



Dear CAH Patient Community,

Neurocrine Biosciences is pleased to announce that the Food and Drug Administration (FDA) recently approved CRENESSITY™ (crinecerfont) capsules and oral solution as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic congenital adrenal hyperplasia (CAH).

CRENESSITY is a first-in-class treatment developed for individuals living with classic CAH. For the past 70 years, people with CAH and their doctors have only had one treatment option available to them. Steroids have been used to both replace cortisol and address excess adrenocorticotropic hormone (ACTH) and androgens.

High doses of steroids are often required to manage the issue of excess ACTH and androgens. High-dose steroids are associated with many short- and long-term health risks that can affect quality of life. CRENESSITY offers a game-changing approach to manage classic CAH that may allow people to maintain or improve their adrenal androgens and take lower doses of steroids.

As this advancement illustrates, Neurocrine Biosciences is committed to relieving suffering for people with great needs, but few options. Since the company's founding more than 30 years ago, Neurocrine Biosciences has been dedicated to developing life-changing treatments for patients with unmet medical needs, including those living with neuroendocrine disorders.

Our focus on neuroendocrine disorders began together with our late co-founder, Wylie W. Vale, Ph.D. who made contributions to Nobel Prize-winning work in endocrinology, specifically around the biology of CAH. This is one of the driving forces behind Neurocrine's continued focus on neuroendocrine disorders. Years of research have culminated in the study and FDA approval of CRENESSITY.

We want to thank everyone in the CAH community who made the FDA approval of CRENESSITY possible. It would not have been possible without the time and commitment of clinical trial participants and their families and the collaboration from the patient organizations dedicated to the CAH community.

You can learn more about CRENESSITY by visiting www.crenessity.com. We encourage you to talk to your doctor to determine if adding CRENESSITY to your treatment plan is right for you or your loved one living with classic CAH.

Approved Uses:

CRENESSITY (crinecerfont) is a prescription medicine used together with glucocorticoids (steroids) to control androgen (testosterone-like hormone) levels in adults and children 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

IMPORTANT SAFETY INFORMATION

Do not take CRENESSITY if you:

Are allergic to crinecerfont, or any of the ingredients in CRENESSITY.

CRENESSITY may cause serious side effects, including:

Allergic reactions. Symptoms of an allergic reaction include tightness of the throat, trouble breathing or swallowing, swelling of the lips, tongue, or face, and rash. If you have an allergic reaction to CRENESSITY, get emergency medical help right away and stop taking CRENESSITY.

Risk of Sudden Adrenal Insufficiency or Adrenal Crisis with Too Little Glucocorticoid (Steroid)

Medicine. Sudden adrenal insufficiency or adrenal crisis can happen in people with congenital adrenal hyperplasia who are not taking enough glucocorticoid (steroid) medicine. You should continue taking your glucocorticoid (steroid) medicine during treatment with CRENESSITY. Certain conditions such as infection, severe injury, or shock may increase your risk for sudden adrenal insufficiency or adrenal crisis. Tell your healthcare provider if you get a severe injury, infection, illness, or have planned surgery during treatment. Your healthcare provider may need to change your dose of glucocorticoid (steroid) medicine.

Before taking CRENESSITY, tell your healthcare provider about all of your medical conditions including if you: are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of CRENESSITY in adults include tiredness, headache, dizziness, joint pain, back pain, decreased appetite, and muscle pain.

The most common side effects of CRENESSITY in children include headache, stomach pain, tiredness, nasal congestion, and nosebleeds.

These are not all the possible side effects of CRENESSITY. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

Dosage Forms and Strengths: CRENESSITY is available in 50 mg and 100 mg capsules, and as an oral solution of 50 mg/mL.

Please see full [Prescribing Information](#).

Best regards,

Kyle Gano
Chief Executive Officer
Neurocrine Biosciences, Inc.