

## Kamada Announces Publication in *Pediatric Diabetes*

*Demonstrated profound safety of multiple intravenous doses of AAT therapy for treatment of newly diagnosed type 1 diabetes while maintaining glycemic control and less of a decrease in C-Peptide levels*

**NESS ZIONA, Israel (July 6, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, reports the publication of positive data from a Phase 1/2 clinical study of its lead product, intravenous Alpha1-Proteinase Inhibitor–Human (AAT), to treat recently diagnosed type 1 diabetes (T1D) pediatric patients in *Pediatric Diabetes*, a peer-reviewed journal. The article titled, “Alpha-1 antitrypsin therapy is safe and well tolerated in children and adolescents with recent onset type 1 diabetes mellitus,” can be accessed [here](#) and on the Company’s website [www.kamada.com](http://www.kamada.com).

The study evaluated a pediatric population with recent onset type 1 diabetes (T1D) in a 37-wk prospective, open-label, phase 1/2 interventional trial, comprised of 24 recently diagnosed subjects who received 18 infusions of 40, 60, or 80 mg/kg/dose of AAT over 28 weeks. The primary endpoints were safety and tolerability and secondary endpoints included glycemic control, C-peptide reserve, and autoantibody levels. Possible responders were defined as individuals with peak C-peptide levels that declined less than 7.5% below baseline.

No serious adverse events, diabetic ketoacidosis (DKA), or severe hypoglycemic episodes were reported. Adverse events were dose-independent and transient. Glycemic control parameters improved during the study in all groups, independent of dosage. Hemoglobin A1c (HbA1c) decreased from 8.43% to 7.09% (mean,  $p < 0.001$ ). At the end of the study, 18 subjects (75%) had a peak C-peptide  $\geq 0.2$  pmol/mL. Eight subjects (33.3%) were considered possible responders and were characterized by shorter duration of T1D at screening ( $54.5 \pm 34.3$  vs.  $95.9 \pm 45.7$  days,  $p = 0.036$ ) and greater decrease in their HbA1c during the study period ( $-2.94 \pm 1.55$  vs.  $-0.95 \pm 1.83\%$ ,  $p = 0.016$ ).

In the article, Rachmiel et al. concluded, “AAT treatment was safe and well tolerated in pediatric subjects with recently diagnosed autoimmune diabetes. Notably, this is the first study to demonstrate profound safety of multiple intravenous doses of AAT therapy for non-AAT-deficient pediatric individuals with recent onset T1D while maintaining glycemic control and demonstrating less of a decrease in C-Peptide levels.”

“We are delighted to have these positive data published in *Pediatric Diabetes* as they corroborate results from previous studies, which showed AAT therapy to reduce pro-inflammatory markers and may protect pancreatic islets from autoimmune responses in newly diagnosed diabetic patients as measured by HbA1c and C-peptide levels,” noted Amir London, Chief Executive Officer of Kamada. “We continue to enroll patients in our Phase 2/3 study of AAT to treat newly diagnosed type 1 diabetic patients and look forward to advancing this important trial, which we believe may change the treatment paradigm for type 1 diabetic patients.”

“The scientific rationale for Glassia to treat T1D is based on the anti-inflammatory and immunomodulation activities that AAT holds, mainly by modifying dendritic cell maturation and promoting regulatory T cells differentiation, resulting in elevated local expression levels of IL-1Ra, TGF $\beta$  and IL-10. These immunomodulation properties may inhibit insulinitis and beta cell apoptosis rate, delay

the onset of diabetes and reduce diabetes incidence,” noted Eran Schenker, M.D., Kamada’s Vice President-Medical Director. “Additionally, a number of recent studies support the rationale for treating T1D early in the disease diagnosis or the ‘honeymoon’ period, during which a critical mass of functional beta cells still exists. It is hypothesized that AAT therapy may decrease pancreatic inflammation, thereby allowing the survival of active and operating beta cells that secrete insulin longer, a survival which may allow the patient to reduce dependence on external insulin and eventually decrease disease comorbidities.”

#### **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 entered 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 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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