

## **Kamada Provides Update on Alpha-1 Antitrypsin Development in Newly Diagnosed Type 1 Diabetes**

**NESS ZIONA, Israel (December 2, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, announces it will un-blind the current clinical trial of the Company's proprietary human Alpha-1 Antitrypsin (AAT) to treat newly diagnosed pediatric and young adult patients with type 1 diabetes (T1D) at the planned interim analysis. This change will accelerate the timeline for future commercialization of the product, should the analysis be positive.

This double-blind, placebo-controlled, multicenter clinical trial of pediatric and young adult patients with newly diagnosed T1D is evaluating the safety and efficacy of intravenous AAT to halt disease progression and maintain the ability of the pancreas to produce insulin. The study is being conducted at four leading pediatric T1D medical centers in Israel and is evaluating beta cell functioning as measured by C-peptide parameters, glycemic control expressed in HbA1C levels, hypoglycemic events and insulin daily dose, among others. These measurements will be part of the final report.

"The planned interim analysis was intended to establish trial safety and provide futility analysis for approximately 90 patients after one year in the trial, while maintaining the blinding of the trial. After thorough examination of the content of such an analysis, we have concluded that the blinded results will not provide us with sufficient information for discussions with potential strategic partners and/or to determine whether to continue with the study. In consultation with our regulatory and clinical advisors, as well as the trial investigators, we have decided to generate the final report based on clinical data from 60 patients who have completed one year of therapy by the end of 2016, with results expected in the first half of 2017," stated Amir London, Chief Executive Officer of Kamada.

"We expect to enroll 60 patients in this study by year-end 2015, and have determined that this will be sufficient to allow us to explore the differences between treatment groups without the limitations of the blinding. To date the safety profile of AAT is excellent without any major adverse events both in the current trial, which includes pediatric patients, as well as in commercial settings, where the drug has been used to treat hundreds of patients for its U.S. Food and Drug Administration (FDA) approved indication. Further, preclinical data regarding the mechanism of action of AAT supports the positive data demonstrated in the Phase 1/2 clinical trial of AAT for the treatment of newly diagnosed T1D," stated Eran Schenker, M.D., Kamada's Vice President-Medical Director.

"We remain committed to T1D patients and believe AAT offers an exciting opportunity for Kamada to bring a promising therapy to newly diagnosed pediatric and young adult patients. Consequently, we have agreed with the clinicians that all patients who complete the current clinical trial will be eligible to continue treatment under an investigator-initiated trial," added Dr. Schenker.

"We strongly believe that obtaining the data more than two years sooner than under the original plan will afford us a number of significant advantages, as it will provide data to discuss with potential strategic partners and to plan a pivotal trial. During the past two years we have gained additional noteworthy knowledge on the mechanism of action of AAT that correlates well with our treatment of newly diagnosed T1D, and have consulted with both the FDA and the European Medicine Agency regarding pivotal trial design. Subject to successful results

in the current trial, we plan to initiate a pivotal study together with strategic partners that would expand the study to other geographies, such as the U.S. and Europe, which would allow us to accelerate product commercialization,” concluded Mr. London.

In T1D, autoimmune attacks occur on pancreatic beta cells that secrete insulin, thereby compromising insulin level and glycemic control. Over time there is progressive deterioration of self-insulin secretion, poor capability to control glucose levels and, eventually, full external insulin dependence. By maintaining its ability to produce insulin, the body can independently control glucose level and reduce diabetes complications that result from poor glycemic control (e.g., cardiovascular disease, kidney disease, eye and vision problems, neurological damage and more).

Kamada previously reported positive preliminary data from the extension portion of its Phase 1/2 clinical trial of AAT to treat pediatric patients newly diagnosed with T1D. That preliminary data showed that at approximately 26 months from diagnosis and approximately 10 months following the last AAT infusion, 60% of study subjects who participated in the extension portion of the trial had peak C-peptide levels greater than 0.2 pmol/ml, which indicates a functioning beta cell capacity and is considered to be a higher percentage than would be expected without intervention.

