“Lack of effective therapies for mucociliary clearance defects in primary ciliary dyskinesia (PCD) leaves patients with inadequate options to manage their disease and contributes to severely impaired quality of life for affected individuals” said Michele Manion, Executive Director of the PCD Foundation. “We are delighted at the publication of positive results showing improved lung function in patients with PCD from the CLEAN-PCD study, the first study employing a novel therapeutic agent to directly address the mucociliary clearance issues in PCD.”

“Given the results of this study, we are enthusiastic about working towards initiating the Phase 3 clinical study with Idrevloride Inhalation Solution in people with PCD” said Karl Donn, SVP Drug Development, Parion.

In addition to publication in The Lancet Respiratory Medicine, Thomas W. Ferkol, Jr MD will present the CLEAN-PCD study results at the European Respiratory Society International Congress 2023 during the Abstracts Leading to Evolution in Respiratory Medicine Trials (ALERT) session on the morning of 10 September. “There is a clear need for newer and better treatments for this rare lung disease, and hopefully the planned, more extensive clinical trials will further show the benefits of inhaled idrevloride in hypertonic saline” said Thomas W. Ferkol, Jr MD.

About Primary Ciliary Dyskinesia (PCD)

PCD is a rare genetic disease characterized by loss of cilia function in the lining of the airways, sinuses, and reproductive tract. In the lung, this loss of cilia function results in accumulation of thick mucus, inflammation and repeated infections, leading to permanent damage and progressive loss of lung function. People with PCD rely on cough to clear their lungs, as the cilia cannot perform that normal function. Until this study, there were no clinically proven therapies to improve mucus clearance from the lungs and none that restore cilia function in people with PCD.

About Idrevloride

Idrevloride is an inhaled investigational epithelial sodium channel (ENaC) inhibitor being developed by Parion for treatment of PCD. ENaC inhibitors are designed to block the sodium channels on the airway surface, thus both blocking the absorption of water and stimulating fluid secretion in people with functional CFTR. Inhaled Idrevloride Inhalation Solution is formulated to hydrate the mucus in the lung, thereby improving clearance of mucus by cough, thus improving lung function in people with PCD and other respiratory diseases who accumulate excessively concentrated mucus in their lungs. Idrevloride has been well-tolerated 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 planned.

About PCD Foundation

The Primary Ciliary Dyskinesia Foundation (‘PCDF’) is a not-for-profit 501(c)(3) patient advocacy foundation for individuals with inherited ciliary disorders and their caregivers. The primary purpose for starting the PCDF was to address severe unmet needs in the PCD patient community, including diagnostic challenges, lack of evidence to support therapies, inadequate demographic information and paucity of data related to the natural history of this disorder. The PCDF’s programs reflect its efforts to create an infrastructure and processes to address these unmet needs.

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 preclinical 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. For more information, please see our website at www.Parion.com.