Laurent Pharmaceuticals Receives FDA and Health Canada Clearance to Initiate APPLAUD Phase 2 Clinical Study of LAU-7b for the Treatment of Cystic Fibrosis

MONTREAL, QC, Canada – April 19th, 2017 - Laurent Pharmaceuticals Inc., a clinical stage orphan drug company, today announced the clearance of its Investigational New Drug Application ("IND") with the U.S. Food and Drug Administration and the Clinical Trial Application ("CTA") with Health Canada to initiate APPLAUD (**A** double-blind, randomized, **P**lacebo-controlled, **P**hase 2 study of the efficacy and safety of **LAU**-7b in the treatment of Cystic Fibrosis in a**d**ults), planned to start later this year in the United States and Canada. This Phase 2 trial aims to evaluate LAU-7b's effect on the preservation of lung function in patients with Cystic Fibrosis ("CF") by reducing persistent unresolved inflammation in the lung and stimulating its return to homeostasis.

"There are no drugs approved for treating lung inflammation in CF and, despite the emergence of important new therapies, pulmonary insufficiency continues to be the primary cause of mortality in patients with CF" said Radu Pislariu, MD, President and CEO of Laurent Pharmaceuticals. "Both the therapeutic concept and the design of the Phase 2 are ground-breaking and we are pleased to have achieved these important regulatory milestones. We believe LAU-7b has the potential to make a life-changing impact for patients with CF."

LAU-7b is a once-a-day oral pro-resolving therapy with potential to treat chronic pulmonary inflammation that leads to irreversible lung damage in patients with CF, regardless of their CFTR genotype. As opposed to traditional anti-inflammatory approaches that focus on the inhibition of the inflammatory response, LAU-7b works by activating the resolution phase of inflammation, responsible for endogenous termination and start of the healing process, thus having the potential to address chronic inflammation without inducing immune-suppression.

"Current anti-inflammatory therapies have limited potential for chronic use, either because their questionable long term benefits in patients with CF or due to concerns over safety", added Larry Lands, MD, PhD, Director, Pediatric Respiratory Medicine at McGill University Health Centre in Montreal and Canadian Principal Investigator for this trial. "LAU-7b proposes an interesting treatment approach that uses the body's own ability to resolve inflammation, which is a more natural way to modulate inflammatory response without directly interfering with defense mechanisms."

"New anti-inflammatory treatments are needed to stop lung destruction in CF, as well as dedicated approaches toward trial design for these therapies", added Michael Konstan, MD, Vice Dean for Translational Research at Case Western Reserve University School of Medicine in Cleveland and US Principal Investigator for the study. "The design of this Phase 2 follows the recommendations of the US Cystic Fibrosis Foundation's Anti-inflammatory Therapy Working Group and is well informed by the LAU-7b Phase 1b trial and a natural history study conducted previously in adult patients with CF."

The Phase 2 study, which will enrol approximately 136 adults with CF for a treatment duration of 6 months, received support from Cystic Fibrosis Canada and a US$3 million development award from US-based Cystic Fibrosis Foundation Therapeutics, Inc.

About Cystic Fibrosis

Cystic Fibrosis ("CF") is a progressive, life-threatening, genetic disease affecting about 75,000 people worldwide. CF is caused by mutations in the CFTR gene and is characterized by viscous secretions in different exocrine tissues and an aberrant inflammatory response leading to pulmonary chronic infection and loss in lung function over time. Severe pulmonary dysfunction is the primary cause of death in CF.

About LAU-7b

LAU-7b (fenretinide) is a new chemical entity with a well-documented history of safety. LAU-7b works by up-regulating the anti-inflammatory docosahexanoic acid (DHA) pathway involved in the resolution of inflammation and down-regulating the pro-inflammatory arachidonic acid (AA) pathway, a novel mechanism supported by a strong rationale linked to the expression of the CF genetic defect. Fenretinide was shown to normalize the plasma levels of DHA and AA in a specific animal model of CF, resulting in reduced lung inflammation and increased clearance of pulmonary infection with *Pseudomonas aeruginosa*, a bacterium involved in perpetuating the vicious cycle of inflammation-infection. Results from a recent Phase 1b clinical trial in adult patients with CF have shown LAU-7b to have good safety and pharmacokinetic profiles, coupled with promising pharmacodynamics on specific markers of inflammation.

About Laurent Pharmaceuticals

Laurent Pharmaceuticals is a Montréal-based clinical stage company focusing on rare inflammatory diseases, with a lead program in Cystic Fibrosis. Laurent's lead candidate (LAU-7b) is a one-a-day oral drug targeting the resolution phase of the inflammatory response, a new treatment paradigm for addressing chronic inflammation. For more information, please visit www.laurentpharma.com.

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