Press Release

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SHIRE AND KAMADA ANNOUNCE FDA APPROVAL OF EXPANDED LABEL FOR SELF-INFUSION OF GLASSIA FOR THE TREATMENT OF EMPHYSEMA DUE TO SEVERE AAT DEFICIENCY

- *GLASSIA [Alpha-1 Proteinase Inhibitor (Human)] is the only FDA approved alpha-1 antitrypsin (AAT) augmentation treatment that patients can self-infuse at home*

[Lexington, Mass., and Ness Ziona, Israel] – [June 15, 2106] – Shire plc (LSE: SHP, NASDAQ: SHPG) and Kamada Ltd. (NASDAQ & TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, today announced that the United States Food and Drug Administration (FDA) has approved an expanded label for GLASSIA [Alpha-1 Proteinase Inhibitor (Human)], marking the first treatment for adult patients with emphysema due to severe Alpha-1 Antitrypsin (AAT) Deficiency that can be self-infused at home after appropriate training.

Patients with AAT Deficiency have low or undetectable levels of a protein called alpha-1 antitrypsin or AAT, which helps protect lung tissue from damaging enzymes that are released by white blood cells.[1] AAT deficiency can result in early onset emphysema.[2] Treatment with GLASSIA replaces the missing or deficient AAT protein in the blood and lungs.

There are an estimated 100,000 people in the United States who have the disorder, though under-diagnosis remains an issue, as fewer than 10 percent of those living with AAT deficiency have been properly diagnosed.[3,4] The World Health Organization (WHO), the American Thoracic Society (ATS), the European Respiratory Society (ERS), and the Alpha-1 Foundation's Medical and Scientific Advisory Committee (MASAC) recommend that all patients with Chronic Obstructive Pulmonary Disease (COPD) be tested for the disorder.[5]

"Patients with Alpha-1 Antitrypsin Deficiency are managing a challenging disorder that may require regular regimented care. For these patients, our company strives to find ways to provide them with more choices and flexibility in their treatment regimen," said Blaine Forshage, Head of the US Immunology Franchise for Shire. "With this new label for GLASSIA, we're now able to offer the only AAT augmentation treatment that is approved for patients to self-administer at home, helping to deliver on our goals to support the Alpha-1 community."

Approved in 2010, GLASSIA is the first and only liquid ready-to-use augmentation product approved for treatment of clinically evident emphysema due to severe AAT Deficiency. Kamada and Baxalta (formerly Baxter International Inc's BioScience business and now part of Shire) entered into an exclusive strategic cooperation agreement for the distribution and license of GLASSIA in 2010. Under the terms of the agreement, Baxalta is the exclusive distributor of GLASSIA in the U.S., Canada, Australia and New Zealand, and is licensed to produce GLASSIA using Kamada's technology at a Baxalta facility for sales in those countries.

"Self-infusion, after proper training, can be a convenient way for Alphas to receive their augmentation therapy," said Henry Moehring, Alpha-1 Foundation president and CEO. "We at the Foundation are always gratified to see expanded treatment options for Alphas, and we applaud the FDA's approval of this new labeling."

“We are excited that the FDA has now permitted patients to self-infuse GLASSIA at home,” said Amir London, Kamada’s Chief Executive Officer. “By avoiding the need for reconstitution, our product allows for an overall reduced treatment preparation time. With this new approval, patients have the convenience of self-infusion at home, in addition to potentially reducing costs previously associated with infusion services for administering augmentation therapy in the hospital. We are very pleased with the continued increase in the number of U.S. patients treated with GLASSIA, and believe that self-infusion will contribute significantly to future growth. Importantly, due to the Company’s state-of-the-art production facility, Kamada has the capacity to support the increasing demand for GLASSIA. Finally, we look forward to a strong partnership with Shire that is beneficial to the patients we serve, and both of our companies.”

About GLASSIA [Alpha$_1$-Proteinase Inhibitor (Human)]

INDICATION

GLASSIA is an Alpha$_1$-Proteinase Inhibitor (Human) (Alpha$_1$-PI) indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha$_1$-PI (alpha$_1$ antitrypsin deficiency). GLASSIA increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha$_1$-PI.

LIMITATIONS OF USE

The effect of augmentation therapy with any Alpha$_1$-PI, including GLASSIA, on pulmonary exacerbations and on the progression of emphysema in Alpha-1 antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials.

Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with GLASSIA are not available.

GLASSIA is not indicated as therapy for lung disease in patients in whom severe Alpha$_1$-PI deficiency has not been established.

Important Risk Information for GLASSIA

HYPERSENSITIVITY

GLASSIA is contraindicated in immunoglobulin A (IgA) deficient patients with antibodies against IgA or individuals with a history of anaphylaxis or other severe systemic reaction to Alpha$_1$-PI products.

