# AbelZeta Presents Data from Two Clinical Studies Relating to its Immuno-Oncology Drug Development at the 65th ASH Annual Meeting

- *C-CAR039 study at median follow up of 30.0 months demonstrated a 91.5% overall response rate and an 85.1% complete response rate among evaluable patients with r/r NHL*
- *C-CAR066 study at median follow up of 27.7 months demonstrated a 92.9% overall response rate and a 57.1% complete response rate among evaluable patients with LBCL who failed prior CD19 CAR-T therapy*

ROCKVILLE, MD, December 12, 2023 – 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, presented clinical data for both C-CAR039 for the treatment of patients with relapsed or refractory (r/r) B-cell non-Hodgkin lymphoma (B-NHL), and C-CAR066, for the treatment of patients with r/r large B-cell lymphoma (LBCL) who failed prior CD19 CAR-T therapy at the 65th American Society of Hematology (ASH) Annual Meeting.

"We are thrilled to share the long-term follow-up results from our clinical studies of C-CAR039 and C-CAR066 at the Annual Meeting of ASH, said Tony (Bizuo) Liu, Chairman and CEO of the Company. "The positive outcomes underscore the potential of these novel therapies in advancing the treatment landscape for patients with r/r B-NHL. The observed response rates, durability, and manageable safety profile demonstrated in both studies reinforce our commitment to pioneering innovative and effective solutions in immuno-oncology for patients suffering from serious hematological malignancies."

"We are proud of our collaboration and license agreement with Janssen to facilitate the global development and accessibility of C-CAR039 and C-CAR066. This strategic partnership aligns with our mission to bring innovative and life-changing therapies to patients worldwide."

In May 2023, AbelZeta Pharma (formerly CBMG) entered into a global collaboration and license agreement with Janssen Biotech, Inc. (Janssen), a Johnson & Johnson company, for C-CAR039, an anti-CD19 & CD20 bi-specific CAR-T therapy, and C-CAR066, an anti-CD20 CAR-T.

**Study Conclusions**

- At a longer median follow-up of 30.0 months, **C-CAR039** demonstrated a favorable safety profile with deep and durable response in patients with r/r B-NHL, especially in LBCL patients.
- Longer term follow-up demonstrated that **C-CAR066** can produce a deep and durable response with a favorable safety profile in patients with r/r LBCL who failed prior CD19 CAR-T therapy.

**About the C-CAR039 Study**

C-CAR039 has been developed as a novel 2nd generation 4-1BB bi-specific CAR-T targeting both CD19 and CD20 antigens with an optimized bi-specific antigen binding domain. C-CAR039 has consistently shown ability to eradicate CD19/CD20 single or double positive tumor cells in vitro and in vivo. GMP manufacturing of C-CAR039 was carried out in a serum free and fully closed semi-automatic system.

In the Phase I clinical trials in China (NCT04317885, NCT04655677, NCT04696432, NCT04693676), dose escalation and expansion studies were conducted to evaluate the safety and efficacy of C-CAR039 in r/r B-NHL patients. C-CAR039 was administered as a single intravenous dose after a 3-day cyclophosphamide ($300mg/m^2x3d$) plus fludarabine ($30mg/m^2x3d$) conditioning regimen.

**Key Results of C-CAR039**

Between November 5, 2019, and January 11, 2022, 48 patients received C-CAR039 at the dose ranges of 1.0 x $10^6$ to 5.0x$10^6$ CAR-T cells/kg. Of the 48 patients, 44 (91.7%) patients had large B-cell lymphoma (LBCL) (DLBCL, n=37; PMBCL, n=3; tFL, n=4), 3 patients had FL and 1 patient had MCL. The median age was 55 (range, 25-71) years, and 11 (22.9%) patients were ≥ 65 years. Thirty-six (75%) patients were in Ann Arbor Stage III/IV with 3 median prior lines of therapy, 32 (66.7%) patients were refractory to their last treatment, and 22 (45.8%) patients never achieved CR to their prior therapies.

