



Media Release

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MorphoSys Announces that its Licensee Janssen has Expanded Clinical Development of Guselkumab (Tremfya®) into Familial Adenomatous Polyposis

MorphoSys AG (FSE: MOR; Prime Standard Segment, MDAX & TecDAX; NASDAQ: MOR) announced today that its licensee Janssen Research & Development, LLC (Janssen), has further expanded the clinical development of guselkumab (Tremfya®) into familial adenomatous polyposis (FAP), a disease of the gastrointestinal tract.

Janssen has initiated a phase 1b proof-of-concept clinical trial of guselkumab in patients with FAP, a dominantly inherited disorder characterized by the early onset of polyps throughout the colon which may develop into colon cancer, if not treated. This randomized study will evaluate the efficacy and safety of guselkumab vs. placebo in approximately 72 patients with FAP.

In connection with the start of clinical development in FAP, MorphoSys received a milestone payment from Janssen. Financial details were not disclosed.

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

Dr. Markus Enzelberger, Chief Scientific Officer of MorphoSys AG, said: "We are very pleased that our licensee Janssen has further expanded the clinical development program of guselkumab by initiating the clinical study in familial adenomatous polyposis. We see a high medical need to investigate new treatment options for patients suffering from this serious inflammatory disease of the gastrointestinal tract which, if not treated, may develop into colon cancer."

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, psoriatic arthritis, and palmoplantar pustulosis. Guselkumab is currently being investigated in clinical studies in several indications, including additional studies in plaque psoriasis, pediatric psoriasis, psoriatic arthritis, Crohn's disease, hidradenitis suppurativa, ulcerative colitis and now familial adenomatous polyposis. MorphoSys is eligible to certain milestone payments and receives royalties on net sales of Tremfya®.

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

About Familial Adenomatous Polyposis (FAP) Syndrome

Familial adenomatous polyposis (FAP) is the most common adenomatous polyposis syndrome. It is an autosomal dominantly inherited disorder characterized by the early onset of hundreds to thousands of adenomatous polyps throughout the colon. FAP has a birth incidence of about 1 out of 8,300 worldwide, manifests equally in both sexes¹, and, if left untreated, patients with this syndrome will most likely develop colorectal cancer. In addition, an increased risk exists for the development of other malignancies². Removing the colon is currently the only way to prevent colorectal cancer from developing in these patients¹.

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 U.S. subsidiary MorphoSys US Inc., has approximately 330 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.

MorphoSys forward-looking statements

This communication contains certain forward-looking statements concerning the MorphoSys group of companies, expectations regarding the clinical development of guselkumab (Tremfya[®]) in patients with familial adenomatous polyposis (FAP), milestone payments received on the start of the clinical development of Tremfya[®] in FAP, MorphoSys's eligibility to receive certain milestone payments and royalties on net sales of Tremfya, the further clinical development of Tremfya[®] including the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, hidradenitis suppurativa, ulcerative colitis and now FAP. 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's 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' expectations regarding the clinical development of guselkumab (Tremfya[®]) in patients with familial adenomatous polyposis (FAP), milestone payments received on the start of the clinical development of Tremfya[®] in FAP, MorphoSys's eligibility to receive certain milestone payments and royalties on net sales of Tremfya, the further clinical development of Tremfya[®] including the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, hidradenitis suppurativa, ulcerative colitis and now FAP are false, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements, MorphoSys's reliance on collaborations with third parties and other risks as indicated in the risk factors included in MorphoSys's Annual Report on Form 20-F 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. Half *et al*: Familial adenomatous polyposis; Orphanet Journal of Rare Diseases (2009): 4:22 doi:10.1186/1750-1172-4-22 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2772987/pdf/1750-1172-4-22.pdf>. Accessed December 13, 2018.
- 2. <https://www.cancer.net/cancer-types/familial-adenomatous-polyposis>. Accessed December 13, 2018.

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