AbelZeta Receives EMA PRIME Designation for C-CAR168 in Lupus Nephritis and Systemic Lupus Erythematosus

July 20, 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 European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has granted PRIority MEdicines (PRIME) designation for C-CAR168, the Company's novel autologous anti-CD20/BCMA CAR-T product candidate, for the treatment of refractory Systemic Lupus Erythematosus (SLE), with or without Lupus Nephritis (LN).

The granting of EMA PRIME designation marks one of the first major regulatory recognitions of a CAR-T therapy for SLE, highlighting both the significant unmet need faced by lupus patients and the potential of this approach to transform treatment. Building on the clinical promise demonstrated by earlier CAR-T therapies, AbelZeta has applied extensive expertise in developing dual-target CAR-T technology to engineer its dual anti-CD20/BCMA-targeted CAR-T. This next-generation construct has been rationally designed to more effectively address the underlying immunopathology of lupus by targeting both autoreactive B cells and antibody-producing plasma cells, with the goal of achieving deeper, more durable remissions while maintaining a favorable safety profile.

"The PRIME designation represents another significant milestone for AbelZeta's scientific capabilities and further demonstrates that well-designed early clinical trials can generate highly clinically meaningful results that translate into regulatory recognition and inform global drug development. This recognition reflects the strength of our scientific platform, the dedication of our team, and the significant progress we have made in expanding cell therapy well beyond oncology," said Tony (Bizuo) Liu, Chairman and Chief Executive Officer of AbelZeta. "It provides important momentum as we advance C-CAR168 through global development in multiple disease indications and further establishes AbelZeta as a leader in cell therapy for autoimmune diseases."

In May 2025, the U.S. Food and Drug Administration (FDA) also granted Regenerative Medicine Advanced Therapy (RMAT) designation to C-CAR168 for the treatment of refractory SLE, including LN.

About EMA PRIME

PRIority MEdicines, or PRIME, is a scheme established by the EMA, granted to promising medicines that may address significant unmet medical needs and that provides enhanced regulatory support, including early dialogue and scientific advice, to help optimize development and potentially accelerate evaluation.

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 SLE and LN, progressive Multiple Sclerosis (MS) and others.

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, 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, 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 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.

Company Contact:
Sarah Kelly
Director of Communications
AbelZeta Pharma, Inc.
+1 (240) 552 5870
sarah.kelly@abelzeta.com
www.abelzeta.com