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COMPANY INTERVIEW

JULIAN ADAMS

Gamida Cell Ltd.

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Gamida Cell Ltd. (NASDAQ:GMDA)

JULIAN ADAMS, PH.D., joined Gamida Cell Ltd.'s leadership team as Chief Executive Officer in November 2017, bringing more than 30 years of drug discovery and development experience to his role. He has served on the board since September 2016. Prior to his CEO appointment, Dr. Adams served as President and Chief Scientific Officer at Clal Biotechnology Industries (CBI), where he oversaw the Boston office, evaluating investment opportunities and supporting portfolio companies, including Gamida Cell. Before joining CBI, he served as the President of Research and Development at Infinity Pharmaceuticals, Inc., where he built and led the company's R&D efforts. Dr. Adams also served as Senior Vice President of Drug Discovery and Development at Millennium Pharmaceuticals, Inc., where he played a key role in the discovery of Velcade® (bortezomib), a therapy widely used for treatment of the blood cancer, multiple myeloma. Earlier in his career, he was credited with discovering Viramune® (nevirapine) for HIV at Boehringer Ingelheim. He has also held senior leadership roles in research and development at LeukoSite, Inc. and ProScript. Dr. Adams has won several awards for his drug development efforts throughout his career, holds more than 40 patents from the United States Patent and Trademark Office and has authored more than 100 papers and book chapters in peer-reviewed journals. Dr. Adams holds a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology. He also holds a Sc.D., *honoris causa*, from McGill University.

SECTOR — PHARMACEUTICALS

(BDU604) TWST: Let's start with a brief overview of the company and your technology.

Dr. Adams: The company was founded in Jerusalem, Israel, and has been around since 1998. In the last 12 years or so, we have been developing a cell expansion technology using a proprietary approach to expand the number of cells of interest, whether they'd be hematopoietic stem cells for bone marrow transplantation or other immune cells, such that we can expand those cells and retain their properties.

Typically, if you put cells in culture and try to expand them with growth factors, they lose their intrinsic properties, they become exhausted and there is a limitation to how much you can expand those cells. With our technology, which we call NAM, we are able to enhance the number of cells and keep those cells rejuvenated in a healthy state. In fact, we can, in many cases, improve their properties and get an even better cell source. And the purpose of expanding cells is to give better, more effective clinical doses to patients in need.

TWST: How is what you do different from other therapies?

Dr. Adams: Gamida Cell is unique because we are pioneers in the field of cell expansion. Companies in the cell therapy space have been trying to do this approach for three decades. Gamida Cell has been doing this for the past 12 years, not just having tremendous laboratory results in animal models, but now having fully conducted human clinical trials as well. With our most advanced program being for bone marrow transplantation, we've conducted a randomized Phase III clinical trial — which includes a global trial across four continents — showing the vast superiority of our cell culture, of our cell product. Our NAM technology platform is a critical differentiator that we are able to use across multiple innate and adaptive immune cells.

TWST: And you completed a BLA submission in June. Can you talk about that and explain why that's important?

Dr. Adams: Our lead program, Omidubicel, achieved FDA Breakthrough Designation several years ago, which allowed us to work collaboratively with the FDA to design the study and to agree on the endpoints of the study. The success of the clinical trial has been published in the journal *Blood,* and presented at major medical conferences. We have met both primary endpoints and also three secondary endpoints, including additional analyses showing neutrophil engraftment of the new cells, for the as-treated patients, with a median of 10 days. That compares favorably with any other modality of transplant, including a matched sibling donor, where our product engrafts about a week faster than even a sibling donor.

TWST: And now that you've completed the BLA submission, what happens next?

Dr. Adams: I am pleased to say that on August 1st, we shared with our stakeholders that the FDA accepted our BLA with Priority Review signifying a critical milestone in our mission to deliver a new stem cell therapy option for patients in need of a donor for an allogeneic stem cell transplant. Importantly, the FDA granted Priority Review for the BLA and has set a Prescription Drug User Fee Act — PDUFA — target action date of January 30, 2023. The FDA grants Priority Review to product applications that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to current options for patients.

