



Collect Biotechnology Receives Approval for U.S. Clinical Trial

December 23, 2019

First-ever U.S. Clinical Trial to Assess the ApoGraft Technology for Haploidentical Bone Marrow Transplantations to be Conducted at Washington University School of Medicine (St. Louis)

TEL AVIV, Israel, Dec. 23, 2019 /PRNewswire/ -- Collect Biotechnology Ltd. (NASDAQ: [APOP](#)), a developer of innovative technology to enable the functional selection of stem cells, has received approval to initiate the trial in the U.S. to evaluate the safety and tolerability of the ApoGraft technology for haploidentical bone marrow transplantations. The company is collaborating with Washington University School of Medicine in St. Louis on the trial. A total of 18 patients are planned for this initial phase, with enrollment expected to begin in the first half of 2020. The company has received the approval of the protocol by Washington University's Institutional Review Board, which is required before the trial can begin, follows other successful milestones, such as the IND approval from the U.S. Food and Drug Administration (FDA) in November 2019, positive feedback from the institutional independent scientific committee and a complete technology transfer during 2019.

"With the succession of executed milestones, we are getting closer to achieving our primary objective of commencing our first clinical trial in the U.S.," commented Dr. Shai Yarkoni, Chief Executive Officer. "Our team, together with Washington University, is focused on this goal in the first half of 2020, aiming to achieve a level of success similar to our ongoing Phase 1/2 clinical trial being performed in Israel that shows initial promising results."

The Principal Investigator for the U.S. clinical trial is Zhifu Xiang, M.D., Ph.D., of Washington University School of Medicine. Dr. Xiang is an Associate Professor in the Division of Oncology's Bone Marrow Transplantation & Leukemia Section in the Department of Medicine. In addition, John Dipersio M.D., Ph.D., will act as co-Principal Investigator for the study. He is the chief of the Division of Oncology in the Department of Medicine at Washington University.

In 2017, the FDA granted orphan drug designation for ApoGraft™, and the Company is planning to request for ApoGraft™ be designated a Regenerative Medicine Advanced Therapy (RMAT) under the 21st Century Cures Act. The RMAT designation is intended to facilitate expedited development, review and approval for important new regenerative medicine therapies for which preliminary clinical evidence indicates the potential to address a serious or life-threatening disease or condition. In addition to providing an avenue for increased and earlier interactions with the FDA, RMAT-designated products may be eligible for priority review and accelerated approval – thus dramatically shortening time to market and commercial value.

An Institutional Review Board (IRB) is formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications (to secure approval), or disapprove research. Protocol review by an institutional IRB serves an important role in protecting the rights, safety and welfare of human research subjects.

About Collect Biotechnology Ltd.

Collect Biotechnology ([APOP](#)) has developed a breakthrough technology, for the selection of stem cells from any given tissue, that aims to improve a variety of stem cell-based therapies.

The Company's technology is expected to provide researchers, clinical community and pharma companies with the tools to rapidly isolate stem cells in quantity and quality allowing stem cell-based treatments and procedures in a wide variety of applications in regenerative medicine. The Company's current clinical trial is aimed at bone marrow transplantations in cancer treatment.

Forward Looking Statements

This press release contains forward-looking statements about the Company's expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements and their implications are based on the current expectations of the management of the Company only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In addition, historical results or conclusions from scientific research and clinical studies do not guarantee that future results would suggest similar conclusions or that historical results referred to herein would be interpreted similarly in light of additional research or otherwise. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: the Company's history of losses and needs for additional capital to fund its operations and its inability to obtain additional capital on acceptable terms, or at all; the Company's ability to continue as a going concern; uncertainties involving any strategic transaction the Company may decide to enter into as the result of its current efforts to explore new strategic alternatives; uncertainties of cash flows and inability to meet working capital needs; the Company's ability to obtain regulatory approvals; the Company's ability to obtain favorable pre-clinical and clinical trial results; the Company's technology may not be validated and its methods may not be accepted by the scientific community; difficulties enrolling patients in the Company's clinical trials; the ability to timely source adequate supply of FasL; risks resulting from unforeseen side effects; the Company's ability to establish and maintain strategic partnerships and other corporate collaborations; the scope of protection the Company is able to establish and maintain for intellectual property rights and its ability to operate its business without infringing the intellectual property rights of others; competitive companies, technologies and the Company's industry; unforeseen scientific difficulties may develop with the Company's technology; and the Company's ability to retain or attract key employees whose knowledge is essential to the development of its products. Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review

any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in Collect Biotechnology Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission, or SEC, which is available on the SEC's website, www.sec.gov, and in the Company's periodic filings with the SEC.

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