AbelZeta announces clinical data showing preliminary anti-tumor activity for C-CAR031, an armored autologous GPC3 CAR-T, in patients with advanced hepatocellular carcinoma, at ASCO Annual Meeting 2024

CAR031 study at 9.03-mo median follow up achieves disease control rate (DCR) of 91.3% and objective response rate (ORR) of 56.5% for patients across all dose levels (DLs) and ORR of 75.0% at DL4

ROCKVILLE, MD, June 4, 2024 – 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 preliminary safety and efficacy results from its first time in human investigator-initiated trial (IIT) of C-CAR031 in connection with the Company's oral presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. The presentation shared data indicating a manageable safety profile and encouraging anti-tumor activity of C-CAR031 in patients with heavily pretreated advanced hepatocellular carcinoma (HCC) (1-6 lines of prior therapy). C-CAR031 is based on a novel GPC3-targeting CAR-T designed by AstraZeneca (LSE/STO/Nasdaq: AZN) and is manufactured by AbelZeta. C-CAR031 is being co-developed in China by AbelZeta and AstraZeneca.

"We are encouraged by the first clinical results of C-CAR031 in advanced hepatocellular carcinoma (HCC) patients," said Tony (Bizuo) Liu, Chairman and CEO of AbelZeta. "The early data presented today provide compelling proof-of-concept to potentially redefine therapeutic paradigms in HCC and other GPC3-expressing solid tumors."

Principal Investigator (PI) of the study, Professor Tingbo Liang from the First Affiliated Hospital of Zhejiang University, stated "C-CAR031 showed a good safety profile and promising efficacy in late-stage hepatocellular carcinoma patients, who typically have a limited number of treatment options available. The observed tumor shrinkage in the large/vast majority (91.3%) of the patients suggests that C-CAR031 has the potential to bring clinical value and offer hope to these patients."

As of March 14, 2024, 23 of 24 patients on the study were eligible for efficacy assessment. Tumor reductions were observed in 91.3% patients, in both intrahepatic and extrahepatic lesions, with a median reduction of 42.2% (range, -28.1% 94.4%). The disease control rate was 91.3% and the ORR was 56.5% for patients across all DLs. In DL4, the ORR was 75.0%. With 9.03-month median follow-up, Kaplan-Meier estimation of median overall survival (mOS) is 11.14 months (95% CI, 7.56-NE).

No dose-limiting toxicity or immune effector cell associated neurotoxicity syndrome (ICANS) was observed. Cytokine release syndrome (CRS) was observed in 22 (91.7%) patients with the majority (87.5%) grade 1/2 CRS and only 1 (4.2%) grade 3 CRS.

About C-CAR031

C-CAR031 is an autologous, armored GPC3-targeting chimeric antigen receptor T-Cell (CAR-T) therapy, being studied for the treatment of HCC. It is based on a novel GPC3-targeting CAR-T designed by AstraZeneca using their dominant negative transforming growth factor-beta receptor II dominant negative (dnTGFβRII) armoring discovery platform and is manufactured by AbelZeta in China. C-CAR031 is being developed in China under a co-development agreement between AbelZeta and AstraZeneca.[1]

About the Study

A Phase I clinical study (NCT05155189) aiming to assess the safety and anti-tumor activity of C-CAR031 injection in advanced/unresectable HCC patients is being conducted in China. As of March 14, 2024, a total of 24 patients received C-CAR031 infusion at 4 dose levels (DLs). 83.3% (20/24) had extrahepatic metastasis. The median number of prior lines of systemic therapy was 3.5 (range 1-6).

Abstract Title: "Phase I study of C-CAR031, a GPC3-specific TGFβRIIDN armored autologous CAR-T, in patients with advanced hepatocellular carcinoma (HCC)."
Abstract Number: 4019
Session Type and Title: Rapid Oral Abstract – Gastrointestinal Cancer – Gastroesophageal, Pancreatic, and Hepatobiliary
Session Date and Time: 6/3/2024; 9:45 AM-11:15 AM CDT

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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References

1. AbelZeta Pharma Announces Agreement with AstraZeneca to Co-Develop a novel Glypican 3 (GPC3) Armored CAR-T Therapy in China. December 2023. https://www.abelzeta.com/abelzeta-pharma-announces-agreement-with-astrazeneca-to-co-develop-a-novel-glypican-3-gpc3-armored-car-t-therapy-in-china/