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IASO Bio and Innovent Announce the NMPA Approval of the NDA for Equecabtagene Autoleucel, the World's First Fully-human BCMA CAR-T Therapy, for the Treatment of RRMM

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SHANGHAI, NANJING, CHINA, AND SAN JOSE, Calif., July 3, 2023 - IASO Biotechnology ("IASO Bio"), a clinical-stage biopharmaceutical company engaged in discovering, developing, manufacturing and marketing innovative cell therapies and antibody products, and Innovent Biologics Inc. ("Innovent", HKEX: 01801), a world-class biopharmaceutical company that develops, manufactures and commercializes high-quality medicines for the treatment of cancer, metabolic, autoimmune, ophthalmology and other major diseases, today announced that China National Medicines Administration (NMPA) has approved the New Drug Application (NDA) for FUCASO (Equecabtagene Autoleucel, co-developed and commercialized by IASO Bio and Innovent, IASO Bio R&D code: CT103A, Innovent R&D code: IBI326), the world's first fully-human anti-BCMA maturation antigen (BCMA) chimeric antigen receptor (CAR) T-cell therapy for the treatment of relapsed and/or refractory multiple myeloma (MM) who received ≥ 3 lines of prior therapies containing at least one proteasome inhibitor and an immunomodulatory agent.

FUCASO® (Equecabtagene Autoleucel) is an autologous BCMA CAR-T cell injection, transduced by a lentiviral vector containing a CAR structure with a fully human scFv, CD8 α hinge and transmembrane, 4-1BB co-stimulatory and CD3 ζ activation domains. FUCASO® was given as a one-time treatment with a recommended dose of 1.0×10^6 CAR-T cells/kg. Based on strict selection and screening of the molecular structures, using its proprietary in-house optimization platform and integrated in-house manufacturing process, FUCASO® is potent and shows prolonged persistence in patients. It will bring new treatment options to R/R MM patients with higher and more profound responses.

The NDA approval is based on the data from the pivotal FUMANBA-1 study (CTR20192510, NCT05066646) conducted at multiple sites in China. In June 2023, the updated data from FUMANBA-1 study was presented at the 2023 Annual Meeting of the American Society of Clinical Oncology (ASCO) (Abstract Number: 8025). The study enrolled 103 R/R MM patients with a median follow-up time of 13.8 (0.4, 27.2) months.

- Among the 101 evaluable patients, the overall response rate (ORR) was 96%, with the stringent complete response/ complete response (sCR) rate of 74.3%. Median time to response (mTTR) was only 16 days, and the 12-month Progression-Free Survival (PFS) rate was 78.8%. 94% of the patients achieved minimal residual disease (MRD) negativity, and all sCR/CR patients achieved MRD negativity. Of the 12 patients with prior CAR-T therapy, 9 achieved response, and 5 achieved sCR (including 4 patients achieved sustained sCR for over 18 months post-infusion). In 89 patients without prior CAR-T therapy, ORR was 98.9%, 78.7% reached sCR/CR.
- Of the 103 safety evaluable patients, only one experienced grade ≥ 3 cytokine release syndrome (CRS), and 2 experienced grade 1-2 immune effector cell-associated neurotoxicity syndrome (ICANS). All patients with CRS or ICANS recovered after the treatment.
- FUCASO® was still detectable in 50% and 40% respectively of the patients who completed 12-month and 24-month follow-ups after infusion. Only 19.4% of the patients were anti-drug antibody (ADA)-positive.

investigators of the registration trial of FUCASO[®].

Ms. Jinghua Zhang, Chairman and Chief Executive Officer of IASO Bio, stated, "We are excited that FUCASO[®] was approved, it significant milestone for the Company. FUCASO[®] is not only IASO Bio's first marketed product but is also the world's first commercially available fully-human CAR-T therapy. Furthermore, FUCASO[®] is the first self-developed and in-house manufactured CAR-T cell therapy in China as well as China's first approved BCMA CAR-T for the treatment of multiple myeloma. The NMPA NDA approval of FUCASO[®] will help us in achieving our strategic goal of bringing breakthrough therapy to patients in unmet need, with the hope for a potential cure."

Dr. Hui Zhou, Senior Vice President of Innovent Biologics, stated, "Multiple myeloma is a common hematology malignant disease with high incidence rate, and relapse and refractory are inevitable after current treatments. There's an urgent unmet need requesting a treatment that is more tolerated and long persistence for patients. FUCASO[®], as an innovative fully-human cell therapy, has demonstrated robust and long-lasting efficacy and outstanding safety in long-term follow-up data from the registrational clinical study, which underscores its potential to be a pioneering treatment option for patients with RRMM. We are very pleased with the successful approval of FUCASO[®] and hope it could benefit RRMM patients as the first approved BCMA CAR-T therapy in China.."

