CLEAN-CF Clinical Trial Expanded to Include Pediatric Cystic Fibrosis Population

Drug Safety Monitoring Board Recommends Expansion of Trial Population to Include 12 to 17 Year Old People with CF

Durham, NC (September 10, 2015) – Parion Sciences, a company dedicated to the development of novel treatments for pulmonary and ocular diseases, announced today that the CLEAN-CF enrollment criteria for the study of P-1037 would be expanded to include people with Cystic Fibrosis (CF) between the ages of 12 and 17 years of age. The trial had previously enrolled people with CF age 18 and above only. The expansion of the age criteria for enrollment was based on a pre-specified safety review by the Data Monitoring Committee (DMC).

The CLEAN-CF study includes people with CF regardless of an individual’s genetic mutation. Based on preclinical studies, inhibiting the epithelial sodium channels (ENaC) in the airways with P-1037 (also known as VX-371), an “ENaC blocker,” is expected to re-hydrate the mucus layers, thus helping to improve airway clearance and potentially lung function. P-1037 has demonstrated to be long acting in preclinical models and the Phase 2 evaluation is supported by the safety and tolerability profile observed in the completed Phase 1 studies. The initiation of the Phase 2 clinical trials was supported by an award from Cystic Fibrosis Foundation Therapeutics Inc. (CFFT), the nonprofit affiliate of the Cystic Fibrosis Foundation.

P-1037/VX-371 is being developed in collaboration with Vertex Pharmaceuticals based on an agreement announced in June 2015.
For additional information on the CLEAN-CF clinical trial, please go to the website link:

https://clinicaltrials.gov/ct2/show/NCT02343445

About ENaC Inhibitors and P-1037

Epithelial sodium channel (ENaC) inhibitors are designed to block the sodium channels on the airway surfaces. In pulmonary diseases where there is a build-up of excessively concentrated mucus, such as cystic fibrosis and chronic obstructive pulmonary disease, preclinical models have demonstrated that blocking the ENaC channel promotes fluid secretion and re-hydrates the mucus layers. Hydration of mucosal surfaces may restore airway clearance, potentially reducing infection and improving lung function.

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 innate mucosal surface defense deficiencies of the eye or airway. 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 novel chemical compounds into new indications to treat mucosal defects. Parion has received support and grant funding from the National Institutes of Health and the Cystic Fibrosis Foundation Therapeutics, Inc. For more information, please see our website at www.Parion.com.