



Media Release

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MorphoSys Announces Its Licensee Janssen Initiated a Phase 2 Study (NOVA) to Evaluate Guselkumab in Hidradenitis Suppurativa

MorphoSys AG (FSE: MOR; Prime Standard Segment, MDAX & TecDAX; NASDAQ: MOR) announced today that its licensee Janssen Research & Development, LLC (Janssen) initiated a phase 2 clinical study of guselkumab in patients with moderate to severe hidradenitis suppurativa (HS), a chronic skin disease also known as acne inversa. According to clinicaltrials.gov, the randomized, double-blind study, NOVA, is expected to enroll approximately 180 adult patients with moderate to severe HS and will evaluate the efficacy, safety and tolerability of guselkumab against placebo.

Guselkumab is a human anti-IL-23 monoclonal antibody developed by Janssen, and was generated utilizing MorphoSys's proprietary HuCAL antibody technology.

Dr. Markus Enzelberger, Chief Scientific Officer of MorphoSys AG, said: "We are pleased to see that our licensee Janssen has started its first clinical study with guselkumab in hidradenitis suppurativa. We see a high medical need for new treatment options to help patients suffering from this very painful and debilitating skin disease."

In addition to the clinical development in HS, guselkumab is currently being investigated in clinical studies including two phase 3 trials in psoriatic arthritis, a phase 3 study in pediatric psoriasis patients, a phase 3 trial evaluating the efficacy of guselkumab compared with secukinumab in the treatment of adults with moderate to severe plaque psoriasis as well as a phase 2/3 clinical study program in Crohn's disease.

Guselkumab (tradename Tremfya®) has been approved in the U.S., Canada, the European Union, and several other countries for the treatment of plaque psoriasis and in Japan for the treatment of various forms of psoriasis and of psoriatic arthritis. MorphoSys is eligible to receive certain milestone payments and receives royalties on sales of Tremfya®.

More information about guselkumab clinical studies is available on clinicaltrials.gov.

About Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS), also known as acne inversa, is a debilitating, painful chronic inflammatory skin disease characterized by the occurrence of inflamed and swollen lumps (nodules) and fistulas. These are typically painful and break open releasing fluid or pus. The areas most commonly affected are the armpits, under the breasts, and groin. Scar tissue remains after healing. The recurrent nodules and abscesses cause chronic pain and can lead to self-consciousness, social isolation, and depression. Currently, there is no known cure. For reasons that are unclear, women are about twice as likely as men to develop the condition¹. HS is a rarely diagnosed, but not a rare disease². According to literature, global estimates of prevalence vary between 0.03% and 4% of the population³. According to a recent population-based analysis, the overall point prevalence of hidradenitis suppurativa was 0.10%, or 98 per 100 000 persons in the United States².

About MorphoSys

MorphoSys (FSE & NASDAQ: MOR) is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of exceptional, innovative therapies for patients suffering from serious diseases. The focus is on cancer. Based on its leading expertise in antibody, protein and peptide technologies, MorphoSys, together with its partners, has developed and contributed to the development of more than 100 product candidates, of which 29 are currently in clinical development. In 2017, Tremfya[®], marketed by Janssen for the treatment of plaque psoriasis, became the first drug based on MorphoSys's antibody technology to receive regulatory approval. The Company's most advanced proprietary product candidate, MOR208, has been granted U.S. FDA breakthrough therapy designation for the treatment of patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Headquartered near Munich, Germany, the MorphoSys group, including the fully owned New Jersey-based U.S. subsidiary MorphoSys US Inc., has approximately 320 employees. More information at <https://www.morphosys.com>.

HuCAL[®], HuCAL GOLD[®], HuCAL PLATINUM[®], CysDisplay[®], RapMAT[®], arYla[®], Ylanthia[®], 100 billion high potentials[®], Slonomics[®], Lanthio Pharma[®] and LanthioPep[®] are registered trademarks of the MorphoSys Group. Tremfya[®] is a trademark of Janssen Biotech, Inc.

Forward-looking statements

This communication contains certain forward-looking statements concerning the MorphoSys group of companies, expectations regarding the start of the phase 2 trial with Tremfya[®] in hidradenitis suppurativa (HS), the further clinical development of Tremfya[®] including the treatment of psoriatic arthritis, Crohn's disease, and the possible further expansion of the therapeutic range of Tremfya[®] as well as expectations regarding the course of disease as well as the prevalence of HS. The forward-looking statements contained herein represent the judgment of MorphoSys as of the date of this release and involve known and unknown risks and uncertainties, which might cause the actual results, financial condition and liquidity, performance or achievements of MorphoSys, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if MorphoSys' results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that MorphoSys's expectations regarding the clinical development program of Tremfya[®] in hidradenitis suppurativa (HS) and the start of the clinical phase 2 with Tremfya[®] in hidradenitis suppurativa, the further clinical development of Tremfya[®] including the treatment of psoriatic arthritis, Crohn's disease, the possible further expansion of the therapeutic range of Tremfya[®] as well as expectations regarding the course of disease as well as the prevalence of HS may be false, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements, MorphoSys' reliance on collaborations with third parties and other risks as indicated in the risk factors included in MorphoSys's Registration Statement on Form F-1 and other filings with the US Securities and Exchange Commission. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. MorphoSys expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

- 1. Genetics Home Reference. Your Guide to Understanding Genetic Conditions. <https://ghr.nlm.nih.gov/condition/hidradenitis-suppurativa>. Accessed November 12, 2018.
- 2. Garg A., et al., Sex- and Age-Adjusted Population Analysis of Prevalence Estimates for Hidradenitis Suppurativa in the United States. JAMA Dermatol. 2017;153(8):760-764. <https://jamanetwork.com/journals/jamadermatology/fullarticle/2626146>. Accessed November 12, 2018.
- 3. Calao M, et. al. Hidradenitis Suppurativa (HS) prevalence, demographics and management pathways in Australia: A population-based cross-sectional study. PLoS One. 2018;13 (7): e0200683.

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0200683>. Accessed November 12, 2018.

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