TWST: Can you talk about some of your other clinical trials and their status?

Dr. Adams: Yes. Based on the robustness of this technology, we have applied this NAM-enhanced expansion to a cell type called Natural Killer — NK — cells. NK cells are innate cells of the immune system, and it is our first line of defense. Normally, 5% of our lymphocytes, of our immune cells, are natural killer cells. But for patients afflicted with malignancies and cancers, their NK cells are not functioning properly. The NK cells become exhausted or dysfunctional. Our ability to yield very highly functional and potent cells has allowed us to conduct a pilot study in lymphoma.

"Upon approval of omidubicel, our hematopoietic stem cell therapy candidate, we are in a position to become a commercial biotech company in the first half of next year. Our mid-term strategy revolves around the success of our GDA-201 NK cell therapy candidate program. If our company-sponsored clinical trials are successful, we could potentially file a BLA in the next two to three years."

At the 2021 American Society of Hematology — ASH — Annual Meeting we reported very high response rates and complete remissions rates; they're quite durable. The safety profile has been encouraging, particularly compared with CAR T-cells where we do not observe neurotoxicities or what's called cytokine release syndrome, where patients develop fevers and cytokine storm. And so, these cells can be administered to patients on an outpatient basis. With CAR T-cells, patients have to be hospitalized for up to two weeks for careful observation since the safety concerns are idiosyncratic and unpredictable.

TWST: At this point, what contributes most to your bottom line?

Dr. Adams: The bottom line is the clinical data, our interactions with the hematology/oncology community, and the steady reporting of data further supporting our hypothesis. We have also engaged in a lot of sophisticated laboratory work to explain how this works at a molecular level. The story really has come together in the last year with gaining a lot of attention from physicians, both who are on our trials or who are not necessarily on our trials. Our medical affairs group continues to connect to the transplant community and we have presented over a dozen abstracts in the last year at major medical meetings, all which have been very well received.

As an example, for the bone marrow transplant, for the Phase III program, we have conducted additional studies on the pharmacoeconomics of the product. There is the potential for better patient outcomes. Also a feature that is very important in the field of bone marrow transplantation is the ability to match patients at a genetic level to omidubicel, and what omidubicel can achieve and what we showed in our clinical trial is that patients of racial and ethnic diversity have a very hard time finding a match in the registry. We have been able to have about 95% matching in our clinical trial.

If a patient cannot find an appropriate donor, they will unfortunately succumb to their cancer. Omidubicel has a less stringent matching criteria for patients. Moreover, we demonstrated our ability to match racially and ethnically diverse patients in our Phase III study as 40% of the patients in our study were non-Caucasian.

In our lymphoma study, we've had patients that are out three and a half years and are disease-free. And the safety profile, as I've mentioned, compares much more favorably to the CAR T therapies in lymphoma, where patients have to be hospitalized, carefully monitored, and there are higher relapse rates.

Also, we have positioned the company for success over the near-, mid- and long-term. Upon approval of omidubicel, our hematopoietic stem cell therapy candidate, we are in a position to become a commercial biotech company in the first half of next year. Our mid-term strategy revolves around the success of our GDA-201 NK cell therapy candidate program. If our company-sponsored clinical trials are successful, we could potentially file a BLA in the next two to three years. Longer term, or five years out, we are advancing a pipeline of genetically modified NK cell therapy candidates, some of which have already reported promising preclinical data in blood and solid tumor cancers.

TWST: What are your priorities for the next year or two? And what would be the benchmark for success for that timeframe?

Dr. Adams: We have a very detailed launch plan for omidubicel upon FDA approval. We are focusing on a targeted launch and the reason for that is, in the United States, the top 70 transplant centers account for 80% of the procedures, and 20 of those centers participated in our clinical trials. A targeted launch will go to centers that have the most experience and then we will onboard centers quarter by quarter to ultimately reach the maximum number of centers. We will begin with our centers that participated in our clinical trial and the other centers within the top 70 of centers.

