

# News Release



## **Kamada Announces Initiation of Phase 2 Clinical Trial with Intravenous Alpha-1 Antitrypsin for the Prevention of Lung Transplant Rejection**

### *First Clinical Trial Designed to Prevent Lung Transplant Rejection*

**NESS ZIONA, Israel (April 6, 2016) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, announces the initiation of a Phase 2 clinical trial with its proprietary Alpha-1 Antitrypsin (AAT) for the prevention of lung transplant rejection. The study is being conducted in collaboration with Baxalta Incorporated (NYSE: BXL), which has distribution rights to the Company's intravenous (IV) AAT for all indications in the U.S., Canada, Australia and New Zealand.

"Lung transplantation can be a life-saving procedure for those with end-stage lung diseases. Unfortunately, long term graft and patient survival are limited by both acute and chronic allograft rejection, with a median survival of just over six years.<sup>1</sup> Fully one-third of all lung transplant recipients experience acute rejection in the first year and 40% will develop chronic rejection within the first five years. As such, I am pleased to be leading this trial to assess the potential of IV AAT in the prevention of lung transplant rejection," stated Prof. Mordechai R. Kramer, M.D., Director of the Institute of Pulmonary Medicine, Rabin Medical Center - Beilinson Hospital, a renowned expert in pulmonary care and a top specialist in his field. "Current treatment options, such as immunosuppressants, have limited efficacy and can have significant adverse side effects and co-morbidities. Preclinical data published in *Blood* suggest that IV AAT has an immunomodulatory and anti-inflammatory mechanism of action that would support its efficacy in the prevention of lung transplant rejection."

The Phase 2 trial is a randomized, open-label, single-site study of 30 lung transplant recipients to evaluate the safety and efficacy of IV AAT on top of standard-of-care (SOC) versus SOC. The study is randomized 2:1 with 20 patients in the treatment group receiving IV AAT treatment every other day for 14 days, then once every two weeks until week eight, followed thereafter by monthly treatments. The 10 patients in the control group will be treated with SOC, which includes systemic corticosteroids and immunosuppressants. Following one year of AAT treatment, there will be a one-year follow-up.

The primary endpoints of the study include safety and tolerability, the incidence of acute lung transplant rejection and changes in Forced Expiratory Volume (FEV<sub>1</sub>) from baseline and overall effect (a measure of Bronchiolitis Obliterans (chronic rejection). Additional endpoints measured will include various inflammatory biomarkers and functional capacity.

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<sup>1</sup> 1. Yusen RD, Christie JD, Edwards LB, et al. The Registry of the International Society for Heart and Lung Transplantation: thirtieth adult lung and heart-lung transplant report--2013; focus theme: age. International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2013;32:965-78

The study is being conducted at Rabin Medical Center - Beilinson Hospital in Israel and is being led by principal investigator, Prof. Kramer. Dr. Kramer completed several fellowships in the U.S. in pulmonary care and lung transplantation, and has published many articles in leading scientific publications.

“We are very excited to be advancing this Phase 2 study of our IV AAT to prevent lung transplant rejection, especially since our AAT has been found to have anti-inflammatory, tissue-protective, immunomodulatory 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,” noted Eran Schenker, M.D., Medical Director of Kamada.

“This is an important milestone for both Baxalta and Kamada, as well as for the transplant community,” said John Davis, M.D., M.P.H., Baxalta’s Vice President, Clinical Research and Global Therapeutic Area Head-Immunology. “Acute rejection is a significant problem in lung transplantation, and AAT has the potential to prevent acute injury and prolong allograft lung survival. Baxalta is committed to developing and expanding access to treatments for patients with immune-mediated conditions, with the goal of reducing the burden for patients worldwide.”

“The Lung Transplant Foundation is very excited for the potential of this IV AAT study being led by Dr. Kramer as it is the first clinical trial designed to prevent lung transplant rejection. Our patient population is truly excited by pre-clinical and early data that support its promise to improve the post lung transplant experience and long term outcomes,” said Jeffrey R. Goldstein, President and Founding Member of the Lung Transplant Foundation, a non-profit patient advocacy group focused on lung transplant recipients. “The Lung Transplant Foundation will work closely with Kamada to enhance awareness of the trial and the potential benefits of this promising therapy throughout our community. We look forward to the completion of this important study and, hopefully, to its positive outcomes, which would be transformational for lung transplant patients.”

“Given the favorable safety profile of our IV AAT, there is a strong rationale to support its development in this indication and an increased likelihood of efficacy for this potentially life-threatening complication,” noted Amir London, Chief Executive Officer of Kamada. “There is a significant unmet need in preventing lung transplant rejection and a significant market opportunity estimated at about \$400 million per year. Lung transplantation is an entry point for potential other solid organ transplantation that represent an even bigger market opportunity.”

Kamada’s proprietary, highly-purified, liquid form of human AAT demonstrated positive interim results in a Phase 1/2 clinical trial to treat steroid-refractory Graft-versus-Host-Disease (GVHD) conducted in collaboration with Baxalta at the Fred Hutchinson Cancer Research Center in Seattle and presented at the American Society of Hematology (ASH) meeting (December 2014). Based on those data, updated interim results (January 2016), preclinical data published in *Blood* (September 2014), and a similar mechanism of action, Kamada and Baxalta look forward to the findings of this trial.

#### **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. 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 that its MAA was submitted to the EMA after completing a 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 to prevent 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 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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