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Cellect Biotechnology receives approval for U.S. clinical trial

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Israel based Cellect Biotechnology Ltd., 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.