Diurnal Ltd., a Neurocrine Biosciences Company, Presents Phase 3 Extension Study Data for Modified-Release Hydrocortisone in Patients with Congenital Adrenal Hyperplasia at ENDO 2023

June 15, 2023

SAN DIEGO, June 15, 2023 /PRNewswire/ -- Diurnal Ltd., a Neurocrine Biosciences company (Nasdaq: NBIX), today announced that it will present new post hoc analyses of Phase 3 extension study data for modified-release hydrocortisone (approved as EFMODY® in United Kingdom and European Union), which is being investigated as a treatment for adults with congenital adrenal hyperplasia (CAH), at ENDO 2023 June 15–18 in Chicago. Diurnal Ltd. developed this modified-release formulation of hydrocortisone, which has been specifically designed to replicate the natural circadian release of cortisol.

Management of CAH involves not only replacing cortisol deficiency but also managing elevated adrenal androgen levels, which are responsible for the detrimental symptoms associated with hyperandrogenism, such as virilization in females and abnormalities in growth leading to short stature and early puberty. Current treatment guidelines recommend a target daily hydrocortisone dose of ≤25 mg (or equivalent dose of prednisone, prednisolone, or dexamethasone) in adult (fully grown) patients with CAH. However, hydrocortisone doses of >25 mg are often necessary to lower adrenal androgens in CAH. Thus, physicians treating CAH patients typically face a difficult dilemma of trying to manage the androgen excess while also trying to avoid the well-known consequences of chronic glucocorticoid overexposure.

The post hoc analyses examined total glucocorticoid daily dose and 9:00 a.m. 17-hydroxyprogesterone (17-OHP) levels in patients treated with modified-release hydrocortisone in an open-label Phase 3 extension study. Of the 71 patients who completed 24 months in the Phase 3 extension study at the time of the interim cut, 64 patients had 9:00 a.m. 17-OHP data for analysis. After 24 months of treatment, median daily hydrocortisone dose was reduced from 30 mg to 20 mg. The number of patients achieving lower androgen levels while receiving ≤25 mg of hydrocortisone per day increased significantly, with 48 percent of the subjects achieving 17-OHP levels <36 nmol/L compared with 31 percent at baseline. See the abstract (Poster # P 72; Improved Biochemical Control with Dose Reduction in Chronic Glucocorticoid Therapy: A Phase 3 Extension Study of CHRONOCORT® (EFMODY®) in the Treatment of Congenital Adrenal Hyperplasia) for more information here.

"These analyses help demonstrate the impact of modified-release hydrocortisone as a potential treatment for adults with congenital adrenal hyperplasia by delivering cortisol in a manner that matches the body's natural circadian rhythm," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences.

About Modified-Release Hydrocortisone
Diurnal Ltd. developed modified-release hydrocortisone, a preparation of hydrocortisone that has been specifically designed to replicate the natural circadian rhythm of cortisol, when given in a twice-a-day "toothbrush" regimen, (administered last thing at night before sleep and first thing in the morning on waking). In 2021, modified-release hydrocortisone (EFMODY®) received marketing authorization for the treatment of congenital adrenal hyperplasia from the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain (England, Wales, and Scotland) and from the European Commission in the European Union. Neurocrine Biosciences acquired Diurnal Group plc. in November 2022. A new drug application for the modified-release hydrocortisone formulation has not been submitted to the U.S. Food and Drug Administration.

About Congenital Adrenal Hyperplasia
Congenital adrenal hyperplasia is a group of rare genetic disorders in which a gene mutation results in the deficiency of one of the enzymes that is involved in the production of adrenal hormones. The most common mutation is to the gene encoding the adrenal enzyme 21-hydroxylase, which is responsible for the synthesis of cortisol in the adrenal glands. The disorder is associated with low cortisol levels that can be life-threatening and excess adrenal androgen that can lead to virilization in females and abnormalities in growth leading to short stature and early puberty.

About Neurocrine Biosciences
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering

for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine, and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, Twitter, and Facebook. (*_in collaboration with AbbVie_)

Neurocrine Biosciences Forward-Looking Statement
In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the potential benefits to be derived from certain of our products. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements include: our future financial and operating performance; risks and uncertainties associated with the commercialization of our products; the risk that our products and/or product candidates will not be found to be safe and/or effective or may not prove to be beneficial to patients; that development activities for our products and/or product candidates may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory or other reasons, may not be successful or replicate previous and/or interim clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions for our products and/or product candidates may not occur or be submitted in a timely manner; risks that our products and/or product candidates may not obtain regulatory approvals; or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding our products and/or product candidates; risks and uncertainties relating to competitive products and technological changes that may limit demand for our products; risks associated with our dependence on third parties for development and manufacturing activities related to our products and our product candidates, and our ability to manage these third parties; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

View original content to download multimedia:https://www.prnewswire.com/news-releases/diurnal-ltd-a-neurocrine-biosciences-company-presents-phase-3-extension-study-data-for-modified-release-hydrocortisone-in-patients-with-congenital-adrenal-hyperplasia-at-endo-2023-301849868.html

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc.: Media: Linda Seaton, 1-858-617-7292, media@neurocrine.com; Investors: Todd Tushla, 1-858-617-7143, ir@neurocrine.com