

October 8, 2020 Company Name: AnGes Inc. Presentative: Ei Yamada, President & CEO

# AnGes and Er-Kim enter into an agreement for the commercialization of Collategene® in Turkey

**October 8, 2020,** AnGes, Inc., a Japanese biopharmaceutical company focused on gene-based medicines and Er-Kim, a leading Turkish specialty pharma company; today announce an exclusive licensing and distribution agreement for Er-Kim to commercialize AnGes' gene therapy product Collategene® for Critical Limb Ischemia patients in Turkey.

Under the terms of the agreement, Er-Kim will have the exclusive rights to commercialize Collategene® in Turkey after obtaining the necessary regulatory approvals. After the approval of the product, Er-Kim will be responsible for sales, marketing and local medical affairs activities as it relates to Collategene®. Moreover, AnGes and Er-Kim will make Collategene® immediately available through Named Patient Program\* prior to approval.

Ei Yamada, President and CEO of AnGes commented, "This collaboration will further expand the geographical reach of our product and provide new treatment options for patients in Turkey. We are confident that the successful track records and high reputation of Er-Kim in the Turkish pharmaceutical market will support all activities necessary to succeed in the Turkish market."

Cem Zorlular, CEO of Er-Kim added, "We are very proud to have built a strong partnership with AnGes to deliver this exceptionally innovative treatment to Turkish patients suffering from Critical Limb Ischemia. We are also very humbled to have the opportunity to achieve another milestone in our industry, as Collategene®, if approved, will be Turkey's first approved gene therapy"

### \* Named Patient Program

Named patient programs (NPP) provide controlled, pre-approval access to drugs in response to requests by physicians on behalf of specific, or "named", patients before those medicines are licensed in the patient's home country. Through these programs, patients are able to access drugs in late-stage clinical trials or approved in other countries for a genuine, unmet medical need, before those drugs have been licensed in the patient's home country.

## About Collategene® (Beperminogene Perplasmid)

HGF (Hepatocyte Growth Factor) was discovered in 1984 in Japan as a protein to accelerate the growth of hepatocytes. Although research on HGF initially focused on the development of medicines for liver diseases, in 1995 the research team, led by Dr. Ryuichi Morishita at Osaka University, found that HGF has a novel function as an angiogenic growth factor that promotes the growth of blood vessels. The local delivery of HGF Plasmid (Plasmid encoding HGF DNA) developed a new method of regenerating blood vessels and has strong potential to become a curative medicine for ischemic patients who are suffering from deteriorating circulation due to clogged blood vessels.

Examples of diseases caused by the clogging of blood vessels include: critical limb ischemia (most advanced stage of peripheral artery disease, consisting of arteriosclerosis obliterans and Buerger's disease), which may ultimately lead to the amputation of a lower limb due to necrosis caused by poor circulation.

In March 2019, AnGes,Inc. obtained conditional and time-limited approval for HGF Plasmid gene therapy indicated for improvement of ulcers in patients with chronic arterial occlusive disease (arteriosclerosis obliterans and Buerger's disease) who have inadequate response to standard drug therapy and who are not eligible for revascularization, and it is the first gene therapy medicine approved in Japan. Commercialization of Collategene® started in September 2019 in Japan.

#### **About Er-Kim**

Er-Kim, a leading commercial partner for global biotech and pharma companies seeking to commercialize their products in Turkey, Middle East and Europe. In its 40-year of presence, Er-Kim commercialized over 150 original therapies from more than 50 leading global pharmaceutical companies. Additionally, Er-Kim operates in drug discovery for unmet needs in rare blood diseases and R&D providing cost-effective manufacturing of advanced medicinal products easing the economic burden of the healthcare system. For more information, visit <a href="http://www.erkim-ilac.com.tr/en/">http://www.erkim-ilac.com.tr/en/</a>

#### **About AnGes**

AnGes, Inc. is a biopharmaceutical company founded in December 1999 based on innovative discoveries by researchers at Osaka University and focuses on the development of gene-based medicines. Regarding our lead product, Collategene® (HGF plasmid gene therapy) for the treatment of critical limb ischemia, the company obtained conditional and time-limited approval in March 2019. And its commercialization started in September 2019 in Japan. This is the world's first marketed drug using plasmid DNA. Development of NF-κB decoy oligonucleotide for diseases including low back pain, and DNA vaccines for high blood pressure is also under way. Furthermore, AnGes started co-development of a DNA vaccine for COVID-19 in Japan with Osaka University from March 2020. The DNA vaccine for COVID-19 is utilize our plasmid DNA technology. For more information, visit <a href="https://www.anges.co.ip/en/">https://www.anges.co.ip/en/</a>

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