AbelZeta Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for C-CAR168 for the Treatment of Refractory SLE, Including LN

ROCKVILLE, MD, May 27, 2025 – AbelZeta Pharma, Inc. ("AbelZeta" or the "Company"), a global clinical-stage biopharmaceutical company focused on discovery and development of innovative and proprietary cell-based therapeutic products, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to its investigational therapy, C-CAR168, for the treatment of refractory Systemic Lupus Erythematosus (SLE), including Lupus Nephritis (LN).

C-CAR168 is a novel autologous bi-specific CAR-T therapy targeting both CD20 and B-cell maturation antigens (BCMA) in the treatment of patients with autoimmune diseases including autoimmune neurological diseases. The RMAT designation, granted under Investigational New Drug (IND) 30283, is based on promising early clinical data demonstrating the potential of C-CAR168 to address serious unmet medical needs in patients with treatment-resistant forms of autoimmune disease. Early clinical results from the Phase 1, first-in-human investigator-initiated trial (IIT) of C-CAR168 in patients with refractory autoimmune disease (NCT06249438) were shared as a podium presentation at the 16th International Congress on Systemic Lupus Erythematosus (LUPUS 2025), in Toronto, Canada on May 22, 2025. The presentation can be viewed on the Company website page "Publications & Presentations".

"We are pleased to receive the RMAT designation from the FDA for C-CAR168, a recognition made possible by the unwavering efforts of our dedicated team," said Tony (Bizuo) Liu, AbelZeta's Chairman and CEO. "This designation represents a significant milestone highlighting the promise that C-CAR168 holds for patients suffering from severe, treatment-resistant lupus and lupus nephritis. It also enables us to work more closely with the FDA, allowing us to accelerate development of this innovative therapy and bring hope and the potential for drug free disease remission to patients around the world who currently face limited treatment options."

The RMAT designation enables sponsors to have early and frequent interactions with the FDA, including obtaining guidance on the development plan and the potential eligibility for priority review and accelerated approval. AbelZeta plans to request a multidisciplinary type B meeting with the FDA to discuss the next steps in the clinical and manufacturing development of C-CAR168.

About AbelZeta Pharma, Inc.

AbelZeta is a global clinical-stage biopharmaceutical company with centers of excellence in Rockville, Maryland and Shanghai, China. AbelZeta is focusing on developing innovative and proprietary cell-based therapeutic products and is committed to ushering in bespoke treatments that harness the body's own immune system to fight against hematological malignancies and solid tumors, as well as inflammatory and immunological diseases. AbelZeta advances research and development in its own GMP facilities at its centers of excellence for early-stage clinical studies, with a pipeline comprised of CAR-T therapies.

Forward-Looking Statements

Statements in this communication relating to plans, strategies, specific activities, and other statements that are not descriptions of historical facts are forward-looking statements. Forward-looking information is inherently subject to risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, which include any risks detailed from time to time in the Company's reports. Such statements are based on the management's current beliefs and expectations and are subject to significant risks and uncertainties outside of management and the Company's control. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as otherwise required by law, the Company does not undertake any obligation, and expressly disclaims any obligation, to update, alter or otherwise revise any

forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

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