## Kamada Provides Update on Clinical Program for Alpha-1 Antitrypsin IV for Treatment of Graft-Versus-Host Disease

Rehovot, Israel, June 7, 2017 – Kamada Ltd. (NASDAQ & TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, today announced that Kamada and Shire have agreed that the Investigational New Drug (IND) application approved by the U.S. Food and Drug Administration (FDA) for the Phase 2/3 study evaluating Alpha-1 Antitrypsin (G1-AAT IV) for the treatment of acute Graft-Versus-Host Disease (GvHD) will be transferred from Shire to Kamada, who will take full ownership and responsibility for the clinical development of the product in this indication. Shire has been leading the G1-AAT IV GvHD program in the U.S., while Kamada is leading the program in the European Union (EU). Shire decided to transfer the IND to Kamada due to pipeline prioritization and slow recruitment rate in its current U.S. study. Kamada will assume control of, and onward funding for the full G1-AAT IV program, and intends to conduct an integrated clinical development program across both territories - the U.S. and the EU.

As the result of this decision, the current Part 1 of the Phase 2/3 study conducted in the U.S. is being halted by Shire. Kamada intends to resume the development program in the upcoming few months upon completion of standardizing the study design across both the U.S. and EU, based on the feedback already received from the FDA and the European Medicines Agency (EMA). Kamada previously received Orphan Drug Designation from the FDA and EMA for G1-AAT IV for the treatment of GvHD.

"Kamada is excited to lead this promising development program globally," said Amir London, Kamada's Chief Executive Officer. "Based on the FDA-approved IND in the U.S. and the guidance received at our Scientific Advice meeting held earlier this year with the EMA, we have a clear understanding of the regulatory path forward in both territories. Moreover, based on our GvHD industry expertise and discussions held with the Key Opinion Leaders (KOLs), from both territories, who strongly support us in this program, we believe that conducting an integrated clinical program across both territories will significantly benefit overall recruitment efforts, as well as provide important operational and financial efficiencies. According to our estimates, GvHD is a \$700 million market globally and, therefore, represents a substantial business opportunity for Kamada. We remain committed to the bone marrow transplant community and the GvHD patients, and look forward to continuing to advance the clinical development of G1-AAT IV with the objective of bringing to market a safe and efficacious product for this life-threatening disease."

Kamada's AAT is currently available to steroid-refractory acute GvHD patients in need on a named-patient basis through an Early Access Program in Europe. The program is already enrolling patients.

Kamada and Shire (Baxter at the time) entered into strategic cooperation agreements, including exclusive supply, distribution, and license agreements for the distribution and license of Kamada's IV AAT, in 2010. Under the terms of the agreements, Shire is the exclusive distributor of the product in the U.S., Canada, Australia and New Zealand. In addition, Kamada and Shire continue to collaborate on the clinical development of AAT IV for prevention of lung transplantation rejection.

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## **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 counties 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.

## **Kamada 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 other markets in which Kamada operates or intends to operate, 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.