

Kedrion Biopharma and Kamada Announce FDA Acceptance of BLA Submission for Human Rabies Immunoglobulin as a Post-Exposure Treatment

- *PDUFA goal date of August 29, 2017*
- *If approved, product would represent new treatment option in \$100M-plus market where supply of post-exposure rabies treatment has been inconsistent over time*

Fort Lee, NJ/NESS ZIONA, Israel -- November 7, 2016 -- [Kedrion Biopharma](#), and Kamada Ltd. (NASDAQ and TASE: KMDA), two leading human-derived protein therapeutics companies, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a Biologics License Application ([BLA](#)) for a human anti-rabies immunoglobulin (IgG) therapy. Rabies is a life-threatening condition that impacts approximately 40,000 people in the U.S. each year. At present, U.S. healthcare professionals have only two rabies IgG therapy options from which to select in preventing the onset of rabies in someone who may have been exposed to the deadly virus. The post-exposure prophylaxis treatment being developed by Kedrion Biopharma and Kamada is a human plasma-derived immunoglobulin (IgG) and has the potential to provide stability and secure availability in a market that has experienced inconsistent supply and supply shortages in recent years.

The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 29, 2017, for completion of the review of the BLA. Kedrion Biopharma and Kamada intend to launch the product soon after a favorable decision is received.

Kamada has been selling the anti-rabies IgG product since 2003 in numerous territories outside of the U.S. under the brand name KamRAB™. Kamada has sold more than one million vials of the product to date, demonstrating significant clinical experience with the product.

The BLA currently under review by FDA is based on results announced in December 2015 from a prospective, randomized, double-blind, non-inferiority [Phase 2/3 study](#) of 118 healthy subjects.

“The FDA’s review of this application is an encouraging step toward bringing to market a needed new treatment option for post-exposure prophylaxis of rabies,” said Garrett Bergman, M.D., Senior Director, Medical Affairs at Kedrion Biopharma. “Rabies is a completely preventable condition, and emergency room healthcare professionals and pharmacists, in particular, will welcome the arrival of an additional choice in providing urgent medical care to those who may have been exposed to this deadly virus.”

“The FDA’s acceptance of our BLA for review is a significant milestone for Kamada,” said Amir London, Kamada’s Chief Executive Officer. “This is an indication with limited treatment options in the U.S. and we are confident that this therapy has the potential to gain meaningful market share

in the U.S. over time. Kedrion has significant expertise in commercializing plasma-derived therapies and we look forward to continuing the successful collaboration between our companies.”

“We are excited about the commercial potential for our rabies IgG therapy in the U.S., where approximately 40,000 post-exposure prophylaxis treatments are administered each year, representing an annual market opportunity of over \$100 million,” said Larry Guiheen, Chief Commercial Officer at Kedrion Biopharma. “Currently, in the U.S., a single company is responsible for supplying most of the rabies IgG therapy to the market. Therefore, we anticipate that healthcare professionals will want to diversify their source of product supply, particularly if a competing product, such as the one Kedrion Biopharma and Kamada have under development, is approved for use. Further, Kedrion Biopharma is one of the world’s leading suppliers of high-titer rabies plasma. We understand this space well and are looking forward to a favorable regulatory outcome and a successful product launch of our rabies IgG therapy.”

Under the clinical development and marketing agreement between Kedrion Biopharma and Kamada, subject to the product receiving FDA marketing approval, Kamada will hold the license for it and Kedrion Biopharma will have exclusive rights to commercialize it in the U.S.

About Kedrion Biopharma

Kedrion S.p.A. is an international company that collects and fractionates blood plasma to produce and distribute plasma-derived therapeutic products for use in treating and preventing serious diseases, disorders and conditions such as hemophilia, primary immune system deficiencies and Rh sensitization which can lead to hemolytic disease of the fetus and newborn. Kedrion Biopharma Inc. (“Kedrion Biopharma”), the US subsidiary of Kedrion, is headquartered in Fort Lee, New Jersey. Kedrion Biopharma launched US operations in 2011, but the company’s international roots stretch back several decades in the production of blood and plasma-derived products. The Company places a high value on the welfare of those who benefit from its products and on the people and communities it serves. Headquartered in Italy, Kedrion has a market presence in approximately 100 countries. Additional information can be found at www.kedrion.com and www.kedrion.us.

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 (formerly Baxter International Inc.’s BioScience business and now part of Shire plc) and in other countries through local distributors. 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. Kamada has also completed its Phase 2 clinical trials in the U.S. In addition, Kamada's intravenous AAT is in development for other indications such as 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.

###

MEDIA CONTACTS:

Gil Efron Chief Financial Officer ir@kamada.com	Bob Yedid LifeSci Advisors 646-597-6989 bob@lifesciadvisors.com	Kedrion Biopharma contacts: Forrest McCaleb Director, Global Communications, U.S. Kedrion Biopharma 201-582-8143 Sheila A. Burke HealthBizWriteNow@gmail.com 484-667-6330
---	--	--