



NEWS RELEASE

INNOVATION PASSPORT GRANTED FOR CRN04777 FOR THE TREATMENT OF CONGENITAL HYPERINSULINISM

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SAN DIEGO, October 5, 2022 — **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX), today announced today that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted **CRN04777** an “Innovation Passport” for the treatment of congenital hyperinsulinism (HI), which enables Crinetics to access the Innovative Licensing and Access Pathway (ILAP). The ILAP was launched in the United Kingdom in 2021 with the goal of reducing the time to market for innovative medicines that treat life-threatening or seriously debilitating conditions and/or conditions for which there is a significant unmet patient need. The ILAP aims to achieve this goal by enabling enhanced coordination between sponsors and MHRA leading up to Marketing Authorization Application (MAA) submissions and by providing the opportunity for accelerated MAA reviews.

“Congenital HI is a rare, life-threatening condition afflicting infants and young children that can lead to complications such as seizures, coma, and brain damage. Many children with the disease require intensive 24-hour glucose management, which is extremely burdensome and of limited efficacy,” stated **Scott Struthers, Ph.D., Crinetics’ president and CEO**. “We believe the Innovation Passport provides important external validation for the CRN04777 program and shows that the MHRA recognizes the struggle congenital HI patients and caregivers face each day. We are pleased to gain access to an expedited review pathway in the UK and look forward to developing CRN04777 as a potential effective oral therapy with the prospect to avoid many of the side effects and burdens associated with current treatments.”

About the MHRA Innovation Passport

The MHRA Innovation Passport is the entry point to the ILAP, which aims to accelerate time to market, facilitating

patient access to new medicines including new chemical entities, biological medicines, new indications and repurposed medicines. An ILAP designation is linked to a portfolio of activities through the product specific creation of a Target Development Profile (TDP). The TDP will define key regulatory and development features, identify potential pitfalls and create a road map for delivering early patient access to designated product candidates. The TDP will include details about how sponsors can work with other UK stakeholders for coordinated and efficient evidence generation and evaluation and address commercial and managed access considerations. More information on TDPs and the ILAP is available on the [UK government website](#).

About CRN04777

CRN04777 is a highly optimized, orally available, small molecule somatostatin receptor type 5 (SST5) selective agonist that is designed to reduce the excess secretion of insulin in patients with congenital monogenic and syndromic HI, and other conditions of excess insulin. Oral administration of CRN04777 has been shown to potently inhibit insulin secretion and normalize glucose levels in preclinical models of hyperinsulinism. A Phase 1 clinical study was conducted in healthy volunteers to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of CRN04777, the results of which demonstrated pharmacologic proof-of-concept for CRN04777, with strong dose-dependent suppression of insulin secretion.

The U.S. Food and Drug Administration granted rare pediatric disease designation for CRN04777 for the treatment of congenital hyperinsulinism. A rare pediatric disease is defined as a serious or life-threatening disease, which primarily affects individuals aged from birth to 18 years and affects fewer than 200,000 people in the United States.

About Crinetics Pharmaceuticals

Crinetics Pharmaceuticals is a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors. **Paltusotine**, an investigational oral somatostatin receptor type 2 (SST2) agonist, is in Phase 3 clinical development for acromegaly and Phase 2 clinical development for carcinoid syndrome associated with neuroendocrine tumors. Crinetics has demonstrated pharmacologic proof-of-concept in Phase 1 clinical studies for CRN04777, an investigational, oral somatostatin receptor type 5 (SST5) agonist for congenital hyperinsulinism, and for **CRN04894**, an investigational, oral ACTH antagonist for the treatment of Cushing's disease, congenital adrenal hyperplasia, and other diseases of excess ACTH. All of the company's drug candidates are orally delivered, small molecule new chemical entities resulting from in-house drug discovery efforts.

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 paltusotine, CRN04777 and CRN04894, including the therapeutic potential and clinical benefits thereof; the ability to gain access to expedited review pathway in the United Kingdom for CRN04777; the expected timing of topline data from the ongoing Phase 3 clinical trials of paltusotine in acromegaly, the preparation of marketing authorization applications and of the development of paltusotine for carcinoid syndrome. 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” 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, topline data that we report may change following a more comprehensive review of the data related to the clinical trials and such data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory authorities may not agree with our interpretation of such results; 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; the COVID-19 pandemic may disrupt Crinetics’ business and that of the third parties on which it depends, including delaying or otherwise disrupting its clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; unexpected adverse side effects 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; the success of Crinetics’ clinical trials and nonclinical studies; regulatory developments in the United States and foreign countries; clinical trials 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; Crinetics may use its capital resources sooner than expected; any future impacts to our business resulting from the conflict between Russia and Ukraine or other geopolitical developments outside our control; and the other risks and uncertainties described in the company’s periodic filings with the 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 reports, including its annual report on Form 10-K for the year ended December 31, 2021. 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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