Enanta Pharmaceuticals Announces First Participant Dosed in Phase 1 Clinical Trial of EDP-978, an Oral, Once-Daily KIT Inhibitor, in Development for the Treatment of Urticaria

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- *Phase 1 Study Will Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of EDP-978 in Healthy Volunteers*
- *Topline Data Expected in Q4 2026*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 13, 2026-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and immunological diseases today announced that the first participant has been dosed in a Phase 1 clinical trial of EDP-978, an oral, once-daily KIT inhibitor in development for urticaria and other mast cell-driven diseases. The Phase 1 single-ascending dose (SAD) and multiple-ascending dose (MAD) clinical trial will evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of EDP-978 in healthy adult volunteers.

"We are excited to move our lead immunology program into clinical development with this Phase 1 study of EDP-978, a potent and selective once-daily KIT inhibitor in development for the treatment of chronic urticaria and potentially other mast cell-mediated diseases," said Scott T. Rottinghaus, M.D., Chief Medical Officer of Enanta Pharmaceuticals. "These severely debilitating inflammatory skin diseases result in itchy, red hives and angioedema that can significantly impact a patient's quality-of-life, causing sleep disturbance, fatigue, irritability, anxiety, and depression. Many patients are refractory to currently approved therapies, creating an unmet medical need for a new efficacious oral agent. We look forward to reporting topline Phase 1 data in the fourth quarter of this year, including effects on biomarkers such as serum tryptase, which will give us insight into the activity of EDP-978."

The randomized, double-blind, placebo-controlled, first-in-human Phase 1 clinical trial is expected to enroll approximately 98 healthy adult volunteers ranging in age from 18 to 65 years old to evaluate the safety, tolerability, PK, and PD (including serum tryptase) of EDP-978. The study includes a SAD phase, with a two-part food-effect (FE) cohort, and a MAD phase with a 14-day treatment period.

About EDP-978

EDP-978 is a novel, potent and selective oral KIT inhibitor in development for the treatment of chronic urticaria and potentially other mast cell driven diseases. EDP-978 demonstrates nanomolar potency in both binding and cellular assays, sub-nanomolar activity *in vivo*, and high selectivity for KIT versus other kinases. EDP-978 also exhibits favorable *in vitro* and *in vivo* ADME properties preclinically.

About Chronic Urticaria

Chronic urticaria is a mast-cell driven skin disorder defined by the spontaneous or inducible occurrence of wheals (hives), angioedema, or both, persisting for six weeks or longer. It includes two main subtypes – chronic spontaneous urticaria (CSU), where there is no consistent identifiable trigger, and chronic inducible urticaria (CIndU), where lesions are reproducibly provoked by a specific stimulus such as cold, pressure, cholinergic activity, or sunlight.[1,2] CSU is unpredictable, with spontaneous remissions and relapses that can persist for months to years.[1,2] Intense pruritus, sleep disturbance, and visible lesions experienced by those living with CSU can have a significant impact on quality of life. Loss of work productivity, anxiety, and depression are part of the patient burden.[3] CIndU can be equally burdensome as exposure to daily stimuli can result in recurrent symptoms and avoidance of behaviors that can impair quality of life. Up to one third of patients with CIndU may also have concurrent CSU. The disease course can be prolonged, with some subtypes persisting for years.[1,2]

About Enanta Pharmaceuticals, Inc.

Enanta is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for viral infections and immunological diseases. In virology, Enanta's clinical programs are focused on the development of first-in-disease and best-in-disease treatments for respiratory syncytial virus (RSV). The Company's immunology pipeline aims to develop treatments for inflammatory diseases by targeting key drivers of the type 2 immune response, with KIT, STAT6 and MRGPRX2 inhibition.

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing hepatitis C virus (HCV) infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). A portion of Enanta's royalties from HCV products developed under its collaboration with AbbVie contribute ongoing funding to Enanta's operations. Please visit www.enanta.com for more information.

Forward-Looking Statements

This press release contains forward-looking statements, including statements with respect to the timeline and prospects for advancement of EDP-978 for the treatment of chronic urticaria and potentially other mast cell-mediated diseases. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the impact of development, regulatory and marketing efforts of others with respect to competitive treatments; the discovery and development risks of Enanta's programs in virology and immunology; Enanta's limited clinical development experience; Enanta's ability to partner its programs; Enanta's need to attract and retain senior

management and key research and development personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's Form 10-K for the fiscal year-ended September 30, 2025, and any other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

1. Lang DM. Chronic Urticaria. *N Engl J Med*. Sep 1 2022;387(9):824-831. doi:10.1056/NEJMra2120166
2. Zuberbier T, Bernstein JA, Maurer M. Chronic spontaneous urticaria guidelines: What is new? *J Allergy Clin Immunol*. Dec 2022;150(6):1249-1255. doi:10.1016/j.jaci.2022.10.004
3. Church MK, Kolkhir P, Metz M, Maurer M. The role and relevance of mast cells in urticaria. *Immunol Rev*. Mar 2018;282(1):232-247. doi:10.1111/imr.12632

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