AbelZeta Receives FDA IND Clearance for Phase 1b/2 Clinical Trial of C-CAR168 in Progressive Multiple Sclerosis

- *IND clearance further expands development of C-CAR168 across chronic autoimmune diseases with significant unmet medical need*

ROCKVILLE, MD and SHANGHAI September 14, 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 U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application to initiate a Phase 1b/2 clinical trial evaluating C-CAR168, an anti-CD20/BCMA bispecific CAR-T, in patients with progressive multiple sclerosis refractory to standard therapy.

This IND clearance expands AbelZeta's C-CAR168 clinical development program into refractory chronic autoimmune neurological disease. It follows two recent major regulatory milestones in refractory systemic lupus erythematosus (SLE), including lupus nephritis (LN): FDA clearance, under the Regenerative Medicine Advanced Therapy (RMAT) designation, of a multicenter registrational Phase II clinical trial, and PRIority MEdicines (PRIME) designation from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).

"The FDA clearance of this Phase 1b/2 study represents another important step in realizing the potential of C-CAR168 across refractory chronic autoimmune diseases," said Tony (Bizuo) Liu, Chairman and Chief Executive Officer of AbelZeta. "Progressive multiple sclerosis can cause significant and irreversible neurological disability, and there remains a considerable unmet medical need for therapies capable of addressing the underlying immune dysfunction driving disease progression. Based on updated preliminary efficacy data, including early and sustained Expanded Disability Status Scale (EDSS) reduction and functional improvement observed in two secondary progressive multiple sclerosis (SPMS) patients, one with active and the other with non-active disease, one of whom had over one year of follow-up, we remain cautiously optimistic that the deep immune-cell depletion and reset enabled by C-CAR168 can provide meaningful and durable benefit to these patients."

About Progressive Multiple Sclerosis

Multiple sclerosis (MS) is a chronic immune-mediated disease that damages the brain and spinal cord, leading to symptoms such as weakness, fatigue, mobility impairment, and cognitive dysfunction. MS affects approximately 2.8 million people worldwide, with a prevalence of 35.9 per 100,000 population and an incidence of 2.1 new cases per 100,000 people annually[1].

Progressive multiple sclerosis (PMS) is characterized by gradual worsening of neurological function and disability over time. PMS includes primary progressive MS (PPMS), which

progresses from disease onset, and SPMS, which develops after an initial relapsing-remitting course[2], and treatment options remain limited.

1. Lublin FD, et al., Defining the clinical course of multiple sclerosis: the 2013 revisions. Neurology. 2014 Jul 15;83(3):278-86.
2. Rajabi M, et al., Primary Progressive Multiple Sclerosis: New Therapeutic Approaches. Neuropsychopharmacol Rep. 2025 Sep;45(3):e70039

About the Study

The multi-center, Phase 1b/2 clinical study of an autologous anti-CD20/BCMA chimeric antigen receptor T-Cell therapy (C-CAR168) for the treatment of progressive multiple sclerosis refractory to standard therapy is designed to evaluate the safety, tolerability, and efficacy of C-CAR168 in patients with progressive multiple sclerosis who have inadequate response to standard therapies. Phase 1b will enroll approximately 6 to 24 patients with SPMS or PPMS to identify the recommended Phase 2 dose. The Phase 2 portion will enroll approximately 95 patients in two independent cohorts, one with active SPMS and the other with PPMS/non-active progressing SPMS patients to further assess the safety and clinical efficacy of C-CAR168.

About C-CAR168

C-CAR168 is a novel autologous bispecific CAR-T therapy targeting CD20 and BCMA. It is designed to achieve deep depletion of disease-driving B cells and plasma cells, with the goal of inducing an immune reset in patients with severe autoimmune diseases.

C-CAR168 is being evaluated across multiple autoimmune diseases, including progressive MS, systemic sclerosis (SSc), SLE, and LN.

Early clinical data from a Phase 1 first-in-human trial, presented at ACR 2025, included secondary progressive multiple sclerosis (SPMS) patients. Following treatment with C-CAR168, the patients showed promising early efficacy signals, including improvements in gait and neurological function and reductions in brain inflammation and lesion size.

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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