

## **Kamada Announces Positive Scientific Advice Response from the European Medicines Agency Focused on Alpha-1 Antitrypsin IV for Treatment of Acute Graft-Versus-Host Disease**

*Company Received Important Guidance on European Phase 2/3 Study Design and Regulatory Pathway*

**NESS ZIONA, Israel – January 23, 2017** – Kamada Ltd. (NASDAQ and TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, announced today the positive Scientific Advice response from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) focused on the Company's development program in Europe for Alpha-1 Antitrypsin (G1-AAT IV) for the treatment of acute Graft-Versus-Host Disease (aGvHD) with lower gastrointestinal involvement. The response from the CHMP included important guidance related to the design of the Company's planned Phase 2/3 European study and the regulatory pathway for approval based on conducting such a study.

Kamada is in the process of reviewing the guidance received and, following discussions with the Company's European Scientific Advisory Board, intends to submit a Clinical Trial Authorization (CTA) application to the EMA in 2017 in order to conduct the Phase 2/3 study. Importantly, the design of the Company's U.S. Phase 2/3 clinical trial of G1-AAT IV in aGvHD, which was recently initiated and is being conducted in the U.S. in collaboration with Shire plc, supports the guidance received from the EMA. Kamada intends to conduct the European study in parallel with the U.S. study.

"A substantial unmet need remains globally for the treatment of severe aGvHD, especially intestinal aGVHD," said Prof. Mohamad Mohty, Head of the Clinical Hematology and Cellular Therapy Department at the Saint-Antoine Hospital in Paris and President of the European Society for Blood and Marrow Transplantation (EBMT). "The advent of G1-AAT IV as a potential therapy for gut aGVHD is great news. The stem cell transplant community is looking forward towards investigating this agent."

"I would like to thank the EMA for their critical guidance around our European development program for G1-AAT IV for the treatment of aGvHD," said Amir London, Kamada's Chief Executive Officer. "We are especially pleased that the EMA's guidance is supported by the trial design being utilized in the U.S. Phase 2/3 study. Following discussions with our European Scientific Advisory Board, Kamada looks forward to submitting a CTA in 2017 to conduct a European Phase 2/3 study."

Kamada holds all rights to its G1-AAT IV in Europe, and the product is currently available there to acute GvHD patients in need on a named-patient basis through an Early Access Program. G1-AAT IV previously received orphan drug designation from the U.S. Food and Drug Administration and the EMA for the treatment of GvHD.

### ***About Graft-vs-Host Disease***

Graft vs Host Disease, also called GvHD, is a condition that occurs when donor bone marrow or cells attack the recipient. It is a rare disease, with about 20,000 cases reported in the US and EU per year. GvHD can occur at any time after a transplant. However, it is more common after the marrow has started to make healthy cells. The condition can be mild or severe. Symptoms vary based on how long someone has had the condition, but may include mouth ulcers, abdominal pain, and rash. Treatment includes medication to suppress the immune system, such as steroids.

### ***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 a 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 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 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.

###

**CONTACTS:**

Gil Efron  
Deputy CEO & Chief Financial Officer  
[IR@kamada.com](mailto:IR@kamada.com)

Bob Yedid  
LifeSci Advisors, LLC  
646-597-6989  
[Bob@LifeSciAdvisors.com](mailto:Bob@LifeSciAdvisors.com)