Hypersensitivity reactions have been reported in patients following administration. Patients should be closely followed throughout the infusion and vital signs monitored continuously. Discontinue the infusion if hypersensitivity symptoms occur and administer appropriate emergency treatment.

TRANSMISSION OF INFECTIOUS AGENTS

GLASSIA is derived from pooled human plasma and may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. Despite manufacturing steps designed to minimize the risk of viral transmission, such products may still potentially transmit human pathogenic agents.

ADVERSE REACTIONS

The serious adverse reaction observed during clinical trials was exacerbation of chronic obstructive pulmonary disease (COPD).

The most common adverse reactions occurring in >0.5% of infusions in clinical trials were headache and upper respiratory infection.

For full prescribing information, please visit:
http://www.baxalta.com/assets/documents/Glassia_PI.pdf.

References

1. American Thoracic Society; European Respiratory Society statement: standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. Am J Respir Crit Care Med. 2003 Oct 1;168(7):818-900.

2. Alpha-1 Foundation. What is Alpha-1? Accessed June 1, 2016. Available at: https://www.alpha1.org/what-is-alpha1

3. Alpha-1 Foundation. Lung Disease. Accessed June 9, 2016. Available at: http://www.alpha1.org/Newly-Diagnosed/Learning-about-Alpha-1/Lung-Disease

4. Silverman EK and Sandhous RA. Clinical Practice Alpha1-Antitrypsin Deficiency. N Engl J Med. 2009; 360(26):2749-57

5. Alpha-1 Foundation. Testing for Alpha-1. Accessed June 1, 2016. Available at: https://www.alpha1.org/Newly-Diagnosed/Learning-about-Alpha-1/Testing-for-Alpha-1

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NOTES TO EDITORS

About Shire

Shire is the leading global biotechnology company focused on serving people with rare diseases and other highly specialized conditions. We have best-in-class products available in more than 100 countries across core therapeutic areas including Hematology, Immunology, Neuroscience, Lysosomal Storage Disorders, Gastrointestinal / Internal Medicine / Endocrine and Hereditary Angioedema; a growing franchise in Oncology; and an emerging, innovative pipeline in Ophthalmics.

Our employees come to work every day with a shared mission: to develop and deliver breakthrough therapies for the hundreds of millions of people in the world affected by rare diseases and other high-need conditions, and who lack effective therapies to live their lives to the fullest.

About Kamada Ltd 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.

Shire Forward-Looking Statements

Statements included herein that are not historical facts, including without limitation statements concerning future strategy, plans, objectives, expectations and intentions, the anticipated timing of clinical trials and approvals for, and the commercial potential of, inline or pipeline products are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, the following:

- disruption from the acquisition and integration of Baxalta Incorporated ("Baxalta") may make it more difficult to conduct business as usual or maintain relationships with patients, physicians, employees or suppliers;
- the company may not achieve some or all of the anticipated benefits of Baxalta's spin-off from Baxter International, Inc. ("Baxter") and the acquisition may have an adverse impact on Baxalta's existing arrangements with Baxter, including those related to transition, manufacturing and supply services and tax matters;
- the failure to achieve the strategic objectives with respect to the acquisition of Baxalta may adversely affect the company's financial condition and results of operations;
- products and product candidates may not achieve commercial success;
- product sales from ADDERALL XR and INTUNIV are subject to generic competition;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for the company's products may affect future revenues, financial condition and results of operations, particularly if there is pressure on pricing of products to treat rare diseases;
- supply chain or manufacturing disruptions may result in declines in revenue for affected products and commercial traction from competitors; regulatory actions associated with product approvals or changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the successful development of products in various stages of research and development is highly uncertain and requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval;
- the actions of certain customers could affect the company's ability to sell or market products profitably, and fluctuations in buying or distribution patterns by such customers can adversely affect the company's revenues, financial condition or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to the company's activities in the highly regulated markets in which it operates may result in significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters, tax audits and other disputes, including the company's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on the company's revenues, financial condition or results of operations;
- Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect the company's ability to attract and/or retain the highly skilled personnel needed to meet its strategic objectives;

- failure to achieve the strategic objectives with respect to Shire's acquisition of NPS Pharmaceuticals Inc. or Dyax Corp. ("Dyax") may adversely affect the company's financial condition and results of operations;
- the company is dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on the company's revenues, financial condition or results of operations;
- the company may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners;
- difficulties in integrating Dyax or Baxalta into Shire may lead to the company not being able to realize the expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all; and

other risks and uncertainties detailed from time to time in Shire's, Dyax's or Baxalta's filings with the Securities and Exchange Commission, including those risks outlined in "ITEM 1A: Risk Factors" in Shire's and Baxalta's Annual Reports on Form 10-K for the year ended December 31, 2015.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Kamada 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.