News Release

Kamada Awarded European Orphan Drug Designation for its Alpha-1 Antitrypsin to Treat Graft-versus-Host Disease

NESS ZIONA, Israel (March 23, 2015) – Kamada Ltd. (Nasdaq and TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, announces that the European Commission, acting on the recommendation from the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA), has designated the Company's proprietary human intravenous (IV) Alpha-1 Antitrypsin (AAT) as an orphan medicinal product to treat Graft-versus-host disease (GvHD). In October 2014 Kamada received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for its AAT by IV to treat GvHD.

Orphan designation is a status assigned by regulatory authorities, and in this case, the EMA to a medicine intended to treat a rare condition (prevalence of not more than 5 in 10,000 people in the European Union). The orphan designation allows the awarded pharmaceutical company to benefit from incentives offered by the EU to develop the designated medicine for the rare indication. In addition to a 10-year period of market exclusivity after product approval, Orphan Drug designation provides incentives for companies seeking protocol assistance from the EMA during the product-development phase, reduced regulatory fees, direct access to centralized marketing authorization, European Commission grant programs and more.

"Receipt of European Orphan Drug designation for our AAT to treat GvHD is a key milestone that supports our global regulatory and development strategy," stated David Tsur, co-Founder and Chief Executive Officer of Kamada. "GvHD is a disease of significant unmet medical need, and both the disease and current therapy options carry considerable, debilitating side effects."

Preliminary human and animal studies indicate that AAT may be able to treat and reduce the severity of GvHD, which is one of the key, life-threatening complications of allogeneic stem cell transplantation. GvHD is an immunologically-based disease that may result in significant damage to multiple organs and tissues such as the liver, gastrointestinal tract, skin and mucosal membranes. Tissue destruction also leads to increased inflammatory signals, perpetuating and augmenting the disease process by contributing to the cytokine storm that fuels GvHD even further and, thereby, the damage continues and its intensity is increased.

In recent years, AAT has been investigated extensively and 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 this severe disease.

Kamada's AAT therapy is being investigated in a clinical U.S. Phase 1/2 study that is evaluating 24 GvHD patients with inadequate response to steroid treatment following allogeneic bone-marrow stem cell transplant. The patients are enrolled into 4 dose cohorts, in which they receive up to 8 doses of Kamada's AAT. The study is being conducted by the Fred Hutchinson Cancer Research Center in Seattle in cooperation with Baxter International.

Interim results from this study were presented in a poster at the American Society of Hematology Annual Meeting in December 2014. Preliminary results indicated that continuous administration of AAT as therapy for steroid-resistant gut GvHD is feasible in the subject population. Indication of healing of the bowel mucosa was seen in a decrease in diarrhea, in a decrease in intestinal AAT loss, and improvement in endoscopic evaluation. Additionally, in the preliminary results AAT administration suppressed serum levels of pro-inflammatory cytokines and interfered with GvHD biomarkers.

Separately, investigators at the Fred Hutchinson Cancer Research Center published additional non-clinical and clinical observational data in the September edition of *Blood*, in an article entitled "α-1-antitrypsin (AAT)-modified donor cells suppress GvHD but enhance the GVL effect – a role for mitochondrial bioenergetics."

"The positive interim results from ongoing studies are very encouraging and support continuation of our global clinical development plans for AAT in treating and preventing GvHD. Importantly, the preclinical data support the positive interim results from the Phase 1/2 clinical study of AAT, which is aimed at treating the gut involvement in steroid-resistant GvHD. Given the favorable safety profile of AAT, there is a strong rationale to support the development of this new indication and an increased likelihood of our AAT becoming an effective therapy for this potentially life-threatening disease. With these encouraging results, we intend to commence a Phase 3 trial in 2016, in order to bring this life saving treatment to the market not before 2019," concluded Mr. Tsur.

About Graph-versus-Host Disease

Graft-versus-host disease is a common complication following an allogeneic tissue transplant. It is typically associated with stem cell transplant, but the term also applies to other forms of tissue graft. In GvHD, immune cells (white blood cells) in the tissue (the graft) recognize the recipient (the host) as "foreign," and then attack the host's body cells.

GvHD occurs in 30-70% of patients who undergo a medical procedure of allogeneic hematopoietic stem cell transplantation (HSCT), usually as a treatment to leukemia or other blood cancers or blood conditions. HSCT is a stem cell transplantation that is usually derived from an external (allogeneic) bone marrow donor. One of the most common and dangerous complications of HSCT is GvHD. GvHD is expressed in damage to the recipients' tissues including damage to the liver, gastrointestinal system, skin and mucosal tissues, and is a major cause of morbidity and mortality in these patients.

Intravenous glucocorticoids such as prednisone are the standard of care in acute GvHD[1] and chronic GvHD.[2] The use of these glucocorticoids is designed to suppress the T cell-mediated immune onslaught on the host tissues; however, in high doses this immune suppression raises the risk of infections and cancer relapse. In addition, more than 50% of patients do not respond well to steroids, and consequently have very low survival rates.

About Glassia and AAT

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 immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties. Glassia is approved by the U.S. Food and Drug Administration and is marketed through a strategic partnership with Baxter International in the U.S.

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[1] Goker, H; Haznedaroglu, IC; Chao, NJ (2001). "Acute graft-vs-host disease Pathobiology and management". *Experimental Hematology* **29** (3): 259–77. doi:10.1016/S0301-472X(00)00677-9. PMID

[2] Menillo, S A; Goldberg, S L; McKiernan, P; Pecora, A L (2001). "Intraoral psoralen ultraviolet a irradiation (PUVA) treatment of refractory oral chronic graft-versus-host disease following allogeneic stem cell transplantation". *Bone Marrow Transplantation* **28** (8): 807–8. doi:10.1038/sj.bmt.1703231. PMID 11781637.

Please see the full prescribing information for Glassia at:
http://www.baxter.com/downloads/healthcare_professionals/products/Glassia_PI.pdf

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 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 a pivotal Phase 2/3 clinical trials in Europe and has initiated Phase 2 clinical trials in the U.S. Kamada also leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing about 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 US 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, clinical trials, Intellectual Property, the EMA and U.S. FDA filings and authorizations and timing of clinical trials. 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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