

## **Kamada Meets Primary Endpoint of U.S. Phase 2 Study of Inhaled Alpha-1 Antitrypsin for the Treatment of Alpha-1 Antitrypsin Deficiency**

*Company's Inhaled AAT Demonstrated Significant Increase in Endothelial Lining Fluid Inhibitory Capacity*

*Study Results Also Showed that Inhaled AAT is the Most Efficient Way of Delivering Therapeutic Amounts of AAT to the Primary Sites of Potential Lung Injury*

*Kamada to Utilize Results to Design Pivotal U.S. Study and Support Responses to European Medicines Agency (EMA) Regarding Company's Marketing Authorization Application (MAA) for Inhaled AAT*

**NESS ZIONA, Israel -- August 30, 2016 --** Kamada Ltd. (Nasdaq: KMDA) (TASE: KMDA.TA), a plasma-derived protein therapeutics company focused on orphan indications, today announced positive top-line results, meeting the primary endpoint of the Company's U.S. Phase 2 clinical trial of its proprietary inhaled Alpha-1 Antitrypsin (AAT) therapy for the treatment of Alpha-1 Antitrypsin Deficiency (AATD). AATD is an orphan disease currently treated by intravenous AAT augmentation therapy.

The U.S. Phase 2 clinical trial was a double-blind, placebo-controlled study evaluating the safety and efficacy of AAT by inhalation in 36 AATD patients. Patients were treated with Kamada's AAT for inhalation (80 mg/day or 160 mg/day) or placebo via the eFlow® device for 12 weeks during the double-blind period. Primary efficacy measures included antigenic AAT levels and Anti-Neutrophil Elastase inhibitory (ANEC) levels in the lung as well as additional anti-proteolytic and anti-inflammatory biomarkers. Following this double-blind period, eligible patients (total of 26) entered an additional 12-week open-label extension study with the active drug (160mg/day) to further assess safety and tolerability.

AATD patients treated with Kamada's inhaled AAT demonstrated a significant increase in endothelial lining fluid (ELF) AAT antigenic level compared to the placebo group [median increase 4551 nM, p-value<0.0005 (80 mg/day, n=12), and 13454 nM, p-value<0.002 (160mg/day, n=12)]. These results are more than twice the increase of ELF antigenic AAT level (+2600 nM) observed in Kamada's previously completed intravenous (IV) AAT pivotal study (60mg/kg/week). Antigenic AAT represents the total amount of AAT in the lung, both active and inactive.

In addition, ELF ANEC level also increased significantly [median increase 2766 nM, p-value<0.0005 (80mg/day) and 3557 nM., p-value<0.004 (160 mg/day)]. The increase in ELF ANEC level was also more than twice that demonstrated in Kamada's previously completed IV AAT pivotal study. The ANEC level represents the active AAT that can counterbalance further damage by neutrophil elastase.

"These measures of AAT concentration at the lung target site are extremely encouraging, demonstrating that the inhaled formulation provides substantially higher levels of antigenic AAT and ANEC than those achieved with the existing standard of care given by IV injection," said Dr. Naveh Tov, MD PhD, Kamada's VP Clinical Development and Medical Director for Pulmonary Diseases.

"The results of this study are extremely compelling," said Professor Mark Brantly, MD, the Primary Investigator in this study who serves as a Vice Chair of Research, Department of Medicine, Chief Division of Pulmonary, Critical Care and Sleep Medicine, Professor of Medicine, Molecular Genetics and Microbiology at the University of Florida College of Medicine and Alpha One Foundation Research Professor. "Based on the results of this study, it is clear that inhaled AAT is the most effective mode of treatment for reaching the primary sites of potential lung injury, and restoring AAT inhibitory capacity. I look forward to the start of a pivotal study in the U.S. to confirm these results."

Kamada's inhaled AAT also demonstrated a strong safety profile, adding to the safety data generated in the Company's previously completed European Phase 2/3 clinical study of Inhaled AAT for the treatment of AATD. There were no differences seen in safety parameters (treatment emergent adverse events, serious adverse events, etc.) between the placebo and treatment groups (both 80mg and 160mg) during the double-blind and open-label extension periods. Two patients discontinued the study during the double-blind period, including one in the treated group, which was determined to be unrelated to treatment, and one in the placebo group.

"We strongly believe our inhaled AAT has the potential to change the treatment paradigm for AATD," said Amir London, Chief Executive Officer of Kamada Ltd. "We intend to utilize the excellent results from this successful Phase 2 study to design a pivotal U.S. study and to support our responses to the EMA's 120-day comments in regards to Kamada's MAA for Inhaled AAT, which was submitted earlier this year. We also intend to continue our discussions with the U.S. Food and Drug Administration with this additional phase 2 data and the data from our EU phase 2/3 study in order to obtain guidance on the regulatory pathway for Inhaled AAT in the U.S."

## **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 Immune globulins. 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 (formerly Baxter International Inc.'s BioScience business and now part of Shire plc)

and in other countries through local distributors. In addition to Glassia®, Kamada has a product line of seven other pharmaceutical products administered by injection or infusion, that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America 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 its MAA was submitted to the EMA after completing a pivotal Phase 2/3 clinical trials in Europe. Kamada has also completed its Phase 2 clinical trials in the U.S. for the treatment of AAT deficiency using our proprietary inhaled AAT. In addition, Kamada's intravenous AAT is in development for other indications such as 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 more than 10 pharmaceutical 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 submissions and 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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