

## **Kamada Reports New Data from an Extension Study of its Phase I/II Trial with Glassia in Pediatric Patients with Type 1 Diabetes**

*New results in T1D pediatric patients indicate 60% of patients still maintain active pancreatic beta cells that secrete self-insulin approximately 10 months after last Glassia treatment*

*Large percentage of patients have very good glycemic control; Phase II/III trial to initiate by end of 2013*

**NESS ZIONA, Israel (October 31, 2013) – Kamada Ltd. (Nasdaq and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, today reported preliminary data from the Company's ongoing extension study of a Phase I/II clinical trial with its lead product Glassia® to treat pediatric patients with a recently diagnosed type 1 diabetes (T1D).

In T1D endogenous insulin production is compromised, and with time progressive deterioration of beta-cell reserve occurs due to the continuous autoimmune attack. New interim data from the ongoing extension study showed that at ~20 months from T1D diagnosis and ~10 months following the last Glassia infusion, 60% of study subjects who participated (12/20) in the extension portion of the Phase I/II trial had peak C-peptide levels greater than 0.2 pmol/ml (average >0.4 pmol/ml), which indicates a functioning beta cell capacity and is a higher percentage than expected without intervention.

In addition, patients continued to attain ISPAD (International Society for Pediatric and Adolescent Diabetes) treatment targets with an average HbA1C of 7.5%, and the majority of patients (75%) presented 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 T1D disease compared with adults.

No safety issues were reported.

David Tsur, CEO of Kamada, stated, "We are delighted that these interim data from the extension study continue to demonstrate the positive signals seen in our analysis of study results. These positive data may potentially represent a breakthrough in the treatment of this disease, and encourage us to actively move forward with plans to advance the clinical development of Glassia in this indication. Importantly, the preservation of beta cells may allow patients to reduce dependence on external insulin and eventually decrease disease complications such as cardiovascular disease, kidney failure, eye disease, severe wounds and more. These complications remain an unmet need that is still inadequately answered with 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. These complications compromise the patient's normal life routine, require considerable healthcare resources, have economic impact on the general work capacity of the diabetic employees and reduce their life expectancy."

Kamada plans to initiate a Phase II/III trial with Glassia with newly diagnosed T1D pediatric and young adult patients. The goal of the double-blind, placebo-controlled, multicenter study is to assess the efficacy of Glassia in treatment of new onset type 1 diabetes, as expressed by beta cell function and glycemic control. The clinical study will initiate in Israel, with potential plans to expand the scope to include other countries. The two-year study will randomize approximately 190 patients and will measure C-peptide parameters, HbA1C levels, hypoglycemic events, insulin daily dose and other diabetes-related analytes, as well as safety and tolerability parameters.

### **About Glassia**

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 Baxter International Inc. in the United States.

The scientific rationale for Glassia 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 Glassia 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.

### **Background on the Phase I/II Trial**

The Phase I/II clinical trial was an open-label, proof-of-concept study of the safety, tolerability and efficacy of Glassia in 24 newly diagnosed type 1 diabetes patients age 9 to 17. The study was performed at Schneider Children's Medical Center and Aassaf Harofeh Medical Center, both in Israel. In the study patients were randomized into three treatment groups (40mg, 60mg, 80mg/kg/week). 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 in full and underwent a follow-up period.

Previously reported analysis of the Phase I/II study data showed that Glassia 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, patient diary reports recorded a reduction in insulin consumption in parallel with a reduction in levels of specific T1D disease antibodies, 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 Glassia.

### **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 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 is in pivotal Phase II/III clinical trials in Europe and will be entering Phase II 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.

#### **Contacts:**

Gil Efron  
CFO  
[ir@kamada.com](mailto:ir@kamada.com)

Anne Marie Fields  
LHA  
212-838-3777  
[afields@lhai.com](mailto:afields@lhai.com)

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