



NEWS RELEASE

# Crinetics Pharmaceuticals Announces the European Commission Approval of PALSONIFY® (Paltusotine) for the Treatment of Acromegaly in Adults

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PALSONIFY is the first once-daily, oral therapy approved to treat acromegaly in the European Union

Approval based on strength of data from two pivotal Phase 3 studies studying PALSONIFY in both medical naïve and previously treated patients with acromegaly

Crinetics' first regulatory approval outside of the U.S., with first launch planned for Germany and Austria

SAN DIEGO, April 27, 2026 (GLOBE NEWSWIRE) -- **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX) today announced that the European Commission (EC) has approved PALSONIFY® (paltusotine), the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist, for the treatment of adult patients with acromegaly.

"The European Commission's decision to approve Palsonify reflects the strength of the clinical data and marks a pivotal step toward bringing this important therapy to even more people living with acromegaly," said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. "This approval represents another exciting milestone for Palsonify as it accelerates to become the new standard in acromegaly care in the U.S., and soon abroad. This is also a notable achievement for Crinetics in pursuit of our vision to become the global leader in endocrinology."

The EC approval is supported by positive results from the pivotal data from the **PATHFNR-1** and **PATHFNR-2** Phase 3 trials, which evaluated PALSONIFY's safety and efficacy in previously treated and medically untreated adults

with acromegaly. Across both trials, PALSONIFY consistently demonstrated rapid onset, reliable biochemical control, and sustained efficacy. PALSONIFY also has Orphan Drug Designation in the EU.

Participants also reported significant reductions in signs and symptoms associated with acromegaly – including headaches, joint pain, sweating, fatigue, weakness, swelling, and/or numbness/tingling – as measured by the Acromegaly Symptom Diary (ASD), a validated patient-reported outcome tool developed to capture the symptoms that matter to people living with acromegaly.

Treatment with PALSONIFY was generally well-tolerated, with no serious adverse events reported in the randomized controlled portion of the trial. The most frequently reported adverse reactions with paltusotine were diarrhea, abdominal pain, nausea, and abdominal discomfort.

The approval by the EC is valid in all 27 member states of the EU and three European Economic Area (EEA) countries. Crinetics is currently planning initial commercialization efforts in Germany and Austria.

PALSONIFY is approved by the U.S. Food and Drug Administration (FDA) for the first-line treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. Crinetics is also in partnership with Sanwa Kagaku Kenkyusho Co., Ltd (SKK) to develop and commercialize PALSONIFY for acromegaly in Japan, where the Ministry of Health, Labour and Welfare recently granted an orphan drug designation. SKK recently submitted a new drug application (NDA) in Japan for paltusotine for the treatment of acromegaly. In Brazil, Crinetics recently submitted a Marketing Authorization Application (MAA) to Brazil's National Health Surveillance Agency (ANVISA) 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.

PALSONIFY is approved in the U.S. for the first-line treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. It is also approved for use in the EU for the medical treatment of adult patients with acromegaly.

## Important Safety Information

The full European Summary of Product Characteristics (SmPC) for PALSONIFY will be available on the European Medicines Agency website at [www.ema.europa.eu](http://www.ema.europa.eu).

## 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 healthcare regulatory authorities in U.S. and European Union for the treatment of adults with acromegaly. 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. Crinetics is headquartered in San Diego, with European commercialization operations based in Zug, Switzerland. Please visit [www.crinetics.com](http://www.crinetics.com) for more information.

## 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 Crinetics, its affiliates or license partners to develop and commercialize PALSONIFY for the treatment of acromegaly in Brazil or Japan, for the clinical development of atumelnant and CRN09682 or for paltusotine for the treatment of carcinoid syndrome; or the potential for our discovery programs or 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.

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