AbelZeta Receives FDA Clearance of Registrational Phase II Trial for C-CAR168 in Refractory Lupus Nephritis

ROCKVILLE, MD and SHANGHAI July 27, 2026 – AbelZeta Pharma, Inc. ("AbelZeta" or the "Company"), a global clinical-stage biopharmaceutical company focused on the discovery and development of innovative and proprietary cell-based therapeutic products, today announced that the Company received the U.S. Food and Drug Administration (FDA) clearance under its Regenerative Medicine Advanced Therapy (RMAT) designation regarding the multiple-center registrational Phase II clinical trial for C-CAR168, an anti-CD20/BCMA bispecific CAR-T, in the treatment of patients with Lupus Nephritis (LN) refractory to standard therapy. The Phase II trial will further evaluate the safety and efficacy of C-CAR168 in this patient population with significant unmet medical needs.

"The FDA clearance to proceed with this multiple-center registrational Phase II trial for C-CAR168 in LN represents an important step forward in the development of this promising new modality for patients with severe, treatment-refractory lupus. This is a population with severe unmet medical needs," said Tony (Bizuo) Liu, Chairman and Chief Executive Officer of AbelZeta. "Together with the RMAT and PRIority MEdicines (PRIME) designations granted by the FDA and European Medicines Agency (EMA), respectively, this regulatory progress underscores the tremendous potential of C-CAR168 to address a significant unmet need for autoimmune diseases. We look forward to effectively advancing the program globally. We hope this drug can deliver deep and durable clinical benefits for LN patients. We are also actively and aggressively evaluating the potential of C-CAR168 in other major disease indications."

About C-CAR168

C-CAR168 is a novel autologous bi-specific CAR-T therapy targeting both CD20 and BCMA. C-CAR168 is designed to support deep depletion of disease-driving B cells and plasma cells, with the goal of inducing an immune reset in patients with severe autoimmune diseases, including refractory Systemic Lupus Erythematosus (SLE) and LN, progressive Multiple Sclerosis (MS) and others. The FDA and the EMA have granted RMAT and PRIME designations, respectively, to C-CAR168 for the treatment of refractory SLE including LN.

About SLE and LN

SLE is a chronic autoimmune disease characterized by systemic inflammation and multi-organ involvement. LN is a serious manifestation of SLE involving inflammation of the kidneys and can lead to progressive kidney damage and kidney failure. Despite available standards of care, patients with refractory disease continue to face significant unmet medical needs, including persistent disease activity, risk of organ damage, and cumulative toxicity associated with long-term immunosuppressive treatment.

About AbelZeta Pharma, Inc.
AbelZeta is a global clinical-stage biopharmaceutical company with centers of excellence in Rockville, Maryland and Shanghai. 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, inflammatory and immunological diseases and solid tumors. AbelZeta advances research and development in its own GMP facilities at its centers of excellence, with a pipeline comprised of multiple 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 numerous factors. Forward looking statements are based on the current beliefs and management's expectations and are subject to significant risks and uncertainties outside of AbelZeta Pharma, Inc.'s ("AbelZeta" or the "Company") 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, AbelZeta 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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