

News Release



Kamada Submits Marketing Authorization Application with the European Medicines Agency for its Proprietary Inhaled Alpha-1 Antitrypsin to Treat Alpha-1 Antitrypsin Deficiency

First treatment for AAT deficiency to demonstrate significant improvement in lung function measurements, which are the gold standard for pulmonary diseases

NESS ZIONA, Israel (March 28, 2016) – Kamada Ltd. (NASDAQ and TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, announces the submission of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for the Company's proprietary, inhaled alpha-1 antitrypsin (AAT) therapy as a treatment for AAT deficiency (AATD). The filing was validated by the EMA.

"The submission of this application represents an important achievement that brings us one step closer to our goal of commercializing our inhaled AAT therapy for the benefit of patients suffering with AATD in Europe," stated Amir London, Chief Executive Officer of Kamada. "The EMA has agreed to evaluate the totality of the data from our innovative Phase 2/3 study, and based upon orphan designation of the drug, prior discussions with regulators, the strength of these data, the support we get from the key opinion leaders and the patient community, and the persistent unmet need in this chronic disease, we are highly optimistic of a favorable outcome. Importantly, the combination of lung function measurements, which are the gold standard for pulmonary diseases, and symptom improvements, along with the safety profile of the product, gives us confidence these data meet the risk/benefit balance required by EMA."

"The submission of the MAA for inhaled alpha-1 antitrypsin to treat AATD is a major step toward bringing another treatment to AATD patients. This study is the first study ever that shows inhaled AAT's ability to reduce the decline in FEV₁ in a patient population suffering from frequent exacerbations of dyspnea and coughing. I believe these results support the ability to treat AATD patients with Kamada's inhaled AAT. I am looking forward to the regulatory authorities' approval for the benefit of AATD patients," stated Jan Stolk, MD, Department of Pulmonology, Leiden University Medical Center and Principal Investigator of the Phase 2/3 clinical trial.

"Kamada's MAA submission for its inhaled AAT is a major breakthrough that might affect the critical element of disease progression. This pioneering study demonstrated a significant improvement in lung function. It is to be hoped that this novel treatment will soon be available for the benefit of the AATD patient community," commented Robert Stockley, MB, ChB, MD, DSc, FERS, Professor of Medicine, University Hospital Birmingham, and an Investigator in the Phase 2/3 clinical trial.

"This submission by Kamada marks a significant milestone in the management of pulmonary disease caused by severe AATD. Kamada's inhaled AAT provides a simple treatment with twice-daily inhalation that offers improvements in lung function and reduces the discomfort of exacerbations. Approval of Kamada's AAT for inhalation will offer a new and important intervention to protect this vulnerable

patient population,” noted Kenneth R. Chapman, MD, MSc, FRCPC, FACP, FCCP, Director, Asthma & Airway Centre, University Health Network, Professor of Medicine, University of Toronto, and an Investigator in the Phase 2/3 clinical trial.

Phase 2/3 Trial Summary

The MAA filing is based upon a Phase 2/3 multicenter randomized, double-blind, placebo-controlled study that evaluated the safety and efficacy of Kamada’s inhaled formulation of human AAT to treat AATD in 168 patients. The study involved the inhalation of 80 mg of human AAT or placebo twice daily via the eFlow® device for 50 weeks. The primary endpoint of the study was time to the first moderate or severe exacerbation event. Secondary endpoints included additional parameters of exacerbation events. Lung function parameters including Forced Expiratory Volume in One Second (FEV₁) % of Slow Vital Capacity (SVC), FEV₁ % predicted, FEV₁ (liters) and Diffusing capacity (DLCO), were collected to support safety endpoints. Additional exploratory endpoints included CT densitometry in a subset of subjects, Quality of Life measurements and more.

Despite not meeting the primary or secondary endpoints, lung function parameters, which were collected to support safety endpoints, showed concordance of a significant treatment effect in the reduction of the inflammatory injury to the lung, which is known to be associated with a reduced loss of respiratory function.

Lung Function Results

Analysis of the lung functions in the safety population as described below indicate that after one year of daily inhalation of Kamada’s AAT, clinically and statistically significant improvements were seen in spirometric measures of lung function, particularly in bronchial airflow measurements FEV₁ (L), FEV₁% predicted and FEV₁/SVC.

For lung function overall one-year effect:

- FEV₁ (L) rose significantly in AAT-treated patients and decreased in placebo-treated patients (+15ml for AAT vs. -27ml for placebo, a 42 ml difference, p=0.0268)
- There was a trend towards better FEV₁% predicted (0.54% for AAT vs. -0.62% for placebo, a 1.16% difference, p=0.065)
- FEV₁/SVC% rose significantly in AAT-treated patients and decreased in placebo-treated patients (0.62% for AAT vs. -0.87% for placebo, a 1.49% difference, p=0.0074)

For lung function change at week 50 vs. baseline:

- There was a trend towards reduced FEV₁ (L) decline (-12ml for AAT vs. -62ml for placebo, a 50 ml difference, p=0.0956)
- There was a trend towards a reduced decline in FEV₁% predicted (-0.1323% for AAT vs. -1.6205% for placebo, a 1.4882% difference, p=0.1032)
- FEV₁/SVC% rose significantly in AAT-treated patients and decreased in placebo-treated patients (0.61% for AAT vs. -1.07% for placebo, a 1.68% difference, p=0.013)

About Alpha-1 Antitrypsin Deficiency

Alpha-1 antitrypsin (AAT) is a protein made in the liver. Normally the protein travels through the bloodstream and helps protect the body’s organs from the harmful effects of other proteins. The lungs

are one of the main organs that the AAT protein protects. AAT deficiency (AATD or inherited emphysema) occurs if the AAT proteins made in the liver are not the right shape, and they get stuck inside liver cells and cannot get into the bloodstream. As a result, not enough AAT proteins travel to the lungs to protect them, which increases the risk of lung disease. Also, liver disease can develop because too many AAT proteins are stuck in the liver. Severe AATD occurs when blood levels of the AAT protein fall below the lowest amount needed to protect the lungs.

AATD is an inherited condition that occurs in all ethnic populations, yet most often in Caucasians of European descent. It is not known how many people have AATD and many people who have the condition may not know they have it. According to the National Institutes of Health, estimates of disease incidence range from about 1 in every 1,600 people to about 1 in every 5,000 people.

About eFlow® Technology and PARI Pharma

The Company's inhaled AAT therapy is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for Kamada. The optimized device uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane that includes thousands of laser-drilled holes. Compared with other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size and a high proportion of respirable droplets delivered in the shortest possible period of time. eFlow Technology is not an ultrasonic nebulizer technology and is not a general purpose electronic aerosol generator nebulizer technology. Combined with its quiet mode of operation, small size, light weight and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments.

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, 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 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 prevention of 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.

Contacts:

Gil Efron
CFO
ir@kamada.com

Anne Marie Fields
LHA
212-838-3777
afields@lhai.com

#