AbelZeta Presents New Data on C-CAR168 for the Treatment of Autoimmune Diseases at LUPUS 2025

- *Novel Anti-CD20/BCMA Bispecific Autologous CAR-T Therapy Targeting Lupus Nephritis , Systemic Lupus Erythematosus and Multiple Sclerosis*
- *Phase 1, First-in-Human Investigator-Initiated Trial (IIT)*

ROCKVILLE, MD, May 22, 2025 – 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 data from its Phase 1 first-in-human investigator-initiated trial (IIT) of C-CAR168 study (NCT06249438, the "Study") has been published in an abstract shared in a podium presentation at the 16th International Congress on Systemic Lupus Erythematosus ("LUPUS 2025") in Toronto, Canada. The Principal Investigator (PI) of the Study, Professor Nan Shen from Department of Rheumatology, Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine, presented the early clinical results in patients with refractory autoimmune disease.

- **Abstract ID:** https://cslide.ctimeetingtech.com/lupus25/attendee/confcal/show/session/23
- **Abstract Title:** Clinical Impact of C-CAR168, A Novel Anti-CD20/BCMA Composite Autologous CAR-T Therapy, in Refractory Lupus Nephritis
- The presentation may be viewed on the Company website page "Publications & Presentations".

Key Highlights:

- Overall, 10 patients have been treated with C-CAR168 including 7 LN patients, 1 Secondary Progressive Multiple Sclerosis (SPMS), 1 Neuromyelitis Optica Spectrum Disorder (NMOSD) and 1 Immune-Mediated Necrotizing Myopathy (IMNM) patient as of February 28, 2025;
- Early clinical data showed that C-CAR168 was well tolerated. Four LN patients and one SPMS patient experienced low-grade 1-2 CRS with median time to onset of 2 days post C-CAR168 treatment. Neither ICANS nor severe infection was observed.

Mechanism of Action and Efficacy in LN Patients and a SPMS Patient:

- Robust C-CAR168 expansion and rapid, complete depletion of B cells, CD20dim T cells, and plasma cells in peripheral blood was observed. Complete elimination of B cells, $CD19^+$- and $CD19^-$ long-lived plasma cells in bone marrow was also demonstrated in the only patient in whom bone marrow was examined;
- Four LN patients treated with C-CAR168 reached the 6-month evaluation timepoint. All 4 achieved and remained in SRI (4), 2 patients achieved CR, and 1 PR based on Kidney Disease: Improving Global Outcomes (KDIGO) 2024 LN Response Criteria;
- All patients discontinued IS/biologics after lymphodepletion, and most patients steroid-free after C-CAR168 infusion;
- One LN patient flared before 6-month post treatment;
- Evidence of C-CAR168-induced immune reset was demonstrated through peripheral blood flow cytometry and RNA sequencing analysis in LN patients;
- The SPMS patient treated showed very promising early efficacy signal**,** including improvement in gait and orbital movement, significant reduction of brain inflammation and lesion size, improvement in EDSS, 9-HPT, T25-FW, and biomarker level.

"The early clinical results for C-CAR168 mark a significant step forward in the treatment of patients suffering from LN and SPMS with severe manifestations and few effective treatment options," said Tony (Bizuo) Liu, the Company's Chairman and CEO. "These findings support the extension of our bi-specific CAR-T platform, including anti CD20/19 bispecific CAR-T for NHL and now adding C-CAR168, anti-CD20/BCMA, for autoimmune diseases. Success in treatment with C-CAR168 would enable patients to discontinue immunosuppressive therapy and substantially reduce disease activity. We will work closely with the FDA and the scientific community to move forward with Phase 1b and Phase 2 studies."

About the Study (NCT06249438)

This is an investigator-initiated, multicenter, open-label study of C-CAR168 for the treatment of adult patients with autoimmune diseases and neurological diseases, such as refractory LN, SLE and progressive Multiple Sclerosis (MS), resistant and refractory to standard therapy. As of February 28, 2025, 7 patients with refractory LN received C-CAR168 therapy, with 4 dosed at 0.75×10^6 cells/kg and 3 at 1.5×10^6 cells/kg. The treated population had long-standing refractory disease (median SLE duration 9 years, LN 5 years) with exposure to a median of 4 IS or biologic agents.

About C-CAR168

C-CAR168 is a novel autologous bi-specific CAR-T therapy targeting both CD20 and B-cell maturation antigens (BCMA). The Food and Drug Administration (FDA) has granted clearance of the Investigational New Drug (IND) application of C-CAR168 and preclinical data was presented at the American College of Rheumatology (ACR) Convergence 2024 held in Washington, DC, in November 2024.

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 and TIL 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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