

## **Kamada Reports Encouraging Discussions with European Co-Rapporteurs Regarding European Filing for Inhaled Alpha-1 Antitrypsin to Treat AATD**

*Expects to report results from its Anti-Rabies Immunoglobulin U.S. Phase II/III clinical trial in the first half of 2015*

**NESS ZIONA, Israel (January 7, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, today provides a clinical/regulatory update.

- Kamada has held encouraging pre-submission meetings with its European rapporteur and co-rapporteur with regard to the Company's Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for its inhaled alpha-1 antitrypsin (AAT) for the treatment of alpha-1 antitrypsin deficiency (AATD). The co-rapporteurs advised that they would consider the entire study data once submitted, including post hoc analysis and will not reject the application simply because the primary endpoint of the study was not met. They agreed that the application fulfills the requirements relating to unmet medical need and benefit to public health and that it may meet the scope of Conditional Approval (CA) if the company convincingly proves the positive benefit-risk balance of the product, by the time of MAA filing. The co-rapporteurs have requested the addition of supplemental data analyses that may address the benefit-risk balance and support the already available safety and efficacy data. Kamada has begun conducting the additional data analyses and plans to file the MAA with the EMA in Q4 2015. In addition, the Company expects to present the complete data set from the Phase II/III clinical study at the upcoming American Thoracic Society Annual Meeting in May 2015.
- Kamada expects to report results from its anti-rabies immunoglobulin U.S. Phase II/III clinical trial as a post-exposure prophylaxis for rabies in the first half of 2015 and maintains plans to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in 2015. Kamada has a strategic agreement with Kedrion S.p.A for the clinical development and marketing of the product in the U.S.

"We are particularly pleased with our constructive dialogue with the co-rapporteurs regarding our plans to file for approval with the EMA for our inhaled AAT as a treatment for AATD," said David Tsur, co-founder and Chief Executive Officer of Kamada. "We remain steadfast in our belief that the clinically efficacious differences seen in lung function parameters in our European Phase II/III clinical study are therapeutically relevant. Consequently, we continue to work closely with the European regulatory authorities toward a path to bring this therapy to patients suffering with AATD with a regulatory filing in towards the end of this year."

### **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 Baxter International. 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 II/III clinical trials in Europe and entered Phase II clinical trials in the U.S. 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.

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