

## **Kamada Announces Study in Support of Alpha-1 Antitrypsin for the Treatment of Type-1 Diabetes Published in the *Journal of Diabetes Science and Technology***

*Anti-inflammatory activity of AAT may modulate immune system to prevent it from attacking pancreatic beta cells*

**NESS ZIONA, Israel (October 21, 2014) – Kamada Ltd. (Nasdaq and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, announces that a comprehensive review of the data available in the literature in support of the mechanism of action of Alpha-1 Antitrypsin (AAT) for the treatment of Type-1 Diabetes, was published in the August 2014 edition of the peer-reviewed, *Journal of Diabetes Science and Technology*. The online version of the review article, titled, “Mechanistic Evidence in Support of Alpha-1 Antitrypsin as a Therapeutic Approach for Type-1 Diabetes” can be accessed at: <http://dst.sagepub.com/content/early/2014/08/23/1932296814547096>.

“The scientific rationale for Glassia to treat T1D is based on the anti-inflammatory and immunoregulatory activities that AAT holds, which support beta-cells recovery processes from autoimmuno-mediated tissue injury. Past studies have shown that despite having normal serum levels, the AAT of diabetic patients is inactive in this respect, and therefore, unable to cope with the developing inflammation in the beta cells,” noted Pnina Strauss, Kamada’s Vice President of Clinical Development and Intellectual Property. “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 exists. 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.”

According to the study authors, “Protection of islets by AAT is consistent across multiple diabetes models. Findings from multiple experimental animal models provide clear evidence that AAT possesses broad anti-inflammatory and immune-regulatory activities, promoting tissue recovery processes in the context of immune-mediated  $\beta$  cell destruction. The beneficial effect of AAT on diabetes was first demonstrated using virus-mediated gene delivery of AAT to non-obese diabetic (NOD) mice.<sup>1</sup>”

“This is an important publication because it provides insight into the underlying mechanism of action in support of the use of AAT to treat type-1 diabetes. Moreover, it provides the scientific rationale that corroborates the positive clinical results achieved in our Phase 1b clinical study and validates our continued clinical studies in this serious and life-threatening autoimmune disease,” stated David Tsur, co-Founder and Chief Executive Officer of Kamada. “We continue to enroll patients in our ongoing Phase 2/3 clinical trial. We are very excited about this opportunity as we believe Glassia can be a groundbreaking treatment for newly-diagnosed type 1 diabetes in pediatric patients as it should demonstrate the ability to halt disease progression and allow the pancreas to produce its own insulin.”

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<sup>1</sup> Song S, Goudy K, Campbell-Thompson M, et al. Recombinant adeno-associated virus-mediated alpha-1 antitrypsin gene therapy prevents type I diabetes in NOD mice. *Gene Ther.* 2004; 11(2):181-186.

### **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 to augment the levels of AAT in the blood to normal values. 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.

### **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 nine other 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 a pivotal Phase II/III clinical trial in Europe and has initiated 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, Intellectual Property, the EMA and U.S. FDA filings and 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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