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Cellect Biotechnology and Washington University finalize accelerated Clinical Trial Agreement

July 10, 2019 | News

Collaboration Achieves First Significant Milestone with Successful Execution of Technology Transfer



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, Cellect Biotechnology Ltd. and Washington University (WU) has announced the signing of an Accelerated Clinical Trial Agreement (CTA).

Cellect 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.

Dr. Shai Yarkoni, Chief Executive Officer said, "We are continuing to advance our lead development program, ApoGraft™, and pleased to achieve this milestone with Washington University," commented. "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). 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", Dr. Yarkoni

"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.