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Norgine submits Marketing Authorisation Application to the European Medicines Agency for eflornithine (difluoromethylornithine [DFMO]) in high-risk neuroblastoma

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Norgine today announced that it completed its marketing authorisation application filing to European Medicines Agency (EMA) for eflornithine in high-risk neuroblastoma (HRNB). This follows the submissions in April 2024, via **Project Orbis,** in Australia, Switzerland and the United Kingdom.

This milestone further supports Norgine's efforts to give patients access to eflornithine and bring a further treatment option in the field of paediatric oncology.

Norgine and USWM, LLC (dba US WorldMeds), a Kentucky-based specialty pharmaceutical company, have an exclusive licensing agreement by which Norgine will register and commercialise eflornithine, also referred to as DFMO, in Europe, Australia and New Zealand.

On 13 December 2023, the US Food and Drug Administration (FDA) approved eflornithine as the first oral maintenance therapy for HRNB, indicated to reduce the risk of relapse in adult and paediatric patients who have received certain prior therapies.[1] The approval decision was based on findings from a trial comparing outcomes from patients treated with eflornithine in Study 3b (NCT02395666)[2],[4] to control patients derived from Study ANBL0032 (NCT00026312; clinical-trial-derived external control arm)[3],[4]. The study with eflornithine treated patients showed improved event-free survival and overall survival when compared to outcomes for patients with HRNB treated with the standard of care (SoC).[1]

Dr David Gillen, Chief Medical Officer at Norgine, added, "This submission via the EU Centralised Procedure represents another important step in the regulatory process for eflornithine and further emphasises Norgine's passion and commitment in attempting to secure additional treatment options for patients living with HRNB, a condition with a high level of unmet medical need."

Janneke van der Kamp, CEO of Norgine added "Submitting this marketing authorisation to the EMA marks a pivotal step for patients facing this challenging cancer. We are committed to advancing innovative therapies that address the unmet needs of young patients and their families, and this milestone brings us closer to offering hope where it's most needed".

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Notes to Editors:

HRNB background

Children diagnosed with HRNB undergo an intense SoC regimen that still leaves them vulnerable to relapse and death, a risk that is highest for the first two years after completing treatment.[5] Approximately 30% of patients who attain remission following upfront therapy will relapse, and once relapsed, mortality significantly increases with a post-relapse 4-year overall survival of under 10%.[5], [6] Therefore, avoiding relapse is key to long-term survival, yet outside of the United States there are no approved therapies for sustaining remission following SoC treatment. The data demonstrate that using eflornithine after completion of upfront SoC treatment, as post-maintenance therapy extends remission and reduces risk of relapse in patients with HRNB.

About Norgine

Norgine is a uniquely positioned, specialty pharmaceutical and consumer healthcare company, with over €500 million of annual revenues and a 120-year track record of bringing life-changing products to patients and consumers across our core markets of Western Europe, Australia and New Zealand.

Our integrated approach – strong commercial capabilities, deep medical, regulatory and clinical expertise, in-house manufacturing, robust supply networks, and best in class enabling functions – ensures that we can deliver high-quality, transformative medicines quickly and effectively to over 25 million patients annually.

Today's Norgine is a nimble, innovative, and high-performing company that has been transformed by a relentless focus on operational excellence. This focus will enable us to secure the legacy of more than a century of innovation and doing the right thing by our patients, as we push the boundaries and take strides into new therapeutic areas.

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Contact:

contact@norgine.com