Electra Therapeutics Announces ELA026 Granted EMA Orphan Drug Designation for the Treatment of Secondary Hemophagocytic Lymphohistiocytosis (sHLH)

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ELA026 has demonstrated promising potential to address the high unmet need for patients with sHLH, a rare, life-threatening hyperinflammatory disease with limited treatment options

SOUTH SAN FRANCISCO, CA, August 4, 2025 – Electra Therapeutics, a clinical stage biotechnology company pioneering therapies against novel targets for diseases in immunology and cancer, today announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation (ODD) for ELA026 for the treatment of secondary hemophagocytic lymphohistiocytosis (sHLH). ELA026, Electra's lead drug candidate, is the first investigational therapy designed to broadly treat sHLH. By targeting SIRP-expressing cells, ELA026 selectively depletes pathological myeloid cells and T lymphocytes responsible for the cytokine storm and disease progression.

"This Orphan Drug Designation in Europe complements our U.S. regulatory strategy for ELA026 and underscores the high unmet medical need for patients with sHLH, a rare disease with high mortality and limited treatment options," said Kim-Hien Dao, DO, PhD, Chief Medical Officer of Electra Therapeutics. "Our Phase 1b results for ELA026 demonstrated the therapeutic value of selectively depleting pathological immune cells to modulate inflammation in sHLH. Our team at Electra continues to work diligently to advance the clinical program and bring ELA026 to patients as quickly as possible."

The EMA's Orphan Drug Designation program is designed to encourage the development of drugs that may provide significant benefit to patients with rare diseases. This designation provides several incentives, including reduced fees, protocol assistance, centralized marketing authorization, and ten years of EU market exclusivity.

About Secondary Hemophagocytic Lymphohistiocytosis (sHLH)

Secondary hemophagocytic lymphohistiocytosis (sHLH) is a rare, life-threatening hyperinflammatory disease with a lack of treatment options. It can be triggered by cancer, infection, autoimmune disease, or immunotherapy. sHLH is associated with a severe inflammatory response that requires immediate intervention. Without effective treatment, patients may experience multiorgan failure and death. sHLH is associated with high mortality early in the disease course, with malignancy-associated HLH (mHLH) patients having a mortality rate of approximately 50% at two months with available therapies.

About Electra Therapeutics

Electra Therapeutics is a clinical stage biotechnology company pioneering therapies against novel targets for diseases in immunology and cancer. The company's lead product candidate, ELA026, is a first-in-class monoclonal antibody that targets signal regulatory proteins (SIRP) on immune cells to selectively deplete pathological myeloid cells and T lymphocytes. ELA026 is currently in pivotal development for secondary hemophagocytic lymphohistiocytosis (sHLH) and is also being evaluated in additional indications. Electra is further advancing a second SIRP-targeted program, ELA822, designed to selectively deplete activated T lymphocytes, with broad potential across immunology and inflammation (I&I). For more information, please visit www.electra-therapeutics.com and follow us on LinkedIn.

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