FOR IMMEDIATE RELEASE

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Anwita Biosciences Receives FDA Orphan Drug Designation for AWT020 in Thymic Epithelial Tumors

Santa Clara, CA - October 21, 2025 − Anwita Biosciences Inc., a clinical-stage biotechnology company developing next-generation cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to AWT020 for the treatment of thymic epithelial tumors (TET).

TETs are rare malignancies arising from the thymus, including thymoma, thymic carcinoma, and thymic neuroendocrine tumors. Standard treatments such as surgery, chemotherapy, and radiotherapy provide limited benefit in advanced disease, where recurrence and progression rates remain high. No targeted therapies are currently approved for TET. The FDA's orphan designation underscores the urgent medical need for innovative and effective treatment options in this underserved patient population.

AWT020 is a novel bifunctional fusion protein combining an anti-PD-1 nanobody with a potency optimized no-α-IL-2 mutein, designed to enhance antitumor T-cell responses locally in the tumor microenvironment while minimizing systemic toxicity. AWT020 is being evaluated in Phase 1 clinical trials for patients with advanced cancers. Preliminary data indicates a manageable safety profile and encouraging responses across multiple tumor types, including thymoma and thymic carcinoma (TETs), as well as cervical squamous cell carcinoma, uterine sarcoma, neuroendocrine NSCLC, urothelial carcinoma, and cholangiocarcinoma.

"Receiving ODD for AWT020 is an important milestone for our company, highlighting its differentiated mechanism and its potential to address an unmet medical need in TET," said Ziyang Zhong, Chief Executive Officer of Anwita Biosciences. "We are encouraged by the early clinical signals showing durable responses and disease control in TETs and remain committed to advancing AWT020 in this rare patient population while exploring its benefit across other cancers."

The FDA's orphan drug designation for AWT020 provides Anwita with incentives including tax credits, fee waivers, and seven years of U.S. market exclusivity upon approval.

About AWT020

AWT020, Anwita Bioscience's lead clinical candidate, is a novel bifunctional fusion protein that simultaneously blocks PD-1 and activates IL-2 signaling in a PD-1 dependent manner. The product consists of an anti-PD-1 binding domain fused to an IL-2 mutein that has been optimized with reduced affinity for IL-2Rβγ and without binding to IL-2α. AWT020 combines the dual benefits of PD-1 blockade and IL-2 signaling into a single molecule, representing an innovative cancer

immunotherapy designed to selectively reinvigorate immune responses in the tumor microenvironment while minimizing systemic immune activation. Two Phase 1 trials are ongoing: NCT06092580 sponsored by Anwita Biosciences and NCT06839105 sponsored by Junshi Biosciences.

About Anwita Biosciences, Inc.

Anwita Biosciences is a clinical-stage biotechnology company headquartered in the San Francisco Bay Area, California, dedicated to developing next-generation immunotherapies for cancer and immune-related diseases. The company's pipeline includes multifunctional biologics designed to deliver potent immune modulation with improved safety for patients with advanced cancers, as well as novel program targeting patients with metabolic dysfunction.

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