TWST: And what are the significant milestones, and we've kind of touched on this, that investors should be looking out for in terms of catalysts?

Dr. Adams: The key catalysts are the regulatory and commercial milestones around omidubicel, clinical development and data readouts for the GDA-201 program and advances in the genetically modified NK cell therapy program that hopefully leads to an IND for one the NK cell therapy candidates this year.

TWST: What would you say was the most significant takeaway from your most recent earnings report?

Dr. Adams: The most significant takeaway is that we continue to execute against our clinical and regulatory milestones. Recently, we received acceptance for filing from the U.S. Food and Drug Administration with priority review for our Biologics License Application — BLA — for omidubicel. The BLA has been assigned a Prescription Drug User Fee Act — PDUFA — target action date of January 30, 2023. If approved, omidubicel will be the first allogeneic advanced stem cell therapy donor source for patients with blood cancers in need of a stem cell transplant.

Additionally we announced that we successfully dosed the first patient in a company-sponsored Phase I/II study evaluating a cryopreserved formulation of GDA-201, and continued development of the company's proprietary NAM-enabled NK cell pipeline, including genetically modified product candidates GDA-301, GDA-401, GDA-501 and GDA-601.

TWST: And the current economy — whether you want to call it a recession or not — how is it impacting what you do and your long-term goals?

Dr. Adams: Actually, because we are an orphan disease and payers look at their total budget impact model, looking at their per-member per-month costs, and the pharmacoeconomics, including the reduction in health care resource utilization, make it very favorable to save these patients' lives and save them in years where they're still productive, still returning to work, and contributing in the form of taxes and their work contributions. Recessions do not stop the progress of cancers and the business of medical innovation that helps manage and one day, ultimately cure cancers.

TWST: What's the most important thing a potential investor should know about your company?

Dr. Adams: We have two unique strengths. First, we have a highly skilled commercial team that has done successful launches in cell therapy. Second, our R&D team has been able to not just make one product but has made multiple products. Our NK cell therapy candidate, GDA-201, for the treatment of follicular and diffuse B cell lymphomas, is progressing nicely. We have initiated a company-sponsored phase I/II study for an off-the-shelf product to support a multicenter study.

The GDA-201 study is open for enrollment. We recently announced that we have dosed the first patient. The study is currently open to enrollment at Henry Ford Health in Detroit, Michigan, and the Masonic Cancer Center at the University of Minnesota. Additional sites will be added in the coming months and updated in Clinicaltrials.gov.

In addition, we have a strong team of scientists that can genetically engineer those cells using CRISPR technologies, CAR technologies, to enhance the potency and the specific targeting of certain hematologic malignancies, but also solid tumors. We have two clinical-stage programs, but we have four laboratory-stage programs on the heels of that, and we hope to nominate a third such program by the end of this year for IND-enabling activities.

Furthermore, our proprietary NAM technology platform allows us to explore even further opportunities beyond what we're working on right now, other innate and adaptive immune cells. With the appropriate funding there is an opportunity to expand our NAM-enabled pipeline of cell therapies significantly .

TWST: Before I wrap things up, is there anything you wanted to discuss that we haven't?

Dr. Adams: Again, our NAM platform can be applied to other cell types. We have successfully expanded gamma-delta T cells, dendritic cells, and mesenchymal cells, so different cells of the immune system, to take a holistic approach of how can we best harness the enormous power of the immune system, which is being defeated by the cancer. We can rejuvenate those cells and provide adequate doses to patients to combat their cancers, but not just in a temporary fashion, but we've been able to show that we can also use innate cells to engage the adaptive immune response, where CD4 and CD8 T cells can produce long and durable remissions of their disease and potentially a cure. Some of our first patients were transplanted in 2011 and remain disease-free today 11 years later.

TWST: Thank you. (CJ)

JULIAN ADAMS, PH.D.
Gamida Cell Ltd.
673 Boylston Street, 4th Floor
Boston, MA 02116
(617) 892-9080
www.gamida-cell.com