FDA clears investigational new drug application for Calibr's 'switchable' CAR-T therapy

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Calibr, the drug discovery and development division of Scripps Research, today announced that the U.S. Food and Drug Administration has given clearance to the Investigational New Drug (IND) application for Calibr's "switchable" CAR-T cell therapy, which is being evaluated for the treatment of certain cancers, including relapsed/refractory B-cell malignancies such as non-Hodgkin lymphoma and chronic lymphocytic leukemia.

Having achieved this regulatory milestone, Calibr can begin clinical trials for its novel cell therapy candidate, CLBR001 + SWI019. The therapy leverages a patient's own immune cells to treat cancer, putting them under the control of a novel molecular "switch" that seeks to eliminate life-threatening side effects that have hampered the use of cell therapies to date.

"CLBR001 + SWI019 is a first-in-class switchable CAR-T cell platform designed to confer the efficacy associated with engineered T cell therapies, while potentially affording greater safety and versatility through the incorporation of a control switch," says Travis Young, Ph.D., Calibr's vice president of biologics and leader of its CAR-T development program. "If successful, this approach holds promise to be universally applied to other types of cancer, including solid tumor cancers that have yet to reap the benefits of CAR-T therapies."

CAR-T, short for chimeric antigen receptor T-cell, is a relatively new form of cancer therapy that has achieved remarkable responses in patients with blood- or bone marrow-based diseases such as leukemias and lymphomas. It works by genetically engineering a patient's own T cells— which play a key role in immune response—to seek and destroy cancer within the body. However, some patients who receive T-cell therapies experience an adverse effect, which can be severe, called cytokine release syndrome, which occurs when the immune system reacts too strongly and causes dangerous inflammation.

Calibr's switchable CAR-T cell platform incorporates an antibody known as SWI019 that acts as a switch, activating the engineered cell and directing it to engage the cancer target. This may allow doctors to more precisely regulate the potency of the therapy and is expected to provide a significant safety advantage. In preclinical studies, the approach proved highly effective at eliminating tumors while controlling the level of cytokines produced in response to treatment.

"AbbVie continues to be impressed by Calibr's progress on advancing this innovative switchable cell therapy technology," says Mohit Trikha, Ph.D., vice president, head of Oncology Early Development and Bay Area site head at AbbVie. "This milestone is an important step forward for this potential CAR-T therapy and our recently expanded collaboration with Scripps Research, which holds promise to rapidly advance additional treatment options for patients."

The launch of the clinical study—the third being run independently by the institute and the fifth study to originate from Calibr's research—is another major landmark for Scripps Research's pioneering nonprofit drug development model. News of the FDA's decision comes on heels of another recent IND acceptance for Calibr's first-in-class bispecific antibody for prostate cancer; that drug candidate, CCW702, is now being tested in a phase I trial for patients with metastatic, castrate resistant

prostate cancer.

The switchable CAR-T cell platform was invented at Scripps Research and progressed to the Investigational New Drug stage with support from the Wellcome Trust. Calibr recently partnered its platform with biopharmaceutical company AbbVie, which holds certain rights to commercialization.

"AbbVie has been an outstanding partner for Scripps Research on this CAR-T cell program," says Scripps Research President and CEO Peter Schultz, Ph.D. "We look forward to continuing to bring novel therapies to the clinic through this collaboration."

Clinical development of CLBR001 + SWI019 will be led by Calibr's Chief Medical Officer Pamela D. Garzone, Ph.D. Calibr expects to begin enrolling patients for the phase 1 clinical trial in the first half of 2020, with the potential to expand the platform to solid tumors in coming years.

Provided by The Scripps Research Institute

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