

Kamada Reports Encouraging Interim Data from its Phase 1/2 Extension Study: AAT in Pediatric Patients with Type 1 Diabetes

Majority of patients who continued treatment with AAT maintained capability of insulin secretion and attained glycemic targets with HbA1C level below 7.5% for more than 2 years after diagnosis of type 1 diabetes

NESS ZIONA, Israel (February 2, 2015) – Kamada Ltd. (Nasdaq and TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, today reported additional data from the company's ongoing extension study of its open-label Phase 1/2 clinical trial with its lead product, intravenous Alpha1-Proteinase Inhibitor–Human (AAT), to treat recently diagnosed type 1 diabetes (T1D) pediatric patients. Treatment of T1D patients with Kamada's AAT may have several medical benefits including slowing the progression of the disease, improved metabolic control, reduction of daily insulin dose requirements, and most importantly, reduction of diabetes complications.

Twenty four subjects participated in Kamada's initial Phase 1/2 clinical study and received a total of 18 infusions of AAT over 28 weeks. Nineteen subjects were enrolled in the extension study in either the treatment arm (n=10) or follow-up arm (n=9) and five subjects chose not to participate. This interim report from the extension study is presented following 6 additional AAT infusions for subjects in the AAT treatment arm. Interim data from an average of 26 months post T1D diagnosis show that mean peak C-peptide levels, a peptide which represents the endogenous insulin production and thereby the beta cell activity, were 0.40 pmol/ml and that 60% of these patients exhibited a level ≥ 0.2 pmol/ml. A level ≥ 0.2 pmol/ml is considered to be a clinically meaningful trough level, which negatively correlates with future serious diabetes complications. C-peptide data was not collected for the untreated patient group.

In addition, patients receiving AAT continued to attain ADA (American Diabetes Association) and ISPAD (International Society for Pediatric and Adolescent Diabetes) treatment targets of 7.5% for HbA1C. This is considered the clinically desired level for glycemic control in pediatric diabetes patients who usually demonstrate a more severe or volatile form of T1D disease compared with adults. Treated patients demonstrated an average HbA1C of 7.5% in comparison to 7.9% for the untreated patients. The majority of treated patients (60%) had HbA1C levels lower or equal to 7.5% vs. 44% of the patients in the untreated group. Despite these important differences, these were not found to be statistically significant, as this study was not powered to show statistical significance. Median insulin intake for the treated patients group was lower than the untreated patient group, 0.6 IU/kg/d compared to 1.00 IU/kg/d, respectively ($p = 0.025$).

No safety issues were reported during this interim review of trial data.

David Tsur, co-founder and Chief Executive Officer of Kamada, stated, "We are encouraged by the ongoing positive results from the extension study of our Phase 1/2 trial as they corroborate earlier results from this study and demonstrate the durability of the effect of Kamada's AAT treatment in newly diagnosed type 1 diabetes. Despite the limitation of the small sample size, these results are favorable. The scientific rationale for administering AAT to treat type 1 diabetes is based on the anti-inflammatory and immune-modulatory activities of AAT, which was recently published in the *Journal of Diabetes*

Science and Technology. This mechanism of action supports beta-cells' recovery processes from autoimmune-mediated tissue injury."

Mr. Tsur continued, "The preservation of beta cells is important as it may allow patients to exhibit decreased diabetes complications such as cardiovascular disease, kidney failure, eye disease, severe dermal wounds and more, thanks to the extended time period by which they are able to produce insulin and better maintain their glycemic control. These complications represent the real unmet need in this condition as they are inadequately served by existing therapies, which include insulin, diet and behavioral treatment. Moreover, these complications have direct correlation with the extent of glycemic control the patient reaches during early disease phases. We believe our intravenous AAT can be a groundbreaking treatment for newly diagnosed type 1 diabetes patients, as it may demonstrate the ability to halt disease progression and allow the pancreas to maintain secretions of self- insulin."

In March 2014 Kamada initiated a Phase 2/3 trial with AAT in newly diagnosed T1D pediatric and young adult patients. The goal of the double-blind, placebo-controlled, multicenter study is to assess the efficacy of AAT to halt disease progression and maintain the ability of the pancreas to produce insulin, as expressed by beta cell function and glycemic control. The clinical study is being conducted in Israel, with potential plans to expand to other countries. The two-year study is randomizing approximately 190 patients and is measuring C-peptide parameters, HbA1C levels, hypoglycemic events, insulin daily dose and other diabetes-related analytes, as well as safety and tolerability parameters.

Background on the Phase 1/2 Trial

The Phase 1/2 clinical trial was an open-label, proof-of-concept study of the safety, tolerability and efficacy of AAT in 24 newly diagnosed type 1 diabetes patients who were 9 to 17 years of age. The study was performed at Schneider Children's Medical Center and Assaf Harofeh Medical Center, both in Israel. In this study, patients were randomized into three treatment groups (40mg, 60mg, 80mg/kg/dose). All patients received the study drug for a period of 28 weeks in three treatment intervals. All patients continued standard-of-care treatment and were not deprived of insulin or any other drugs required for disease management. All patients completed the treatment per protocol and underwent a follow-up period.

Previously reported analysis of the Phase 1/2 study data showed that AAT may slow the rate of disease progression by allowing continued functionality of insulin-secreting beta cells, thus providing better glycemic control and potentially reducing future severe disease complications. In all study periods, the patients' diary reports recorded a reduction in insulin consumption in parallel with a reduction in levels of specific pancreatic autoantibodies, a sign that may indicate a diversion or re-modulation of the immune system from attacking the body's own pancreatic cells.

The drug showed a high safety and tolerability profile with all patients completing the clinical trial with no serious adverse events. Other adverse events were mild in intensity and not related to the study drug, underscoring the strong safety profile of AAT.

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 Type 1 Diabetes

T1D is an autoimmune disease in which the pancreatic beta cells responsible for insulin production 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

Glassia is the first available ready-to-infuse liquid alpha1-proteinase inhibitor (Alpha1-PI) and is indicated as a chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe congenital AAT deficiency. Glassia is administered intravenously once a week to augment 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 and is marketed through a strategic partnership with Baxter International Inc. in the United States. **Please see the full prescribing information for Glassia at:**

http://www.baxter.com/downloads/healthcare_professionals/products/Glassia_PI.pdf

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 Baxter International. In addition to Glassia®, Kamada has a product line of 9 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 5 late-stage plasma-derived protein products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency that has completed pivotal Phase 2/3 clinical trials in Europe and is in Phase 2 clinical trials in the U.S. 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 US 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, clinical trials, the EMA and U.S. FDA authorizations and timing of clinical trials. 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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