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TC BioPharm Shifts Focus to FDA Clinical Trials

Company to explore US IND pathway for additional combination trials

EDINBURGH, Scotland, March 7, 2023 /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, today announced that the company has taken steps to focus its clinical strategy on the planned future FDA trials for TCB-008 in AML as a monotherapy and other oncology indications in combination with additional assets.

The pending protocol submission will be a Phase 1b safety trial, with a relatively small patient population and a short timeline to completion. In conjunction with refocusing the clinical team's efforts on the USA, the Company intends to file the first IND in the third quarter of 2023 with an expected additional IND to be filed in the fourth quarter or early 2024. At this juncture, the Company is anticipating a dose escalating study of approximately 9 patients with an expansion cohort at the optimal dose.

"Our business development efforts over the last 12 months have generated multiple research collaborations and strategic relationships, the majority of which are US based and beginning to come to fruition," said Bryan Kobel, Chief Executive Officer. "Prioritizing US trials realigns us with our long term goal of becoming a leading commercial stage company, with a myriad of oncological treatment applications for TCB-008 (Omnimmune™) as both a monotherapy and as a combination therapeutic. We firmly believe in the potential of our asset and the best way to position the Company for success is to commence with this proposed US trial protocol and to pursue future trials through the FDA pathways. Our partnership with MD Anderson will be valuable, both for this study and future FDA trials, and I anticipate that we're now better positioned for near term success and sustainability, including potentially multiple data readouts in 2024."

TC BioPharm expects this US clinical trial enrollment to be relatively rapid due to the the fact that America offers a significantly greater pool of patients with [more than 20,000 AML diagnoses each year](#). This transition will allow TC BioPharm to become more economically efficient by simplifying its strategy and reducing manufacturing and production efforts.

About TC BioPharm (Holdings) PLC


TC BioPharm is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell therapies for the treatment of cancer 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 uses an allogeneic approach in both unmodified and CAR modified gamma-delta

T cells to effectively identify, target and eradicate both liquid and solid tumors in cancer.

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 for OmniImmune® in treatment of acute myeloid leukemia using the Company's proprietary allogenic CryoTC technology to provide frozen product to clinics worldwide. TC BioPharm also maintains a robust pipeline for future indications in solid tumors as well as a significant IP/patent portfolio in the use of CARs with gamma-delta T cells and owns our manufacturing facility to maintain cost and product quality controls.

Forward Looking Statements

This press release may contain statements of a forward-looking nature relating to future events. These forward-looking statements are subject to the inherent uncertainties in predicting future results and conditions. These statements reflect our current beliefs, and a number of important factors could cause actual results to differ materially from those expressed in this press release. We undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. The reference to the website of TC BioPharm has been provided as a convenience, and the information contained on such website is not incorporated by reference into this press release.

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