TITLE	**A PHASE 2/3, OPEN-LABEL, SINGLE-ARM, MULTICENTER, HISTORICAL CONTROL STUDY TO EVALUATE ELA026 IN PARTICIPANTS WITH SECONDARY HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (SHLH) (NCT05416307)**
TRIAL DESIGN	• 12-week treatment period followed by safety and long-term survival follow-up • Potential for optional treatment extension
STUDY POPULATIONS	**Cohort A:** • ≥ 18 years old, treatment-naïve (TN)[1] malignancy-associated HLH (mHLH) meeting HLH-2004 diagnostic (Dx) criteria **Cohort B:** • B1: ≥ 18 years old, TN1 sHLH not triggered by malignancy meeting HLH-2004 Dx criteria • B2: ≥ 18 years old, TN1 mHLH diagnosed by Optimized HLH Inflammatory (OHI) index criteria but not meeting HLH-2004 Dx criteria • B3: 13-17 years old, TN1 sHLH meeting HLH-2004 Dx criteria • B4: 6-12 years old, refractory[2] sHLH meeting HLH-2004 Dx criteria (safety lead-in) • B5: 6-12 years old, TN[1] sHLH meeting HLH-2004 Dx criteria
ELA026 & DOSING	**ELA026:** • **ELA026** is a first-in-class, fully human IgG1κ monoclonal antibody that binds to SIRPα, -β1 and -γ • Formulated for intravenous (**IV) or** subcutaneous **(SC) administration** **Dosing:** • Includes initial priming and loading doses followed by **2x weekly maintenance dosing**
ENROLLMENT	Study is actively recruiting
KEY OBJECTIVES	**Primary:** **8-week survival** in ELA026-treated TN lymphoma-associated HLH participants enrolled in Cohort A[3] **Secondary/Exploratory:** Additional Efficacy Parameters, Safety, Healthcare Outcomes, Pharmacokinetics, Pharmacodynamics

KEY ELIGIBILITY CRITERIA

INCLUSION CRITERIA

Refer to "Study Populations" section above

EXCLUSION CRITERIA

- Refractory sHLH (except for sub-group B4)
- Known or suspected primary or hereditary HLH
- Severe organ dysfunction
- Any other significant concurrent, uncontrolled medical condition that contraindicates participation in this study or prohibits completion of study procedures
- End-stage malignancy for which no suitable therapies are available to treat the malignancy triggering the HLH
- Allogeneic hematopoietic stem cell transplant within 100 days prior to the first dose of ELA026

[1]treatment-naïve (TN): has not received any HLH-directed therapy excluding glucocorticoids
[2]refractory: ≤2 weeks of HLH-directed therapy with suboptimal response
[3]Note: a narrow primary analysis population has been defined to reduce the heterogeneity of the population for efficacy analyses