

Adare Pharmaceuticals Announces Achievement of the Primary End-Point in Phase IIb Study (FLUTE™) for APT-1011 in Patients with Eosinophilic Esophagitis

PRINCETON, N.J.-- Adare Pharmaceuticals (Adare) today announced positive results from its Phase IIb study (FLUTE™) for one of its rare disease investigational products, APT-1011 (AdvaTab® Fluticasone) for Eosinophilic Esophagitis (EoE). Eosinophilic Esophagitis (EoE) is a chronic, allergic inflammatory disease characterized by eosinophilic infiltration of the esophagus, which can lead to inflammation and ultimately strictures and narrowing of the esophagus, putting patients at risk of food impaction. APT-1011 is a novel formulation incorporating Adare's proprietary AdvaTab® technology and is the only fluticasone product in advanced clinical development for EoE. Currently, there are no FDA approved EoE treatments available in the US.

The FLUTE trial is designed to measure the efficacy and safety of a number of doses of APT-1011 in more than 100 patients identified as having EoE and to advance Adare's proprietary patient reported outcome tool PROSE™ for EoE. The study results indicate that the primary end-point was achieved, as were a number of secondary endpoints that measured patient symptoms and improvement of characteristic features of the disease. The product was found to be well tolerated at all doses tested. Significant progress was also achieved in the development of PROSE. The FLUTE study, will continue in 2019 and will characterize the persistence of treatment effect. The Company anticipates initiation of its Phase 3 program in the second half of 2019.

"We are very pleased with the results achieved in the FLUTE study," said John Fraher, CEO, Adare. "Adare is committed to developing value-added therapies, such as APT-1011, for itself and for partners by leveraging our comprehensive and proven technology platforms and globally focused product development capabilities. We look forward to bringing this product to the patients who live with this chronic disease and need it most."

About The FLUTE Study and APT-1011

The FLUTE study is part of Adare Pharmaceuticals HARMONY Clinical Trial program, which is focused on the development of APT-1011 in eosinophilic esophagitis (EoE) in adults, adolescents and children. APT-1011 is a novel, oral formulation of fluticasone incorporating Adare's proprietary AdvaTab® technology that allows for topical delivery of the drug to the esophagus whilst minimizing residence time in the oral cavity. In earlier clinical trials, APT-1011 was shown to be effective in reducing esophageal eosinophil counts and endoscopic findings in adults with a diagnosis of EoE. APT-1011 has received orphan drug designation from the FDA and EMA.

About Eosinophilic Esophagitis (EoE)

Eosinophilic Esophagitis or "EoE" is a chronic and rare disease. EoE prevalence rate in the US is estimated at 57 in 100,000 (Dellon E et al. 2014) and is evolving due to increasing awareness of the disease. The exact cause of EoE is unknown, however it is believed to be triggered by a variety of stimuli, including certain foods and environmental allergens. Symptoms of EoE in adults include dysphagia (difficulty or discomfort in swallowing) and, in severe cases, food impaction (obstruction of the esophagus by food) and strictures (narrowing of the esophagus due to scar tissue formation). Early



diagnosis and treatment of EoE is important to prevent progression to fibrotic changes in the esophagus which may be only partially reversible. Current management of EoE includes, food elimination diets, off-label use of proton pump inhibitors and glucocorticoid steroid formulations. Currently in the United States, there are no therapeutic products approved for the treatment of EoE.

About Adare Pharmaceuticals

Adare Pharmaceuticals utilizes its differentiated Pharmaceutical Technology and Microbiome scientific platforms to develop novel value-added products for the global market. Through its Specialty CDMO business, Adare provides co-development and contract services to biopharmaceutical companies to develop and manufacture products that are marketed by its partners. Through its Adare Development affiliate, Adare invests in its own product pipeline and currently has a number of investigational products in various stages of development. Adare has developed and manufactured more than 40 products sold by partners in more than 100 countries globally including Lacteol™, Zoolac™, Viactiv™, Amrix® and a number of branded and complex generic products. <http://www.adarepharma.com>

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