## **News Release**



# Kamada Completes Enrollment of U.S. Phase 2 Study of Inhaled Alpha-1 Antitrypsin for the Treatment of AAT Deficiency

**NESS ZIONA, Israel (December 8, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA),** a plasma-derived protein therapeutics company focused on orphan indications, announces the completion of enrollment in the Company's U.S. Phase 2 clinical trial of its proprietary inhaled Alpha-1 Antitrypsin (AAT) therapy for the treatment of Alpha-1 Antitrypsin Deficiency (AATD, or Inherited Emphysema). The Company expects to report top-line data by mid-2016.

The U.S. Phase 2 clinical trial is a double-blind, placebo-controlled study evaluating the safety and efficacy of AAT by inhalation. The study is measuring AAT levels in the lung and serum as well as additional inflammatory biomarkers in 36 AATD patients. The study involves the inhalation of 80 mg or 160 mg of human AAT or placebo twice daily via the eFlow® device for 12 weeks. All subjects were eligible to enter an additional 12-week open-label extension study with the active drug to further assess safety and tolerability.

"We are very excited to complete enrollment for this U.S. study of our inhaled AAT to treat AATD, which represents a potentially innovative, user-friendly, convenient and efficient treatment compared with the current AAT treatment that requires weekly invasive, intravenous infusions. The U.S. market offers a significant opportunity to bring an inhaled therapy to patients suffering from this genetic lung disease, not merely as a more user friendly treatment, but also because the targeted delivery and treatment rationale directly to the lung are expected to enhance efficacy. Our intention is to use the results from this study along with the complete data set from our European Phase 2/3 study to discuss a regulatory path forward with the U.S. Food and Drug Administration," said, Amir London, Chief Executive Officer of Kamada.

#### **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 proteins. 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. In addition to Glassia, Kamada has a product line of nine other injectable pharmaceutical products that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America, Eastern Europe 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 completed pivotal Phase 2/3 clinical trials in Europe and is in Phase 2 clinical trials in the U.S. and its

intravenous AAT to treat 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 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 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 CFO ir@kamada.com Anne Marie Fields LHA 212-838-3777 afields@lhai.com

###