



NEWS RELEASE

Crinetics Pharmaceuticals Announces Submission of Marketing Authorization Application in Brazil for Palsonify™ (Paltusotine) in Acromegaly

2026-03-26

Application supported by comprehensive clinical program, including two positive Phase 3 trials evaluating once-daily oral paltusotine in acromegaly

SAN DIEGO, March 26, 2026 (GLOBE NEWSWIRE) -- **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX) today announced the submission of a Marketing Authorization Application (MAA) to Brazil's National Health Surveillance Agency (ANVISA) for PALSONIFY™ (paltusotine), the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist, for the proposed treatment of acromegaly in adults.

"The submission of our MAA for Palsonify in Brazil represents another important global milestone for this important therapy," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "Once-daily, oral Palsonify is redefining the treatment paradigm as the next generation of acromegaly care in the US, following its approval by the FDA. We now look forward to working with ANVISA as they evaluate our MAA for Palsonify to treat acromegaly in adults in Brazil."

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.

PALSONIFY is approved in the US to treat adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. In Europe, Crinetics recently received a positive opinion from the



Committee for Medicinal Products for Human Use (CHMP) for granting the MAA for Palsonify for the proposed treatment of acromegaly in adults.

About PALSONIFY™ (Paltusotine)

PALSONIFY, a selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist, is the first and only once-daily, oral therapy approved for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. In Phase 3 studies, once-daily, oral PALSONIFY 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. Paltusotine is also in Phase 3 clinical development for carcinoid syndrome associated with neuroendocrine tumors (CAREFNDR). 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.

About Crinetics Pharmaceuticals

Crinetics Pharmaceuticals is a global pharmaceutical company committed to transforming the treatment of endocrine diseases and endocrine-related tumors through science rooted in patient needs. Crinetics is focused on discovering, developing, and commercializing novel therapies, with a core expertise in targeting G-protein coupled receptors (GPCRs) with small molecules that have specifically tailored pharmacology and properties.

Crinetics' lead product, PALSONIFY™ (paltusotine), is the first once-daily, oral treatment approved by the U.S. FDA for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. Paltusotine is also in clinical development for carcinoid syndrome associated with neuroendocrine tumors. Crinetics' deep pipeline of 10+ disclosed programs includes late-stage investigational candidate atumelnant, which is currently in development for congenital adrenal hyperplasia and ACTH-dependent Cushing's syndrome, and CRN09682, a nonpeptide drug conjugate candidate that is being developed to treat SST2 expressing neuroendocrine tumors and other SST2 expressing solid tumors. Additional discovery programs address a variety of endocrine conditions such as neuroendocrine tumors, Graves' disease (including Graves' hyperthyroidism and Graves' orbitopathy, or thyroid eye disease), polycystic kidney disease, hyperparathyroidism, 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 and paltusotine for the treatment of

carcinoid syndrome; or the potential for our development candidates to transition to clinical development; 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, we may not be able to obtain, maintain and enforce our patents and other intellectual property rights, and it may be prohibitively difficult or costly to protect such rights; geopolitical events may disrupt Crinetics’ business and that of the third parties on which it depends, including delaying or otherwise disrupting clinical studies and preclinical studies, manufacturing and supply chain, or impairing employee productivity; unexpected adverse side effects, complications and/or drug interactions or inadequate efficacy of the Company’s product candidates that may limit their development, regulatory approval and/or commercialization; the Company’s dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; regulatory developments or political changes, including policies related to pricing and pharmaceutical drug reimbursement, 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; Crinetics may use its capital resources sooner than expected or our cash burn rate may accelerate; any future impacts to our business resulting from geopolitical developments outside our control; 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, 2025. 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.