As of September 25, 2023, 45 patients (93.8%) experienced CRS, only 1 (2.1%) were grade 3. Three patients had grade 1 or 2 ICANS at a dose of 5.0x$10^6$ CAR-T cells/kg. Grade 3 or higher cytopenia not resolved by Day 30 following C-CAR039 infusion included neutropenia (54.2%), thrombocytopenia (20.8%), and anemia (20.8%). At cutoff date, 66.7% patients had infections with 25% grade 3 or higher. Second primary malignancy after C-CAR039 infusion was observed in 3 patients and none were related to C-CAR039. Fifteen deaths occurred, 11 due to disease progression.

Of the 48 patients, 47 patients were evaluable for efficacy. The median follow-up time was 30.0 months. The ORR and CR rate among evaluable patients were 91.5% and 85.1% respectively. Of the 43 LBCL patients, the ORR was 90.7%, with 86.0% CR. Median duration of response (DOR) was not reached. 23/47 (48.9%) patients remain in CR, 10 of them for more than 36 months. Median PFS has not been reached. KM estimates of 24-m PFS rate were 62.6% (all patients) and 64.1% (LBCL). Median OS has not been reached. KM estimates of 24-m OS rate were 76.5% (all patients) and 79.0% (LBCL).

The complete text of the abstract can be found
https://ash.confex.com/ash/2023/webprogram/Paper182817.html

**About the C-CAR066 Study**

C-CAR066 is a novel second generation CAR-T therapy targeting the CD20 antigen. Preclinical studies suggest that C-CAR066 has superior anti-tumor activity compared to anti-CD20 CAR-Ts derived from scFVs of Leu16, Rituximab and Obinutuzumab, and to anti-CD19 CAR-Ts derived from scFV FMC63.

The Phase I clinical trials (NCT04036019, NCT04316624) were conducted in Shanghai Tongji Hospital and Institute of Hematology & Blood Diseases Hospital in Tianjin, China, to evaluate the safety and efficacy of C-CAR066 in subjects with r/r B-NHL who were previously treated with and failed after an anti-CD19 CAR-T therapy. C-CAR066 was administered as a single intravenous dose after a 3-day cyclophosphamide (300mg/$m^2$x3d) plus fludarabine (30mg/$m^2$x3d) conditioning regimen.

**Key Results of C-CAR066**

Between October 16, 2019, and August 17, 2021, a total of 14 patients received C-CAR066 at doses of 2.0x$10^6$ CAR-T cells/kg and 3.0x$10^6$ CAR-T cells/kg. Eleven patients (78.6%) were DLBCL, 3 patients (21.4%) were tFL. The median age was 54.5 years (range, 37-67). Twelve patients (85.7%) were in Ann Arbor Stage III/IV. The median number of prior lines of therapy was 5 (range, 2-7). All patients had prior CD19 CAR-T therapy.

As of October 10, 2023, 12/14 patients (85.7%) experienced CRS, all were grade 1/2, except for 1 patient who

experienced a grade 4 CRS. No patients experienced ICANS. Grade 3 or higher cytopenia not resolved by Day 30 following C-CAR066 infusion occurred in 28.6% patients and included neutropenia (21.4%), thrombocytopenia (14.3%), and anemia (14.3%). At cutoff date, 8 patients experienced infections, only 2 were grade 3. Seven deaths occurred and all due to disease progression. No SPM and new safety signals were observed with longer follow-up.

The investigator assessed ORR was 92.9%, with 57.1% CR. With the median follow-up of 27.7 months, median PFS and DOR were 9.4 months and 8.3 months, respectively. Four patients had remained in CR for more than 30 months. The Kaplan-Meier estimate of median OS was 34.8 months (11.4 - NA).

The complete text of the abstract can be found
https://ash.confex.com/ash/2023/webprogram/Paper181527.html

**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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