AnGes and Kamada entered into agreement for the commercialization of HGF gene therapy product in Israel

AnGes Inc. (Head office: Osaka, Japan, President: Ei Yamada, “AnGes”) has been developing HGF gene therapy drug*1*2 for critical limb ischemia (“CLI”). We now entered into agreement with Kamada Ltd. (Head office: Rehovot, Israel, CEO: Amir London, “Kamada”) to grant Kamada exclusive commercialization rights of our HGF gene therapy drug for the Israeli market.

We have been developing this HGF gene therapy drug as our main project since the foundation of our company. We filed application for Marketing Approval for Cellular and Tissue-based Products*3 to the Japanese Ministry of Health and Welfare (“MHLW”) on January 22, 2018 and is currently under review.

Based on the agreed terms, Kamada will exclusively commercialize this HGF gene therapy drug for critical limb ischemia in Israel after obtaining regulatory approval in Japan and in Israel. In Israel, ethical drugs that are approved in certain reference countries including Japan are likely to be approved without conducting an additional clinical trial in Israel. Subject to obtaining Japanese regulatory approval for the use of the product for CLI and the subsequent similar Israeli regulatory approval, the launch of the product in Israel may be as early as 2020. In addition, if the product is granted regulatory approval and reimbursement approval by the Israeli authorities, AnGes is eligible to receive milestones up to US $1.25 million and after commercialization, milestones of up to US $2.85 million based on meeting certain annual and cumulative sales targets of the product in Israel. Moreover, AnGes and Kamada agreed to negotiate in good faith the possibility of granting rights to AnGes for distribution and sales of Kamada’s Alpha-1 Antitrypsin (AAT) product, Glassia® in Japan.

We already have an exclusive partnership with Mitsubishi Tanabe Pharmaceuticals for the sales and distribution of our HGF gene therapy drug for peripheral artery diseases including CLI in Japan and in USA. With this agreement, together with Kamada we will focus on promoting the use of HGF gene therapy in CLI patients in Israel. Moreover, we will continue to commit to find partners for territories other than Japan, USA, and Israel.
We are currently evaluating the impact to the 2019 financials among other factors, and we will disclose promptly once a change is necessary.

*1: HGF gene therapy drug: JAN/INN: Beperminogene Perplasmid, Code name: AMG001
*2: Gene therapy drug: A drug that uses genes or part of the genes as the active ingredient
*3: Cellular and Tissue-based Products: Gene therapy products are also included. For cellular and tissue-based products, a conditional and time-limited approval system is introduced under certain circumstances to allow quick approval of the product.

(References)

About Kamada
Head Office: 2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel
Representative Officer: Amir London (CEO)
Foundation: 1990 (Listed on the Israeli Stock Exchange on 2005, Listed on USA NASDAQ on 2013)
Corporate Summary: Kamada Ltd. is a biopharmaceutical company focused on plasma-derived protein therapeutics for orphan indications, and has a commercial product portfolio and a late-stage clinical 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. The Company’s flagship product is GLASSIA®, the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. FDA. Kamada's rabies immune globulin (Human) product received FDA approval for Post-Exposure Prophylaxis against rabies infection in August 2017 and was launched in the US during Q1-2018. Kamada also leverages its expertise and presence in the Israeli therapeutics market by distributing more than 20 complementary products that are manufactured by third parties.

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