

## **Kamada Receives Positive Scientific Advice from European Medicines Agency on a New Phase 3 Study Design for Inhaled AAT**

*Company Plans to Submit Clinical Trial Application and Intends to Engage in Discussions for Strategic European Partner for Commercialization Rights for Inhaled AAT*

**Rehovot, Israel, July 10, 2018** – Kamada Ltd. (the "Company") (NASDAQ & TASE: KMDA), a plasma-derived protein therapeutics company, today announced that it has received positive scientific advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) related to the development plan for its proposed pivotal Phase 3 study for its proprietary Inhaled Alpha-1 Antitrypsin therapy (Inhaled AAT) for the treatment of alpha-1 antitrypsin deficiency (AATD).

The Company requested scientific advice (protocol assistance) from the CHMP following the results of the previous Phase 2/3 (EU) and Phase 2 (US) studies conducted by the Company with respect to a proposed subsequent Phase 3 study design.

The CHMP notified the Company that it concurs with the overall design of the proposed study, including its objectives, patient population, proposed endpoints and their clinical importance, and the safety monitoring plan. The CHMP had some minor comments, which Kamada intends to address in the final study protocol.

“The CHMP’s acceptance of the overall study design is an important milestone in the development of the Inhaled AAT treatment for the benefit of AATD patients,” said Dr. Jan Stolk, chairman of the Core Group AATD ERN LUNG, director of the Dutch National Expertise Centre for patients with AATD and Principal Investigator in the Phase 2/3 study (EU) conducted by Kamada. “Inhalation of AAT represents an alternative to the intravenous (IV) administration, offering the patient a more convenient delivery of AAT directly to the lungs, enriching the lung epithelial lining fluid (ELF) with AAT at a level which, as demonstrated in Kamada’s Phase 2 (US) study, is at least three times greater than what can be achieved by IV administration. I am looking forward to continue the collaboration with Kamada and to initiate the next pivotal Phase 3 clinical trial, with the goal of confirming the effect on lung function improvement as seen in the previous study.”

“This EMA decision is an important milestone for Kamada. We believe this official feedback means that the path for a European Phase 3 study is clear and new opportunities are now available to us. We intend to work with our internal and external experts to finalize a detailed plan for the clinical program, proceed with the submission of a Clinical Trial Application (CTA), and seek to engage in discussions with strategic European partners with the goal of signing a collaboration agreement for commercialization rights,” said Amir London, Kamada’s Chief Executive Officer. “Kamada is committed to the AATD patient population and medical community, and we are working with the regulators and key opinion leaders to advance innovative solutions for this disease. We are excited by the opportunity to move into the EU pivotal trial.”

The EMA process is conducted in parallel with the Company’s continued discussions with the U.S. Food and Drug Administration (FDA) on the Phase 3 study of Inhaled AAT for AATD. As

previously communicated, following feedback received from the FDA in April 2018, Kamada intends to provide the FDA additional requested information and data, as well as an amended study protocol, during the third quarter of 2018. The proposed modifications and additional information are intended to mitigate the continued safety-related concerns communicated by the FDA.

### ***About Kamada***

Kamada Ltd. is focused on plasma-derived protein therapeutics for orphan indications, and has a commercial product portfolio and a 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 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 six other plasma-derived 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 late-stage products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency, and in addition, its intravenous AAT is in development for other indications, such as type-1 diabetes, GvHD and prevention of lung transplant rejection. Kamada's rabies immune globulin (Human) product received FDA approval for Post-Exposure Prophylaxis against rabies infection in August 2017 and was launched in the US during Q1-2018. 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 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 viability of the European Phase 3 study for Inhaled AAT, including the acceptance of the final study protocol by CHMP and the successful submission of a CTA; the advantages of Inhaled AAT over IV administration; opportunities to seek engagement in discussions with strategic European partners with the goal of signing a collaboration agreement for commercialization rights; and the provision to the FDA of additional requested information and data, as well as an amended study protocol, during the third quarter of 2018. 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, further regulatory delays, prevailing market conditions, and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise. 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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