NEWS RELEASE

CRINETICS PHARMACEUTICALS ANNOUNCES EUROPEAN MEDICINES AGENCY (EMA) VALIDATION OF MARKETING AUTHORIZATION APPLICATION (MAA) AND ORPHAN DRUG DESIGNATION (ODD) FOR PALTUSOTINE IN ACROMEGALY

2025-03-27

SAN DIEGO – March 27, 2025 – **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX) today announced that the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) for paltusotine, the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist, for the proposed treatment and long-term maintenance therapy of acromegaly, a serious, rare and progressive endocrine disorder characterized by consistently elevated levels of growth hormone. The MAA will now be reviewed by the Committee for Medicinal Products for Human Use (CHMP). Additionally, the EMA on February 27, 2025 granted paltusotine Orphan Drug Designation (ODD) for the treatment of acromegaly.

“The submission of our MAA for paltusotine to the EMA is a significant milestone and underscores our commitment to making our therapies accessible worldwide,” said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. “As we focus on our anticipated U.S. launch, this submission demonstrates our global capabilities and sets the stage for the continued growth of Crinetics.”

“Orphan designation from the EMA further highlights the unmet need in acromegaly and the potential benefit paltusotine can bring for patients,” said Dana Pizzuti, MD, Chief Medical and Development Officer of Crinetics. “We look forward to continued collaboration with the European regulatory authorities throughout their review process.”

The MAA submission is supported by data from 18 clinical trials, including two Phase 3 trials that evaluated paltusotine for the treatment of acromegaly in medically untreated and treated patients. All primary and secondary endpoints were met in both Phase 3 studies. Treatment with paltusotine was well-tolerated and resulted in statistically significant biochemical control and patient reported symptom control compared to placebo.

MAA validation follows the acceptance by the U.S. Food and Drug Administration (FDA) of the New Drug Application (NDA) for paltusotine for the treatment and long-term maintenance of acromegaly. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 25, 2025.

The EMA grants orphan designation to medicines intended for the treatment, prevention, or diagnosis of life-threatening or chronically debilitating diseases affecting no more than 5 in 10,000 people in the European Union, among other criteria. The medicine must also provide significant benefit to those affected by the condition. Orphan designation provides certain benefits, including reduction in regulatory fees and potential for 10 years of market exclusivity.

About Paltusotine

Crinetics' lead development candidate, paltusotine, is the first investigational once-daily, oral, selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist that has completed Phase 3 clinical development for acromegaly and is initiating Phase 3 clinical development for carcinoid syndrome associated with neuroendocrine tumors. It was designed to be a once daily oral option for the control of acromegaly and the symptoms related to carcinoid syndrome. In Phase 3 studies, once-daily, oral paltusotine maintained IGF-1 levels and symptom control in patients with acromegaly who were switched from monthly injectable medications (PATHFNDR-1) and rapidly decreased IGF-1 levels and symptom burden in medically untreated acromegaly patients (PATHFNDR-2). IGF-1 is the primary biomarker endocrinologists use to manage acromegaly patients. Results from a Phase 2 study in carcinoid syndrome demonstrated rapid and sustained reductions in flushing episodes and bowel movement frequency, which are the most common symptoms of carcinoid syndrome. Crinetics is preparing to initiate a global Phase 3 trial for control of symptoms associated with carcinoid syndrome in patients with neuroendocrine tumors.

About Acromegaly

Acromegaly is a serious rare disease generally caused by a benign pituitary adenoma (tumor) that secretes excess growth hormone (GH). Excess GH secretion causes excess secretion of insulin-like growth factor-1 (IGF-1) from the liver. Prolonged exposure to increased levels of IGF-1 and GH leads to progressive and serious systemic complications, often resulting in bone, joint, cardiovascular, metabolic, cerebrovascular, or respiratory disease. Acromegaly symptoms include headache, joint aches, fatigue, sleep apnea, severe sweating, hyperhidrosis/oily skin, bone and cartilage overgrowth, abnormal growth of hands and feet, enlargement of heart, liver and other organs

and alteration of facial features. Uncontrolled acromegaly results in increased mortality and has a debilitating impact on daily functioning and quality of life.

Monthly depot injections of peptide somatostatin receptor ligands are the most common pharmacologic treatment for people suffering with acromegaly. However, these depots typically require many months to achieve the correct dose level. People suffering with acromegaly often experience a return of symptoms towards the end of the monthly injection cycle and many must adjust their injection frequency to more often than monthly. Further, these depots are difficult to administer and employ large gauge needles that are commonly associated with pain, injection site reactions and an increased burden on the lives of patients.

About Crinetics Pharmaceuticals

Crinetics Pharmaceuticals is a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for endocrine diseases and endocrine-related tumors. Crinetics' lead development candidate, paltusotine, is the first investigational once-daily, oral, selective somatostatin receptor type 2 (SST2) nonpeptide agonist that is in clinical development for acromegaly and carcinoid syndrome associated with neuroendocrine tumors. Atumelnant is currently in development for congenital adrenal hyperplasia and ACTH-dependent Cushing's syndrome. All of the company's drug candidates are orally delivered, small molecule, new chemical entities resulting from in-house drug discovery efforts, including additional discovery programs addressing a variety of endocrine conditions such as hyperparathyroidism, polycystic kidney disease, Graves' disease (including thyroid eye disease), diabetes, obesity and GPCR-targeted oncology indications.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements about the expected MAA review process, the potential global direction and growth of Crinetics, the plans and timelines for the commercial launch of paltusotine for acromegaly, if approved, the plans for initiating a Phase 3 program of paltusotine for carcinoid syndrome, and the potential of our other research, discovery, and clinical trial programs. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential," "upcoming" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including, without limitation, potential delays in the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; clinical studies and preclinical studies may not proceed at the time or in the manner expected, or at all; regulatory developments in the United States and foreign

countries; the timing and outcome of research, development and regulatory review is uncertain, and Crinetics' drug candidates may not advance in development or be approved for marketing; and the other risks and uncertainties described in the company's periodic filings with the Securities and Exchange Commission (SEC). The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Additional information on risks facing Crinetics can be found under the heading "Risk Factors" in Crinetics' periodic filings with the SEC, including its annual report on Form 10-K for the year ended December 31, 2024. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by applicable law, Crinetics does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Investors:
Gayathri Diwakar
Head of Investor Relations
gdiwakar@crinetics.com
(858) 345-6340

Media:
Natalie Badillo
Head of Corporate Communications
nbadillo@crinetics.com
(858) 345-6075

Source: Crinetics Pharmaceuticals, Inc.