In addition, patients continued to attain HbA1C targets according to International Society for Pediatric and Adolescent Diabetes standards, with an average HbA1C of 7.5%, with 75% of the patients attaining HbA1C levels even lower than 7.5%, which is the clinically desired level for glycemic control in pediatric diabetic patients, who usually demonstrate a more severe or volatile form of disease compared with adults.

### **About Type 1 Diabetes**

T1D is an autoimmune disease in which the pancreatic beta cells responsible for insulin secretion are attacked by the immune system. In the absence of self-produced insulin and the concomitant glycemic control, there is a need to supply extraneous insulin in order to regain glycemic control and prevent future disease complications that include heart disease, blood vessels disease, nerve and eye disease, infections, hypoglycemic events and many more ailments. According to the U.S. Centers for Disease Control and Prevention, there are more than 10 million diabetic type 1 patients worldwide, with more than 100,000 newly diagnosed each year.

### **About Glassia**

Kamada AAT product, Glassia (Alpha1-Proteinase Inhibitor -Human), is the first available ready-to-use liquid alpha1-proteinase inhibitor (Alpha1-PI) and is indicated as a chronic augmentation and maintenance therapy in adults with alpha-1 antitrypsin (AAT) deficiency. Glassia is administered once a week and is augmenting the levels of AAT in the blood. AAT is a protein derived from human plasma with known and newly discovered therapeutic roles given its immunomodulatory, anti-inflammatory, tissue protective and antimicrobial properties. Glassia is approved by the U.S. Food and Drug Administration for the treatment of AAT deficiency. It is marketed through a strategic partnership with Baxalta Incorporated in the United States.

The scientific rationale for AAT to treat T1D is based on the fact that AAT has an adjunct anti-inflammatory activity that may modulate the immune system in a way that prevents it from attacking the pancreatic beta cells that would be destroyed by the autoimmune attack. Past studies have shown that despite having a normal serum level of AAT, the AAT of diabetic patients is inactive in this respect and, therefore, unable to cope with the developing inflammation in the beta cells. Additionally, a number of recent studies support the rationale for treating T1D early in the disease diagnosis or the “honeymoon” period, a period during which there are still some existing functional beta cells. It is hypothesized that AAT may halt pancreatic inflammation, thereby allowing the survival of active and operating beta cells that secrete insulin, a survival which may allow the patient to reduce dependence on external insulin and eventually decrease disease complications.

## **About Kamada**

Kamada Ltd. is focused on plasma-derived protein therapeutics for orphan indications, and has a commercial product portfolio and a robust late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other plasma-derived proteins. AAT is a protein derived from human plasma with known and newly-discovered therapeutic roles given its immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties. The Company's flagship product is Glassia®, the first and only liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. Food and Drug Administration. Kamada markets Glassia in the U.S. through a strategic partnership with Baxalta. In addition to Glassia, Kamada has a product line of nine other injectable pharmaceutical products that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America, Eastern Europe and Asia. Kamada has five late-stage plasma-derived protein products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency that completed pivotal Phase 2/3 clinical trials in Europe and is in Phase 2 clinical trials in the U.S. and its intravenous AAT to treat type-1 diabetes, GVHD and prevention of lung transplant rejection. Kamada also leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing 10 complementary products in Israel that are manufactured by third parties.

## **Cautionary Note Regarding Forward-Looking Statements**

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions and results related to financial results forecast, commercial results, timing and results of clinical trials and EMA and U.S. FDA authorizations. Forward-looking statements are based on Kamada's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors including, but not limited to, unexpected results of clinical trials, delays or denial in the U.S. FDA or the EMA approval process, additional competition in the AATD market or further regulatory delays. The forward-looking statements made herein speak only as of the date of this announcement and Kamada undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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