About Multiple Myeloma (MM)

Multiple Myeloma (MM) is a deadly blood cancer that often infiltrates the bone marrow causing anemia, kidney failure, immune problems and bone fractures. For MM patients, common first-line drug treatments include proteasome inhibitors, immunomodulatory drugs, and alkylating agents. While treatment may result in remission, most patients will inevitably enter the relapsed or refractory stage as there's currently no cure. As a result, there is a significant unmet need for patients with relapsed/refractory multiple myeloma. According to Frost & Sullivan, new MM cases in China rose from 20,100 in 2018 to 22,400 in 2022 and are expected to increase to 25,700 by 2027.

About IASO Bio

IASO Bio is a biopharmaceutical company engaged in discovery and development of novel cell therapies and biologics for oncology and autoimmune diseases. Leveraging its proprietary fully human antibody discovery platform (IMARS), high-throughput chimeric antigen receptor (CAR-T) drug screening platform, and proprietary manufacturing processes, IASO Bio is developing a rich clinical-stage pipeline of multiple autologous and allogeneic CAR-T and biologics product candidates. This pipeline includes a portfolio of over 10 novel products, including FUCASO[®] (Equecabtagene Autoleucel). Equecabtagene Autoleucel received New Drug Application (NDA) approval from China's National Medical Products Administration (NMPA) and U.S. FDA IND approval for the treatment of R/R MM. IASO also received Breakthrough Therapy Designation (BTD) from the NMPA in February 2021 and Orphan Drug Designation (ODD) from the FDA in February 2022, Regenerative Medicine Advanced Therapy (RMAT) and Fast Track (FT) Designations from the FDA in February 2023. In addition to multiple myeloma, NMPA has approved application of FUCASO[®] for the new expanded indication of Neuromyelitis Optica Spectrum Disorder (NMOSD).

Additionally, the company's in-house developed fully human CD19/CD22 dual-targeted CAR-T cell therapy received two IND clearance for treating relapsed/refractory B-cell non-Hodgkin's lymphoma (r/r B-NHL) and relapsed/refractory acute B-lymphoblastic leukemia (r/r B-ALL) currently in Phase I clinical trial for r/r B-NHL. It was also granted ODD for treatment of acute lymphoblastic leukemia by the FDA in October 2021. And the fully human monoclonal antibody targeting human CD19, IASO-782 Injection, received both FDA and NMPA IND approvals in 2023 for use in U.S. and China clinical trials for Autoimmune hematological disorders, including primary immune thrombocytopenia (ITP) and warm autoimmune hemolytic anemia (wAIHA).

Leveraging its strong management team, innovative product pipeline, integrated manufacturing and clinical capabilities, IASO aims to develop transformative, curable, and affordable therapies that fulfill unmet medical needs to patients in China as well as around the world. For more information, visit www.iasobio.com or www.linkedin.com/company/iasobiotherapeutics.

About Innovent Biologics

Inspired by the spirit of "Start with Integrity, Succeed through Action," Innovent's mission is to develop, manufacture and commercialize high-quality biopharmaceutical products that are affordable to ordinary people. Established in 2011, Innovent is committed to developing, manufacturing and commercializing high-quality innovative medicines for the treatment of cancer, autoimmune disease, metabolic disorder and other major diseases. On October 31, 2018, Innovent was listed on the Main Board of the Stock Exchange of Hong Kong Limited with the stock code: 01801.HK.

cancer, metabolic disorder, autoimmune disease and other major therapeutic areas, with 9 approved products on the market. These include: IYVY1® (sintilimab injection), BYVASDA® (bevacizumab injection), SULINNO® (adalimumab injection), HALPRYZA® (rituximab injection), Pemazyre® (pemigatinil inhibitor), olverembatinib (BCR ABL TKI), Cyramza® (ramucirumab), Retsevmo® (selpercatinib) and FUCASO® (Eqeucabtagene Autoleucl). An additional 6 assets are under NMPA NDA review, 6 assets are in Phase III or pivotal clinical trials, and 18 more molecules are in clinical studies.

Innovent has built an international team with advanced talent in high-end biological drug development and commercialization, including many global experts. The company has also entered into strategic collaborations with Eli Lilly, Roche, Sanofi, Adimab, Incyte, MD Anderson Cancer Center and other international partners. Innovent strives to work with many collaborators to help advance China's biopharmaceutical industry, improve drug availability and enhance the quality of the patients' lives.

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