Renaissance Pharma Limited, an Essential Pharma company, secures FDA Fast Track Designation and IND clearance for Daretabart (hu1418K322A) in high-risk neuroblastoma

- *FDA grants Fast Track Designation for Daretabart (hu1418K322A), recognising the significant unmet medical need in high-risk neuroblastoma and enabling access to accelerated and rolling review*
- *FDA clearance of IND application enables initiation of the SHINE Phase II/III clinical trial in relapse and refractory patients with high-risk neuroblastoma*
- *First commercial-scale GMP batch of Daretabart (hu1418K322A) successfully manufactured*
- *Programme builds on positive Phase II data which demonstrated overall survival rate of 86.0%*

UK – 21 April 2026 – Renaissance Pharma Limited, an Essential Pharma company focused on development stage assets, today announces that the US Food and Drug Administration (FDA) has granted Fast Track Designation for Daretabart (hu1418K322A), a novel anti-GD2 monoclonal antibody in development for the treatment of high-risk neuroblastoma (HRNB), a rare paediatric cancer. The designation recognises the significant unmet medical need in HRNB and will support more frequent interactions with the FDA throughout development, as well as eligibility for accelerated and rolling review.

The company also confirms it has received IND clearance from the FDA, enabling initiation of the SHINE Phase II/III clinical trial in relapse or refractory children with HRNB in the United States. The first commercial-scale Good Manufacturing Practice (GMP) batch of Daretabart (hu1418K322A) has also been successfully manufactured for use in the SHINE trial.

Daretabart (hu1418K322A) is being developed by Renaissance Pharma under an exclusive license agreement with St. Jude Children's Research Hospital, a global leader in pediatric cancer research and treatment. The antibody targets GD2, a cell surface antigen highly expressed on neuroblastoma cells. By binding to GD2, Daretabart (hu1418K322A) is designed to enhance immune-mediated tumour cell killing, while incorporating novel structural modifications intended to improve tolerability profile.

The programme builds on encouraging Phase II data evaluating Daretabart (hu1418K322A) as part of first-line therapy and in the post-consolidation setting for patients with HRNB. The study demonstrated a three-year event-free survival (EFS) rate of 73.7% and an overall survival (OS) rate of 86.0%. These results were published in the *Journal of Clinical Oncology* in December 2021.

The successful manufacture of the first commercial-scale GMP batch marks a key operational milestone and underscores Renaissance Pharma’s commitment to ensuring reliable, high-quality supply as the

programme advances. This achievement supports ongoing clinical development and represents an important step towards future commercial readiness.

Simon Ball, Interim CEO of Essential Pharma and Director of Renaissance Pharma Limited said: "*Daretabart has the potential to make a real difference for children with high-risk neuroblastoma, a disease where outcomes remain deeply inadequate despite intensive treatment. FDA Fast Track Designation is an important external validation of that potential, and together with IND clearance and our ability to manufacture at commercial scale, reflects the strength and maturity of this programme. Having worked exceptionally hard behind the scenes for a number of months, it is with great excitement that we announce this update today. We are executing at pace, and look forward to sharing data from the SHINE trial as it progresses. Today's news brings us another step closer to delivering Daretabart as a meaningful new treatment option for children facing this aggressive cancer.*"

References

[1] Furman WL, McCarville B, Shulkin BL, Davidoff A, Krasin M, Hsu CW, et al. Improved Outcome in Children With Newly Diagnosed High-Risk Neuroblastoma Treated With Chemoimmunotherapy: Updated Results of a Phase II Study Using hu14.18K322A. Journal of Clinical Oncology [Internet]. 2022 Feb 1;40(4):335–44. Available from: http://dx.doi.org/10.1200/jco.21.01375

[2] News Medical Life Sciences. European scientists target high-risk childhood cancer with liquid biopsy. Available from: https://www.news-medical.net/news/20240129/European-scientists-target-high-risk-childhood-cancer-with-liquid biopsy.aspx#:~:text=Neuroblastoma%20mainly%20affects%20toddlers%20and,patients%20are%20high%2Drisk%20cases

St. Jude Children's Hospital. - https://www.stjude.org/disease/neuroblastoma.html

About Renaissance Pharma

Renaissance Pharma Limited, an Essential Pharma company, focused on development stage assets, is currently focused on improving treatment options within rare paediatric diseases. Lead candidate – Daretabart (hu1418K322A) is targeting the treatment of neuroblastoma.

About Essential Pharma

Essential Pharma is a global pharmaceutical company developing and delivering medicines for patients in niche populations. Our growing product portfolio reaches patients in approximately 70 countries and covers multiple therapy areas with a particular focus on speciality medicines used to treat rare diseases and cardiorespiratory disease. Our first development-stage asset, managed through our wholly owned subsidiary, Renaissance Pharma Limited, is an anti-GD2 antibody for the treatment of high-risk neuroblastoma – Daretabart (hu1418K322A). We challenge convention and work smarter to help ensure patients in small, underserved or rare disease populations have access to the medicines they need.

For more information, visit www.essentialpharmagroup.com

About Neuroblastoma

Neuroblastoma represents 7-10% of all childhood cancers and is the most common extracranial cancer in children and the most common cancer in children under one year of age. Each year, more than 1,500 people are diagnosed in Europe and 800 in the United States. Approximately half of all neuroblastoma patients have high risk (HRNB) disease which has an overall five-year survival of ~50%. The current standard of care is intensive and multimodal, including chemotherapy, surgery, radiotherapy, stem cell transplantation and anti-GD2 monoclonal antibody (mAb) treatment. Despite these interventions, a significant unmet medical need remains for more effective and better-tolerated treatments for HRNB[1,2]

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