

# **Kamada Submits Proposed Phase 3 Protocol to FDA for Inhaled Alpha-1-Antitrypsin for Treatment of Alpha-1 Antitrypsin Deficiency Disease**

***Patients would be treated with 80 mg/day; intended primary endpoint of lung function and lung density as planned secondary endpoint***

Rehovot, Israel, July 20, 2017 – Kamada Ltd. (NASDAQ & TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, today announced that the Company has submitted to the U.S. Food and Drug Administration (FDA) for review a proposed pivotal Phase 3 protocol for its proprietary inhaled Alpha-1 Antitrypsin (AAT) therapy (Inhaled AAT) for the treatment of Alpha-1 Antitrypsin Deficiency (AATD).

The proposed Phase 3 pivotal study is intended to treat AATD subjects with inhaled AAT at a dose of 80 mg once daily for a period of two years, with a placebo arm at a 2:1 ratio with cross over to the treatment arm following a period of 12 months. In parallel, a concurrent Intravenous AAT (AAT IV) arm will be evaluated for two years. The study is planned to include approximately 200-300 patients, and is expected to measure lung function as a primary endpoint and lung density as a secondary endpoint.

“The proposed study design is based on Kamada’s experience with previous Inhaled AAT studies. Our Phase 2 US study showed increases in AAT levels in the lungs to the upper normal range with a daily dose of 80 mg of inhaled AAT. The primary endpoint of lung function was selected based on the results of our European Phase 2/3 study, and the secondary endpoint is consistent with prior AAT IV studies,” said Dr. Naveh Tov, MD, PhD, Kamada’s Vice President of Clinical Development & Medical Director for Pulmonary Diseases.

As previously announced, Kamada has completed a Phase 2/3 clinical trial in Europe and a Phase 2 clinical trial in the United States (U.S.) with its Inhaled AAT for the treatment of AATD.

The U.S. Phase 2 study, which was double-blind and placebo-controlled, met its primary endpoint and the results indicated that patients treated with Kamada’s Inhaled AAT, in both dosage arms (80 mg/day and 160 mg/day), demonstrated a significant increase of antigenic AAT, and of Anti-Neutrophil Elastase inhibitory Capacity (ANEC) in the endothelial lining fluid (ELF) levels in the lungs compared to the placebo group.

When the Company presented the data from the European Phase 2/3 study to the FDA, the agency expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. Those questions and concerns will need to be resolved before the FDA will allow the Company to proceed with additional clinical development of Inhaled AAT in the U.S., including the planned Phase 3 pivotal study. In order to address the FDA comments, in April 2017, the Company submitted to the agency the results of the U.S. Phase 2 data together with a

proposed Phase 3 synopsis. The FDA has provided the Company with guidance for further development of the synopsis and requested that the Company submit a complete proposed study protocol for the next phase prior to enabling the Company to continue clinical development in the U.S.

On July 18, 2017, Kamada submitted a full study protocol, which the Company believes addresses the remaining concerns and questions identified by the FDA.

“The submission of our proposed Phase 3 protocol represents an important accomplishment for our inhaled AAT program,” said Amir London, Kamada’s Chief Executive Officer. “Following the guidance received from the FDA, we believe we have appropriately designed our proposed Phase 3 clinical trial protocol. Based on the collective clinical data generated to date, we continue to believe that Inhaled AAT has the potential to be a safe and effective treatment for AATD. If approved to move forward by the FDA, we intend to proceed with a U.S. Phase 3 pivotal clinical trial as expeditiously as possible for the potential benefit of the AATD patient population.”

#### ***About eFlow® Technology and PARI Pharma***

The Company’s Inhaled AAT therapy is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma specifically for Kamada. The optimized device uses eFlow Technology to enable highly efficient aerosolization of medication via a vibrating, perforated membrane that includes thousands of laser-drilled holes. Compared with other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size and a high proportion of respirable droplets delivered in the shortest possible period of time. Combined with its quiet mode of operation, small size, light weight and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments.

#### ***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 (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 for which the Company completed a pivotal Phase 2/3 clinical trial in Europe. Kamada has also completed its Phase 2 clinical trials in the U.S for the treatment of AAT deficiency with 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 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 the Company's belief that the supplementary data needed for approval of the MAA requires an additional clinical trial; the Company's plan to utilize the data to be obtained from the planned U.S. Phase 3 pivotal study, if positive, to resubmit the MAA to the EMA; the Company's plans for the resolution of questions and concerns raised by the FDA, including through its submission of a full study protocol, in order to proceed with additional clinical development of Inhaled AAT in the U.S., including the planned Phase 3 pivotal study; the Company's belief that the full study protocol submitted to the FDA addresses the remaining concerns and questions identified by the FDA when they reviewed the European Phase 2/3 data; expectations regarding the receipt of an authorization from the FDA in order to proceed with the clinical development of Inhaled AAT for the treatment of AATD in the U.S., including the proposed Phase 3 trial; the Company's belief that Inhaled AAT has the potential to be a safe and effective treatment for AATD; and the Company's intention, if approved to move forward by the FDA, to proceed with a U.S. Phase 3 pivotal clinical trial as expeditiously as possible for the potential benefit of the AATD patient population. 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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