



## Media Release

Planegg/Munich, Germany, September 16, 2019

### **MorphoSys's Licensee Janssen Submits Biologics License Application to U.S. FDA of Tremfya® (Guselkumab) for Treatment of Adults with Active Psoriatic Arthritis**

MorphoSys AG (FSE: MOR; Prime Standard Segment; MDAX & TecDAX; Nasdaq: MOR) announced today that its licensee Janssen Research & Development, LLC (Janssen) issued a [press release](#) to report the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of Tremfya® (guselkumab) for the treatment of adult patients with active psoriatic arthritis (PsA).

As Janssen announced, the sBLA is based on results from the phase 3 studies DISCOVER-1 and DISCOVER-2, which met their primary endpoints of patients achieving an American College of Rheumatology 20 percent improvement (ACR20) response after 24 weeks of treatment. According to Janssen, the safety profile observed for Tremfya® in the DISCOVER studies was generally consistent with previous studies as well as the current Tremfya® prescribing information. The DISCOVER program comprises the first phase 3 studies evaluating a human monoclonal antibody against the p19 subunit of interleukin (IL)-23 for active PsA, and the results have been submitted for presentation at an upcoming medical meeting, as Janssen stated.

Tremfya® is a human monoclonal antibody against the p19 subunit of IL-23 developed by Janssen that was generated utilizing MorphoSys's proprietary HuCAL antibody technology.

Dr. Markus Enzelberger, Chief Scientific Officer of MorphoSys AG, said: "Active psoriatic arthritis is very debilitating for patients, limiting mobility, causing pain and continuous fatigue. We are pleased that with submission of the Tremfya® sBLA, our partner Janssen is advancing PsA treatment options and we hope that, given FDA approval, Tremfya® might become a valuable therapy in this indication."

According to Janssen, the company expects to submit a marketing application to the European Medicines Agency seeking approval of Tremfya® as a treatment for PsA before the end of the year. 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. Tremfya® 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 familial adenomatous polyposis. MorphoSys is eligible to certain milestone payments and receives royalties on net sales of Tremfya®.

More information about Tremfya® clinical studies is available on [clinicaltrials.gov](https://clinicaltrials.gov).

#### About the DISCOVER program

The DISCOVER program consists of DISCOVER-1 and DISCOVER-2, two randomized, double-blind, multicenter phase 3 studies designed to evaluate efficacy and safety of subcutaneous Tremfya® in patients with active PsA compared to placebo. In addition to the primary endpoint of ACR20 response at week 24, multiple secondary endpoints were assessed that included ACR50/70, resolution of soft tissue inflammation (enthesitis and dactylitis), disease activity (DAS-28 CRP), improvement in physical function (HAQ-DI), skin clearance (IGA), and quality of life (SF-36 PCS and MCS). DISCOVER-2 also assessed effect on structural damage using the van der Heide-Sharp score (vdH-S) as a key secondary endpoint. DISCOVER-1 evaluated 381 participants, including those previously treated with anti-TNF therapy and continued through 52 weeks. DISCOVER-2 included 739 bio-naive participants and is planned to continue through 100 weeks.

#### 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, tafasitamab (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 370 employees. More information at <https://www.morphosys.com>.

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#### MorphoSys forward looking statements

*This communication contains certain forward-looking statements concerning the MorphoSys group of companies, including the clinical development of guselkumab in psoriatic arthritis led by Janssen, the further clinical development of guselkumab by Janssen as well as interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for guselkumab in psoriatic arthritis. 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 MorphoSys' expectations regarding the clinical development of guselkumab in psoriatic arthritis led by Janssen, the further clinical development of guselkumab by Janssen as well as interactions with regulatory authorities and expectations regarding regulatory filings and possible approvals for guselkumab in psoriatic arthritis, MorphoSys' reliance on collaborations with third parties, estimating the commercial potential of its development programs and other risks 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.*

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