



FDA Grants Orphan Drug Status to Collect's ApoGraft™ for Acute GvHD and Chronic GvHD

September 5, 2017

ApoGraft™ aims to solve Bone Marrow Transplantation (BMT) and other transplant rejection associated diseases

Collect's CEO, Dr. Shai Yarkoni commented "We may provide the answer to a great unmet clinical need causing severe morbidity and death in thousands of patients worldwide. The Orphan Drug status gives us 7 years exclusivity following approval as well as other advantages for ApoGraft™ commercialization."

TEL AVIV, Israel, Sept. 5, 2017 /PRNewswire/ -- Collect Biotechnology Ltd. (NASDAQ: [APOP](#)), a developer of stem cells selection technology, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for Collect's ApoGraft™ for the prevention of acute and chronic graft versus host disease (GvHD) in transplant patients.

GvHD is a transplant associated disease representing an outcome of two immune systems crashing into each other. In many transplantations from donors, and especially in Bone Marrow Transplantations (BMT), the transplanted immune mature cells (as opposed to stem cells) attack the host (patient receiving the transplant) and create severe morbidity and in many cases even death.

This disease happens as a result of current practices being unable to separate the GvHD causing cells from the much needed stem cells. Collect's ApoGraft™ was designed to eliminate immune responses in any transplantation of foreign cells and tissues.

Collect's ApoGraft technology can be utilized already today to help thousands of development and research centers globally engaged in adult stem cells based therapeutics by providing them with a simplified and cost efficient enriched stem cells for use as a raw material for a wide range of stem cells based therapeutics R&D. Before Collect's ApoGraft, such procedures were extremely complex, inefficient and required substantial resources in both cost, time and infrastructure requirements. ApoGraft can now be used to significantly advance the use of stem cells across multiple therapeutics indications as well as research and biobanking purposes.

The FDA Orphan Drug Act provides incentives for companies to develop products for rare diseases affecting fewer than 200,000 people in the United States. Incentives may include tax credits related to clinical trial expenses, an exemption from the FDA user fee, FDA assistance in clinical trial design and potential market exclusivity for seven years following approval.

About Collect Biotechnology Ltd.

Collect Biotechnology (NASDAQ: "APOP", "APOPW") has developed a breakthrough technology for the selection of stem cells from any given tissue that aims to improve a variety of stem cell applications.

The Company's technology is expected to provide pharma companies, medical research centers and hospitals with the tools to rapidly isolate stem cells in quantity and quality that will allow stem cell related treatments and procedures. Collect's technology is applicable to a wide variety of stem cell related treatments in regenerative medicine and that current clinical trials are aimed at the cancer treatment of bone marrow transplantations.

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 the Company's pathway for commercialization of its technology. 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: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications, which could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements. 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, 2016 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 period filings with the SEC and the Tel-Aviv Stock Exchange.

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