



Citrine Medicine Announces Strategic Partnership to bring Efmody® to China for Use in Adrenal Insufficiency (AI), including Congenital Adrenal Hyperplasia (CAH)

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By signing second licensing agreement with Diurnal Group plc, Citrine enhances its ability to support pediatric, adolescent, and adult patient needs across China

Cambridge, Massachusetts and Shanghai, China — May 12, 2021 — [Citrine Medicine](#), a China-based rare disease therapeutics company, today announced that it has signed a licensing agreement with Diurnal Group plc (AIM: DNL), a specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases. The deal provides Citrine with exclusive rights to develop and commercialize Efmody® (hydrocortisone modified-release hard capsules – development name Chronocort®) in the Greater China market. In January, Citrine signed a licensing agreement with Diurnal Group for Alkindi®, the first preparation of hydrocortisone specifically designed for use in children suffering from pediatric adrenal insufficiency (AI) and congenital adrenal hyperplasia (CAH).

By licensing the rights to Efmody, Citrine strengthens its ability to provide therapies to patients in China with AI and CAH. With both Alkindi® and Efmody® as part of its portfolio, Citrine now has the potential to support the needs of pediatric, adolescent and adult patients with these diseases. Efmody® was developed for use in adult and adolescent patients with CAH and has been extensively studied in clinical trials across the U.S. and Europe. In March, the European Medicines Agency issued a positive opinion for Efmody®. The formal approval of marketing authorization from the European Commission for Efmody® is expected in June 2021.

“We are very excited to sign this second licensing agreement with Diurnal, which will ultimately allow us to serve the needs of Chinese patients of all ages suffering from AI and CAH,” said Melissa Bradford-Klug, Chief Business Officer of Citrine Medicine. “Citrine was founded to provide individuals and families in China affected by rare diseases with the very best treatments available in the world, and this partnership brings us one step closer to this goal.”

“This partnership highlights Citrine’s ability to bring clinically-validated treatments developed and marketed in other parts of the world into China,” said Dandan Dong, Managing Director, Vivo Capital. “Citrine is working to leverage its relationships with rare disease drug developers across the globe and with Chinese regulatory bodies to rapidly bring rare disease treatments to the patients in China who need them. Citrine is making important strides in realizing its vision to build a rare disease ecosystem in China.”

¹ Zhong, K. et al. (2016) 'The status of neonatal screening in China, 2013', Journal of Medical Screening, 23(2), pp. 59–61. doi: 10.1177/0969141315597715.

About Efmody® (hydrocortisone modified release hard capsules)

Efmody® is a preparation of hydrocortisone that has been specifically designed to mimic the 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) to control androgen excess and chronic fatigue in patients with diseases of cortisol deficiency. The first indication for Efmody® is Congenital Adrenal Hyperplasia (CAH) in adults and adolescents (children older than 12 years of age). Efmody® has been extensively studied in 239 human subjects including 138 CAH patients who have taken part in clinical trials in Europe and the U.S.

The positive opinion from the CHMP is based on a Phase 3 study conducted in a total of 122 patients enrolled across 11 clinical sites, the largest ever interventional clinical trial completed in CAH. The Phase 3 data was supported by detailed analysis of data from an open-label safety extension study for patients completing treatment in the Phase 3 study, which is assessing the impact of treatment with Efmody® over an extended period, with a number of patients on this trial having been treated for over 54 months. Patient retention rates in this study have been high and patients on this trial have, to date, shown sustained benefit from Efmody® treatment.

About Adrenal Insufficiency (AI) and Congenital Adrenal Hyperplasia (CAH)

AI, including the genetic condition CAH, is a condition characterised by deficiency in cortisol, an essential hormone in regulating metabolism and the response to stress. The primary symptoms of AI are chronic fatigue and patients are at risk of adrenal crisis and death if they do not have adequate cortisol replacement. AI is either primary or secondary, with primary AI resulting from diseases intrinsic to the adrenal gland and secondary AI resulting from pituitary diseases where there is a failure of stimulation of the adrenal by the pituitary of the signalling hormone ACTH (adrenocorticotrophic hormone).

About Citrine Medicine

Citrine Medicine is dedicated to improving the lives of patients with rare and intractable diseases by making diagnosis and essential treatments available and accessible to those who need them in China. Our mission is to build the first rare disease ecosystem in China and in doing so, enable extraordinary people to live more ordinary lives. In addition to developing and marketing rare disease drugs, Citrine aims to establish a patient-centric platform which educates people on rare diseases, trains doctors on diagnosis and treatment, and helps doctors develop a full disease management protocol. Citrine is headquartered in Shanghai and has offices in Beijing, China and Cambridge, Mass.

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About Diurnal Group plc

Founded in 2004, Diurnal is a UK-headquartered, European specialty pharma company developing hormone therapeutics for the global market for the life-long treatment of chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency and hypogonadism. Its expertise and innovative research activities focus on circadian-based endocrinology to yield novel product candidates in the rare and chronic endocrine disease arena.

For further information about Diurnal, please visit www.diurnal.co.uk