

## **Kamada Collaborates with Baxalta on Phase 1/2 Clinical Trial with Alpha-1 Antitrypsin for the Prevention of Lung Transplant Rejection**

**NESS ZIONA, Israel (June 22, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, reports that the Company has entered into a collaboration with Baxalta International, a wholly-owned subsidiary of Baxter International Inc. (NYSE: BAX) on a Phase 1/2 clinical trial of Kamada's proprietary alpha-1 antitrypsin (AAT) treatment for the prevention of lung transplant rejection.

Under the agreement, Baxalta will collaborate in the development and funding of the study, which will be conducted in Israel. The study is expected to initiate in the first half of 2016, with more details on trial design to be provided at a later date.

The principal investigator will be Prof. Mordechai R. Kramer, M.D., Director of the Institute of Pulmonary Medicine, Rabin Medical Center - Beilinson Hospital. Prof. Kramer, a renowned expert in pulmonary care and a top specialist in his field, is a full Professor at Tel Aviv University, Sackler Faculty of Medicine. He completed several fellowships in the U.S. in pulmonary care and lung transplantation, and has published many articles in leading scientific publications.

Kamada's proprietary, highly-purified, liquid form of human AAT has shown positive interim results in a proof-of-concept Phase II study in Graft-versus-Host-Disease (GVHD) conducted at the Fred Hutchinson Cancer Research Center in cooperation with Baxalta. Based on those results, preclinical data published in *Blood* (September 2014), and at the American Society of Hematology (ASH) meeting (December 2014), and a similar mechanism of action, the companies now plan to expand the AAT indication to the prevention of lung transplant rejection and may use this data to support clinical development worldwide. Baxalta has distribution rights to intravenous AAT for all indications in the U.S., Canada, Australia and New Zealand, while Kamada has rights in all other territories and all other formulations.

"Lung Transplantation is the last resort for patients who suffer from end stage lung disease. While survival rates are improving there is a need for reducing acute and chronic rejection rates. AAT offers a promising treatment for developing new strategies to prevent rejection after lung transplantation and I am pleased to be collaborating with Kamada to evaluate its potential in this promising indication," noted Prof. Kramer.

"This agreement underscores the growing strength of the Baxalta-Kamada relationship," stated David Tsur, co-founder and Chief Executive Officer of Kamada. "The lungs have the highest rate of rejection among transplanted solid organs. Approximately one third of lung transplant recipients experience an episode of acute rejection within the first year and 50% of lung transplant recipients will develop chronic rejection within the first 5 years. Our aim is to develop AAT as a protective, immunomodulation therapy that would enhance patients' acceptance of their new lungs in this life-saving transplant."

AAT has been investigated extensively in recent years and has been found to have anti-inflammatory, tissue-protective, immune-modulatory and anti-apoptotic properties in direct or indirect consequence

of its underlying anti-protease capabilities. These properties may attenuate inflammation by lowering levels of pro-inflammatory mediators such as cytokines, chemokines and proteases that are associated with organ transplantation rejection.

“Given the favorable safety profile of Glassia, there is strong rationale to support development to treat lung transplant rejection and an increased likelihood of our AAT becoming an effective therapy for this potentially life-threatening complication,” concluded Mr. Tsur.

#### **About Glassia**

Glassia is the first available ready-to-infuse liquid alpha1-proteinase inhibitor (Alpha1-PI) and is indicated as a chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe congenital AAT deficiency. Glassia is administered intravenously once a week to augment the levels of AAT in the blood. AAT is a protein derived from human plasma with known and newly discovered therapeutic roles given its immunomodulation, anti-inflammatory, tissue-protective and antimicrobial properties. Glassia is approved by the U.S. Food and Drug Administration for the treatment of AAT deficiency and is marketed through a strategic partnership with Baxalta in the United States.

**Please see the full prescribing information for Glassia at:**

[http://www.baxter.com/downloads/healthcare\\_professionals/products/Glassia\\_PI.pdf](http://www.baxter.com/downloads/healthcare_professionals/products/Glassia_PI.pdf)

#### **About Kamada**

Kamada Ltd. is focused on plasma-derived protein therapeutics for immunomodulation 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 entered Phase 2 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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