

Company Statement

Your Contact

alice.mcgrail@emdgroup.com

Phone: 1-781-681-2886

January 10, 2022

Merck KGaA, Darmstadt, Germany Announces Out-licensing Agreement for Osteoarthritis Asset Sprifermin

Darmstadt, Germany, January 10, 2022 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, has, through its subsidiary Ares Trading S.A., entered into an out-licensing agreement for sprifermin with TrialSpark/High Line Bio, New York, USA. Sprifermin, a recombinant form of human fibroblast growth factor 18, is currently being investigated in patients with osteoarthritis (OA). As part of the agreement, Merck KGaA, Darmstadt, Germany will receive an upfront payment as well as equity in TrialSpark/High Line Bio and is eligible for milestone payments related to delivering on certain development and commercial milestones, in addition to royalties on any future net sales. TrialSpark/High Line Bio will assume full responsibility for the research, development and commercialization of sprifermin.

This agreement is a part of the strategic evolution of Merck KGaA, Darmstadt, Germany's immunology pipeline, allowing the company to deliver the greatest impact for patients by building focused leadership positions in neuroinflammatory and immune-mediated conditions with evobrutinib, currently in Phase III development for relapsing Multiple Sclerosis (RMS), cladribine in early-stage development for generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD), and enpatoran - a novel TLR 7/8 inhibitor - entering Phase II studies in Systemic Lupus Erythematosus (SLE) and Cutaneous Lupus Erythematosus (CLE).



Company Statement

Sprifermin is delivered by injection into the joint every 6 or 12 months. The results of the five-year, multicenter Phase II study FORWARD were [published](#) in the Journal of the American Medical Association and showed that sprifermin significantly improved cartilage thickness in knee OA after two years. The complete five-year data from what is the longest trial assessing the efficacy and safety of a potential disease-modifying OA treatment reported to date were [published](#) in Annals of the Rheumatic Diseases earlier this year and showed that sprifermin maintained long-term structural modification of articular cartilage over 3.5 years post-treatment.

OA is the most common form of arthritis. There are approximately 237 million people worldwide living with symptomatic and activity-limiting OA¹ - the third most rapidly rising condition associated with disability globally². Currently, OA therapies primarily target symptoms and there are no approved structure-modifying OA treatments for preventing or slowing disease progression.

Merck KGaA, Darmstadt, Germany, in Neurology and Immunology

Merck KGaA, Darmstadt, Germany has a long-standing legacy in neurology and immunology, with significant R&D and commercial experience in multiple sclerosis (MS). The company's current MS portfolio includes two products for the treatment of relapsing MS – Rebif® (interferon beta-1a) and MAVENCLAD® (cladribine tablets). Merck KGaA, Darmstadt, Germany aims to improve the lives of patients by addressing areas of unmet medical needs. In addition to the Merck KGaA, Darmstadt, Germany's commitment to MS, the company also has a pipeline focusing on discovering new therapies that have the potential in other neuroinflammatory and immune-mediated diseases, including systemic lupus erythematosus (SLE).

All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the USA or Canada please go to www.emdgroup.com/subscribe to register for your online subscription of this service as our geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics. Around 58,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2020, Merck KGaA, Darmstadt, Germany, generated sales of € 17.5 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Electronics. Since its founding 1668, scientific exploration and responsible entrepreneurship have been key

¹ GBD Collaborators et al. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016;388:1545–602

² Osteoarthritis Research Society International. Osteoarthritis: a serious disease.

https://www.oarsi.org/sites/default/files/docs/2016/oarsi_white_paper_oa-serious-disease.pdf
[Accessed October 2021]

Company Statement

to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.