



Collect Biotechnology and Washington University (WU) Finalize Accelerated Clinical Trial Agreement

July 8, 2019

Collaboration Achieves First Significant Milestone with Successful Execution of Technology Transfer

Additional Significant Milestones, Including Submission of the Investigational New Drug (IND) Application Which is Expected by the End of the Third Quarter

TEL AVIV, Israel and ST. LOUIS, Missouri, July 8, 2019 /PRNewswire/ -- As the two organizations move closer to the commencement of the clinical trial to determine the safety and tolerability of the Apograft technology for bone marrow transplantations, Collect Biotechnology Ltd. (Nasdaq: [APOP](#)), and Washington University (WU), a leading academic institution based in St. Louis, MO, announced the signing of an Accelerated Clinical Trial Agreement (CTA). Collect has successfully completed the technology transfer to WU's facility, and results of the in-vivo portion of the toxicology study have shown no signs or symptoms of toxicity.

"We are continuing to advance our lead development program, ApoGraft™, and pleased to achieve this milestone with Washington University," commented Dr. Shai Yarkoni, Chief Executive Officer. "We have had ongoing and positive discussions with the U.S. Food and Drug Administration (FDA), and based on its feedback we can bypass further pre-Investigation New Drug (IND) interactions and proceed directly to IND filing. Therefore, our immediate next step is to complete our IND application and submit it to the FDA during the third quarter, and our objective remains to commence treatment of U.S. patients during the first half of 2020."

"The importance of this trial cannot be underestimated, as finding a suitable donor remains a constant challenge for patients in need of an urgent Hematopoietic stem cell transplantation (HSCT)," added Dr. Yarkoni. "It is well known that the ability to obtain half-matched stem cells from a first degree relative represents a significant breakthrough in the field. However, while Haploidentical (haplo) HSCT is characterized by the nearly uniform and immediate availability of a donor, it has a high risk of graft-versus-host disease (GVHD) and tentative poor immune reconstitution when GVHD is prevented by all existing methods of rigorous ex vivo or in vivo T-cell depletion. As such, the current treatment paradigm is based on chemotherapy post-transplant, which by itself harbors significant morbidity. Our technology is specifically aimed at improving today's standard of care with a safer pre-transplantation procedure that will be of far greater benefit to patients.

"The Company's platform technology, ApoGraft™, is based on findings that GVHD can be prevented by Fas ligand mediated selective depletion of GvHD causing subpopulation of immune mature cells. The combination of haplo-HSCT with the ApoGraft™ process has the potential to improve the safety profile of haplo-HSCT by preventing GVHD without adversely affecting GVL or engraftment," concluded Dr. Yarkoni.

Upcoming Clinical Program Objectives

U.S. ApoGraft02 Study

- *Approval of Scientific Advisory Board Expected by mid-third quarter of 2019*
- *Submit IND application with the FDA by the end of third quarter of 2019*
- *Upon FDA acceptance of the Company's IND application, together with its collaboration partner, Washington University, begin treating U.S. patients in the first half of 2020*

Israel ApoGraft01 Study

- *Complete recruitment by the end of 2019 and release data by the end of the first half of 2020*

The Principal Investigator for the clinical trial is Zhifu Xiang, M.D., of Washington University. He 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. The collaboration is led by Dr. DiPersio, who also is Director of the Center for Gene and Cellular Immunotherapy, Washington University School of Medicine, and President of the American Society for Blood and Marrow Transplantation. The primary endpoint of the study is overall incidence, frequency and severity of adverse events related to ApoGraft™ at one year post-transplantation.

Washington University School of Medicine in St. Louis is among the leading medical centers in the U.S. This is Collect's first collaboration with a U.S. site for clinical development following the establishment of the clinical advisory committee consisting of Prof Negrin of Stanford, Dr. Cutler of Harvard Medical School and Professor Rowe of Northwestern University. Collect's ApoGraft™ is currently being evaluated outside of the U.S. in a Phase I/II clinical trial to evaluate the safety and tolerability of functionally selected donor derived mobilized peripheral blood cells that undergo the ApoGraft process in patients suffering from hematological malignancies that are undergoing allogeneic HSCT.

About Collect Biotechnology Ltd.

Collect Biotechnology (NASDAQ: [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. For example, forward-looking statements are used in this press release when we discuss Collect's expectations regarding timing of the upcoming clinical program objectives. 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 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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