



NEWS RELEASE

# CRINETICS SUBMITS NEW DRUG APPLICATION FOR PALTUSOTINE FOR THE TREATMENT OF ACROMEGALY

2024-09-26

SAN DIEGO – September 26, 2024 – **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for paltusotine, the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist in development for the proposed treatment and long-term maintenance therapy of acromegaly.

“This NDA submission brings us one step closer to our goal of delivering a new generation of therapy that can help people living with acromegaly,” said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. “Based on the comprehensive data from the Phase 3 PATHFNDR program, we are excited about the significance of this potential advancement for the acromegaly community, as well as what it represents to Crinetics as a company. Paltusotine is the leading candidate of a deep, innovative pipeline – the first of many therapeutic candidates that have been purposefully designed in-house to transform the lives of people impacted by a wide range of endocrine conditions.”

The NDA 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 biochemical control and patient reported symptom control compared to placebo.

Crinetics anticipates receiving notification from the FDA on the status of the NDA submission in December.

## 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 in Phase 2 clinical development for carcinoid syndrome associated with neuroendocrine tumors. It was designed by Crinetics with the goal of providing a once-daily, oral option for reliable and consistent control of acromegaly. 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 (PATHFNR-1) and rapidly decreased IGF-1 levels and symptom burden in medically untreated acromegaly patients (PATHFNR-2). IGF-1 is the primary biomarker endocrinologists use to manage acromegaly patients. Results from the Phase 2 study in carcinoid syndrome will provide an opportunity for paltusotine to potentially demonstrate utility in an investigational, Phase 3 trial for another important indication related to the treatment of symptoms in patients with neuroendocrine tumors.

## About Acromegaly

**Acromegaly** is a serious rare disease generally caused by a pituitary adenoma, a benign tumor in the pituitary that secretes 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.

Surgical removal of pituitary adenomas, if possible, is the preferred initial treatment for most people with acromegaly. Pharmacotherapy is used for people who are not candidates for surgery, or when surgery is unsuccessful in achieving treatment goals. Approximately 50% of people with acromegaly prove to be candidates for pharmacotherapy. Injectable somatostatin receptor ligands are the most common initial pharmacologic treatment; however, these drugs require monthly depot injections with 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, selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist that has completed Phase 3 clinical development for acromegaly and is in Phase 2 clinical development for carcinoid syndrome associated with neuroendocrine tumors. Crinetics is also

developing atumelnant (CRN04894), an investigational, first-in-class, oral ACTH antagonist, that is currently completing Phase 2 clinical studies for the treatment of congenital adrenal hyperplasia and Cushing's disease. 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 regarding the plans and timelines for the clinical development of atumelnant, including the therapeutic potential and clinical benefits or safety profile thereof; the expected timing of additional data and topline results from studies of atumelnant in CAH and ADCS; the target enrollment in studies of atumelnant; and the potential outcomes of the Phase 2 participants with CAH and the Phase 1b/2a trial for participants with ADCS. 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, initial or topline data that we report may change following completion or a more comprehensive review of the data related to the clinical studies and such data may not accurately reflect the complete results of a clinical study, and the FDA and other regulatory authorities may not agree with our interpretation of such results; unexpected adverse side effects or inadequate efficacy of the Company's product candidates that may limit their development, regulatory approval and/or commercialization; clinical studies and preclinical studies may not proceed at the time or in the manner expected, or at all; 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, 2023 and its Quarterly report on Form 10-Q for the quarter ended March 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.

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