NEWS

IASO Bio and Innovent Present New Data of FUCASO® (Equecabtagene Autoleucel) for Multiple Myeloma Patients in Oral Presentation at ASH 2023

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Back

SHANGHAI, NANJING, CHINA, and SAN JOSE, Calif., December 11, 2023 – IASO biotechnology ("IASO Bio"), a biopharmaceutical comp engaged in discovering, developing, manufacturing and marketing innovative cell therapies and antibody products, and Innovent Biolo ("Innovent", HKEX: 01801), a world-class biopharmaceutical company that develops, manufactures and commercializes high-quality m for the treatment of cancer, metabolic, autoimmune, ophthalmology and other major diseases, today announced the latest analysis re from the FUMANBA-1 study of Equecabtagene Autoleucel for the treatment of multiple myeloma in an oral presentation at the 65th A Society of Hematology (ASH) Annual Meeting. The presentation highlights the characteristics and efficacy of fully human BCMA-targeti T (Equecabtagene Autoleucel) on multiple myeloma patients who had sustained minimal residual disease (MRD) negativity after receiv treatment.

Oral Presentation Overview

Presentation Title: Efficacy Outcomes and Characteristics of Patients with Multiple Myeloma (MM) Who Achieved Sustained Minima Residual Disease Negativity after Treatment with Equecabtagene Autoleucel (Eque-cel, CT103A) in Fumanba-1

Session Date and Time: Monday, December 11, 2023, 11:30 AM (San Diego)

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Presenter: Dr. Jue Wang, Associate Professor, Tongji Hospital, Tongji Medical College, Huazhong University of Science & Technology

The presentation is based on a post-hoc analysis of the FUMANBA-1 study. The FUMANBA-1 Study(Registration No.: NCT05066646) Phase Ib/II, single-arm, multicenter study to assess the efficacy and safety of the investigational drug Equecabtagene Autoleucel (IAS code: CT103A, Innovent R&D code: IBI326), a fully human CAR-T cell therapy, in patients with relapsed and refractory multiple myel (RRMM) who have received 3 or more lines of treatment.

As of December 31, 2022, with a median follow-up of 18.07 months, deep and sustained responses were observed in 103 evaluable Among these patients, the overall response rate (ORR) was 96.1%, and the stringent complete response/complete response (sCR/CR was 77.7%. Among subjects without prior CAR-T therapy, the ORR reached 98.9%, the sCR/CR rate reached 82.4%, and the 12-montl progression-free survival (PFS) rate was 85.5%.

In addition, **Equecabtagene Autoleucel could persist in the body for an extended period of time** the median duration was 307.5 da months after infusion, 50% of patients had a vector copy number (VCN) above the lower limit of detection; and 24 months after infu VCN could still be detected in 40% of the patients.

Based on the descriptive analysis, patients receiving eque-cel achieved MRD negativity irrespective of cytogenetics status， extramedullary disease status， number of prior lines of therapy， and performance status. It suggests that eque-cel as immune cell therapy showed strong killing effect to myeloma cells without affecting by these factors.

In the FUMANBA-1 study, 90 RRMM patients without prior CAR-T therapy were evaluable for MRD test at 10^{-5}. The results showed:

(1) **An important prognostic factor for progression-free survival (PFS) in patients with RRMM treated with Equecabtage Autoleucel is sustained MRD negativity:** When comparing the PFS of patients in different MRD negative duration groups e the ≥ 6 months and ≥ 12 months group were significantly better than those in the < 6 months group. This was particularly true fo those in the ≥ 12 months MRD negative duration group.

(2) **There is a correlation between the persistence of CAR-T cells and sustainability of MRD negativity after infusion of Equecabtagene Autoleucel:** Overall, there is a positive correlation between the two. This was particularly evident in subgroup analysis. The Triple-class exposure subgroup, the previous autologous transplantation treatment history subgroup, the high-risk cytogenetic abnormality subgroup, etc., showed a moderate to strong positive correlation between the persistence of CAR-T cell (VCN persistence) after infusion of Equecabtagene Autoleucel and the duration of MRD negativity. The correlation may become significant in the future with longer term follow-up data, which could further reveal the positive correlation between long-term survival of CAR-T cells and long-term maintenance of MRD negativity.

"Studies have shown MRD is a biomarker that affects the long-term survival of RRMM patients. It's necessary to maintain MRD nega to improve the prognosis of RRMM patients and extend PFS. Equecabtagene Autoleucel has overcome two difficulties faced by tradi therapies in maintaining MRD negativity. First, it has increased the proportion of patients with MRD-negative persistence past 12 mo from less than 10% to 80%. Second, only one-time infusion is needed to achieve sustainable MRD negativity. Traditional therapies re continuous medication to maintain MRD negativity, and once medication is stopped, patients face the risk of relapse. Patients who do n stop the medication will be facing the potential risk of inducing drug-resistant clones. Long-term medication and complex therapies incre direct treatment costs, seriously affect patients' quality of life. The adverse effects caused by long term treatment also increase indirect c to patients and their families. With its outstanding long-term persistence in the body, Equecabtagene Autoleucel can achieve lasting and remission in RRMM patients who have failed multiple lines of treatment. We expect that it will give more patients the hope of a cure," sa principal investigators **Professor Lu-gui Qiu, Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sci and Peking Union Medical College, and Professor Chunrui Li, Tongji Hospital, Tongji Medical College, Huazhong University of Scier Technology.**

Back

Prev: IASO BIO Announces New Development Partnership with Umoja Biopharma to Develop Ex Vivo and In Vivo Cell and Gene Therapies

Next: IASO Bio Presents Updated Long-Term Follow-Up Data for BCMA CAR-T FUCASO® (Equecabtagene Autoleucel) at IMS 2023

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