

Collect Biomed Ltd.

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Enlisting apoptosis to improve stem cell-based therapies

Collect Biomed has developed a stem cell selection process it hopes will optimize clinical and research applications of stem cells and provide a boon to the stem cell industry. The company's ultimate goal is to make stem cell transplantation a safer and more effective medical procedure.

Standouts among all known stem cells, hematopoietic stem cells (HSCs) have shown huge potential in treating and curing a wide range of diseases owing to their ability to reconstruct and replace damaged tissues and organs.

However, although HSC transplantation—formerly known as bone marrow transplantation—has improved substantially in the past four decades, its use has been restricted to only those patients with life-threatening diseases, because of inefficiencies in the harvesting process and cell impurities in the stem cell extracts that can induce adverse reactions such as rejection and graft-versus-host disease. Collect has now solved both of these issues.

“Most of the companies developing stem cell-based products start with a very low number of cells and try to expand them. Selection techniques are not very good and fail to collect most of the stem cells in a sample while co-purifying significant numbers of non-stem cells,” said Shai Yarkoni, CEO and co-founder of Collect. “Companies attempt to get around this by expanding the stem cell population. But even in the best-case scenario—using cord blood as starting material—the process can take 20 to 25 days, and much longer if starting from mesenchymal cells.”

Tel Aviv-based Collect Biomed has developed a line of products based on its proprietary functional-selection method, which can separate stem cells from other cells in bone marrow, umbilical cord, blood and even fat tissue. Developed by Nadir Askenasy, the company's chief scientist and co-founder, the method separates stem cells from mature cells by taking advantage of the inherent resistance of stem and progenitor cells to receptor-mediated apoptosis signals.

Collect has shown that this selective resistance to apoptosis can help increase stem cell concentrations in extracts from a range of stem cell

sources. “We have optimized the process and are now finalizing preclinical studies showing both reduction of toxicity and potential improvement in the time to engraftment in bone marrow transplantation,” said Yarkoni.

“The ability to select these cells creates an advantage both for medical research and, more importantly, industry. We believe that companies with an interest in developing stem cell-based therapies will adopt our selection technique as a first step in their manufacturing process. Our process takes as little as four to six hours to complete, is simple to perform and needs no special infrastructure. It is expected to dramatically shorten—or even eliminate, in the case of cord blood—the expansion process, thereby improving the outcome and significantly lowering the costs of manufacturing, as well as the regulatory requirements,” he added.

The company's first product line will include unique containers for cell selection. Collect has seven patent families protecting its intellectual property covering composition of matter, method of use and method of production.

Going into the clinic

With proof of concept for its stem cell selection technology in hand, Collect will start a phase 1/2 trial in the second half of 2015 in Israel involving bone marrow transplantation in leukemia patients.

By the end of 2016, Yarkoni expects to have the first human safety data and a prototype of the infusion bag, which will be developed as a single-use medical device with a US partner. “We anticipate starting a pivotal study of dozens of patients and securing CE marking for our first product followed by a PMA [pre-market approval] from the FDA,” he said.

The company motto is designed to emulate Intel's strategy during the 1990s of making its chips ubiquitous and ensuring that all computers carried the “Intel Inside” logo. Similarly, looking at how companies that developed antibody humanization embedded their technologies into what is now one of the most prominent biopharmaceutical sectors, Yarkoni believes that his company's technology will get traction in accelerating the development of regenerative medicine.

“Our primary business model is not selling bags but instead embedding our technology into others' manufacturing processes. The first product is intended to prove the concept of functional selection and will probably be fully reimbursed by insurance companies because it will lower

significantly the cost of both the bone marrow transplantation procedure and post-transplant medical treatments,” Yarkoni noted.

Collect anticipates revenues from industrial, medical and research applications, while at the same time developing its own consumables.

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SHAI YARKONI

The company expects to first roll out research tools while it is waiting for regulatory approval for its medical consumable products. During this time it will also work with other companies interested in adopting the technology for their own stem cell manufacturing processes. “It is how we manage our business risk—targeting different markets with different products at different price points, all underpinned by the same R&D,” Yarkoni added.

Although Collect, which is listed on the Tel Aviv stock exchange, has attracted enough funds to conduct the first tranche of clinical trials and reach commercial proof of concept, Yarkoni concedes that the company may need to expand soon to the United States for further funding and business development opportunities. These could include developing medicinal products based on the technology for marketing through strategic partnerships and establishing the company as a global business outside of Israel, closer to the market and sources of finance.

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