Kamada Announces Plan for Phase 2/3 Clinical Trial with Alpha-1 Antitrypsin IV for Treatment of Graft-Versus-Host Disease

NESS ZIONA, Israel**,** November 2, 2016 – Kamada Ltd. (NASDAQ & TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, today announced the clinical plan for the initiation of a Phase 2/3 clinical trial in the United States of its Alpha-1 Antitrypsin (G1-AAT IV) for the treatment of acute Graft-Versus-Host Disease (GvHD), in collaboration with Shire plc.

Kamada and Shire (Baxter at the time) entered into an exclusive strategic cooperation agreement for the distribution and license of Kamada's AAT IV in 2010. Under the terms of the agreement, Shire is the exclusive distributor of the product in the U.S., Canada, Australia and New Zealand.

GvHD can occur after a stem cell or bone marrow transplant where newly transplanted donor cells attack the recipient. G1-AAT IV previously received orphan drug designation from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for the treatment of GvHD, and an Investigational New Drug Application was submitted to the FDA earlier this year.

"The imminent initiation of this study for acute GvHD represents a significant accomplishment for Kamada and our clinical development plan for AAT IV to treat GvHD, and importantly, signifies another key milestone resulting from our partnership with Shire," said Amir London, Kamada's Chief Executive Officer. "We believe G1-AAT IV has the potential to address a significant unmet need in the treatment of GvHD, which is a life-threatening disease."

This Phase 2/3 clinical trial will be a two-part, multi-center, prospective study to evaluate the safety and efficacy of G1-AAT IV as an add-on biopharmacotherapy to conventional steroid treatment in up to 168 patients with acute GvHD with lower gastrointestinal involvement (LGI-aGvHD). The first part of the trial will be single-arm, open-label and will include 20 patients, while the second will be placebo-controlled, double-blind with approximately 148 patients in two arms. The primary endpoint of the study will be overall response (complete response (CR) and partial response (PR)) rate at Day 28. GvHD CR is complete resolution of all signs and symptoms of acute GvHD in all organs without intervening salvage. GvHD PR is improvement of one stage in one or more organs involved in GvHD without progression in other organs. Study results are expected to be available in 2020.

The trial design and protocol will be available shortly on ClinicalTrials.gov and the trial is expected to begin enrollment imminently.

A Phase 1/2 clinical trial with G1-AAT IV for the treatment of steroid refractory GvHD is currently ongoing at the Fred Hutchinson Cancer Research Center in Seattle, WA, in collaboration with Shire. An interim analysis from this study was published earlier this year in a paper titled, *Response of Steroid-Refractory Acute GVHD to a1-Antitrypsin* (Marcondes, et el. Biology of Blood and Marrow Transplantation (2016)).

"This Phase 2/3 trial will be an important evaluation of a new candidate in this highly under-served patient population," said Philip J. Vickers, Ph.D., Head of R&D, Shire. "The interim data generated in the

ongoing Phase 1/2 clinical trial provide us with initial evidence of the potential of Kamada's G1-AAT IV as an option to treat GvHD, if validated in the Phase 2/3 study. We are pleased to see continuing research into the potential expanded uses of AAT."

"Recent extensive clinical research indicates that AAT has an immune-modulatory, tolerance effect, in addition to the previously established anti-inflammatory, tissue-protective and anti-apoptotic effects," said Dr. Eran Schenker, Vice President and Medical Director, at Kamada. "AAT may reduce inflammation by lowering levels of pro-inflammatory mediators, such as specific cytokines, chemokines and other factors that are associated with GvHD. The previously completed interim analysis from the Phase 1/2 clinical trial indicated that continuous administration of G1-AAT IV as a therapy for steroid-refractory gut GvHD is feasible in this subject population."

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 and 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 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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