December 20, 2024

TCBP Advances ACHIEVE Phase 2b Clinical Trial with Final Dosing of 3 Patients

EDINBURGH, Scotland, Dec. 20, 2024 /PRNewswire/ -- TC BioPharm (Holdings) PLC ("TC BioPharm" or the "Company") (NASDAQ: TCBP) a clinical-stage biotechnology company developing platform allogeneic gamma-delta T cell therapies for cancer and other indications, today announced 3 patients have now completed the full-dose regimen in the ACHIEVE Phase 2b trial in the UK with no drug-related Adverse Events seen in any of the restart patients.

The ACHIEVE UK clinical trial is an open-label, phase II study designed to evaluate the efficacy and effectiveness of TCB008 in patients with AML or MDS/AML, with either refractory or relapsed disease.

To date, 10 patients have received their first dose, 9 patients have received their second dose, 4 patients have received their third dose, and 3 patients have received their fourth and final dose. 9 out of 10 patients recruited to date are in Cohort A, representing relapsed/refractory patients who have been unable to attain remission. One patient has been enrolled into Cohort B, representing patients who have attained remission following prior treatment yet continue to have a detectable residual disease. The patient enrolled in Cohort B received their fourth and final dose in November 2024. Initially, 14 patients are planned to be recruited into Cohort A and Cohort B and, following confirmation of study endpoints, a further 10 patients will be recruited into each cohort, giving a total of 48 patients.

The preliminary safety data shows that the 5mL dose of TCB008 is well tolerated, with no drug-related Adverse Events. These data outputs remain aligned with TCB008's safety profile, in support of the ACHIEVE study safety objectives and endpoints.

"Recruitment into the ACHIEVE trial has been an overwhelming success in 2024," said Alison Bracchi, Executive Vice President of Clinical Operations. "Currently, more than half of the patients in the initial stage of Cohort A have been recruited into the ACHIEVE study. We're also thrilled to observe the progression of Cohort B. This expedited rate of recruitment has been accomplished in less than 5 months due to the hard work and dedication of both the ACHIEVE Clinical sites and the entire TCBP team. The TCBP team and I look forward to continued success with recruitment and preliminary data from the ACHIEVE study in 2025."

"As we progress with Cohort B, there is the potential for an expedited review given these patients' stage and disease expression," said Bryan Kobel, CEO of TC BioPharm. "We believe minimal residual disease represents a high opportunity for TCB008 to be extremely impactful. We could see a response indicating high responsiveness in fewer than the currently proposed cohort size. At this trial stage, we are still collating data, due to the regulatory framework, we cannot yet comment on efficacy specifically, but we are encouraged to see patients completing the dosing regimen successfully and without any safety issues. Our immediate clinical focus will be high recruitment on Cohort B in 2025 and completing the Cohort A patient set for data review. We appreciate the hard work of the King's College Hospital and our fantastic investigator group including Dr. Victoria Potter, and Dr. Emma Nicholson. The recruitment has been exceptional and we look forward to continuing our work with them in 2025."

About TC BioPharm (Holdings) PLC

TC BioPharm is a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing gamma-delta T-cell therapies for cancer treatment with human efficacy data in acute myeloid leukemia. Gamma-delta T cells are naturally occurring immune cells that embody properties of both the innate and adaptive immune systems and can intrinsically differentiate between healthy and diseased tissue.

TC BioPharm is the leader in developing gamma-delta T cell therapies and the first company to conduct phase II/pivotal clinical studies in oncology. The Company is conducting two investigator-initiated clinical trials for its unmodified gamma-delta T cell product line - Phase 2b/3 pivotal trial in the treatment of acute myeloid leukemia using the Company's proprietary allogeneic CryoTC technology to provide frozen product to clinics worldwide.

Forward-Looking Statements for TC BioPharm

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the Company's intent or ability to affect any budget savings or execute on any M&A or capital raising strategy. These statements are based on management's current assumptions and are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. For other important factors that could cause actual results to differ materially from the forward-looking statements in this Current Report on Form 8-K, please see the risks and uncertainties identified under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, and our other reports filed with the SEC, all of which is available on the Company's Investor Relations website at www.tcbiopharm.com and on the SEC website atwww.sec.gov. All forward-looking statements reflect the Company's beliefs and assumptions only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to update forward-looking statements to reflect future events or circumstances.

View original content to download multimedia:https://www.prnewswire.com/news-releases/tcbp-advances-achieve-phase-2b-clinical-trial-with-final-dosing-of-3-patients-

302336819.html

SOURCE TC BioPharm