Elpiscience's Independently Developed BsAb ES014 Receives FDA Orphan Drug Designation, Accelerating Global Development in Desmoid Tumors

- *ES014 demonstrated encouraging single-agent activity in the Phase I study, achieving an objective response rate (ORR) of 40% and disease control rate (DCR) of 100% in patients with desmoid tumors*
- *The designation marks a significant milestone for ES014 in its international regulatory and global development progress, and is expected to further shorten the clinical development timeline and expand global development and potential commercialization processes*

Shanghai and Suzhou, China, March 3, 2026 — Elpiscience announced today that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to ES014, the company's independently developed first-in-class CD39/TGF-β bispecific antibody (BsAb), for the treatment of Desmoid Tumors (DT). The designation represents a significant milestone in ES014's international regulatory recognition and global development and is expected to facilitate its clinical development, regulatory approval, and potential commercialization in the United States, further strengthening its global strategy.

Orphan Drug Designation (ODD) is a regulatory incentive program established by the FDA to encourage the development of therapies for rare diseases affecting fewer than 200,000 people in the United States. Products granted ODD may be eligible for up to seven years of U.S. market exclusivity upon approval for marketing, tax credits for qualified clinical trial costs, waiver of new drug application (NDA/BLA) fees and FDA enhanced regulatory guidance throughout the development process. These incentives are designed to reduce development risk and facilitate the advancement of innovative therapies for rare diseases. For ES014, the designation may help accelerate clinical timelines, expand global development and potential commercialization efforts, and potentially provide a new treatment option for patients with desmoid tumors worldwide more quickly.

Dr. Xiaohui Ji, Co-founder and Chief Executive Officer of Elpiscience, commented: "The FDA Orphan Drug Designation for ES014, as a first-in-class bispecific antibody, represents an important achievement of Elpiscience's commitment to original innovation and a key milestone in our internationalization journey. We are actively advancing the Phase II clinical trial of ES014 and look forward to further evaluating its

efficacy and safety, with the aim of delivering a novel treatment option to patients as early as possible."

About Desmoid Tumors

Desmoid Tumors are rare, locally aggressive soft tissue neoplasms characterized by high recurrence rates. Current treatment options remain limited, and there is significant unmet clinical need for more effective and innovative therapies.

About ES014

ES014 simultaneously blocks CD39 and TGF-β, two key immunosuppressive pathways in the tumor microenvironment, offering a novel therapeutic approach for tumor treatment with potential as both monotherapy and combination therapy. Phase I clinical studies have shown that ES014 exhibits favorable safety profiles and has demonstrated single-agent anti-tumor activity in solid tumors, including Desmoid Tumors, non-small cell lung cancer, and gastrointestinal stromal tumors. Among patients with Desmoid Tumors, ES014 achieved positive monotherapy activity, with an objective response rate (ORR) of 40% and a disease control rate (DCR) of 100%.

About Elpiscience

Elpiscience is a clinical-stage biopharmaceutical company dedicated to the development of innovative immunotherapies for oncology and autoimmune diseases. By advancing breakthrough biologics and leveraging global strategic partnerships, Elpiscience has built a differentiated pipeline to deliver transformative treatment solutions for patients worldwide.

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