Media Release
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MorphoSys Announces that its Licensee Janssen Has Received U.S. FDA Approval for Tremfya® One-Press Patient-Controlled Injector for Adults with Moderate-to-Severe Plaque Psoriasis

MorphoSys AG (FSE: MOR; Prime Standard Segment, MDAX & TecDAX; NASDAQ: MOR) announced today that its licensee Janssen Research & Development, LLC (Janssen), has reported that the U.S. Food and Drug Administration (FDA) has approved Tremfya® (guselkumab) One-Press, a single-dose, patient-controlled injector for adults with moderate-to-severe plaque psoriasis.

According to a press release published by Janssen today, Tremfya® is the first FDA-approved medication of its kind to offer the One-Press patient-controlled injector. Tremfya® is intended for use under the guidance and supervision of a physician, and patients may self-inject with Tremfya® One-Press after physician approval and proper training.

Tremfya® (guselkumab) is a human anti-IL-23 monoclonal antibody developed by Janssen that was generated utilizing MorphoSys's proprietary HuCAL antibody technology. MorphoSys is eligible to certain milestone payments and receives royalties on net sales of Tremfya®.

At times, patients living with plaque psoriasis may struggle with self-administering treatments due to a number of factors including needle phobia. In the phase 3, multicenter and randomized ORION study, patient experience with One-Press was assessed through a validated Self-Injection Assessment Questionnaire (SIAQ), which evaluated patient experience at weeks zero, four and twelve on a scale of 0 (worst) to 10 (best) across six domains (feelings about injections, self-image, self-confidence, pain and skin reactions during or after the injection, ease of use of the self-injection device and satisfaction with self-injection). The mean score for "Satisfaction with Self Injection" was 9.18 (with 10 indicating "very satisfied") and the mean score for "Ease of Use" was 9.24 (with 10 indicating "very easy").

The efficacy and safety of Tremfya® administered with One-Press in patients with moderate to severe plaque psoriasis was also evaluated in the double-blind, placebo-controlled ORION study. In the study, a greater proportion of subjects in the Tremfya® group achieved an IGA score of 0 or 1 or a PASI 90 response at week 16 (81 percent and 76 percent, respectively) than in the placebo group (0 percent for both endpoints). The proportion of subjects who achieved an IGA score of 0 at week 16 was higher in the Tremfya® group compared to the placebo group (56 percent vs. 0 percent). The proportion of subjects who achieved a PASI 100 response at week 16 was higher in the Tremfya® group compared to the placebo group (50 percent vs. 0 percent). The majority of injection-site reaction symptoms with One-Press were mild and transient in nature.

According to Janssen, the design of the Tremfya® One-Press, which is now available in the U.S., is intended to allow patients to control the rate and pressure of their injection. Nearly 99 percent of patients reported a successful first injection in the ORION study. One-Press also includes a safety system intended to protect the needle after use. After three injections, patients still reported favorable outcomes with the usability of the One-Press device in the study.

Dr. Markus Enzelberger, Chief Scientific Officer of MorphoSys AG, said: “We are very pleased that our licensee Janssen has received U.S. FDA approval for the Tremfya® One-Press patient-controlled injector based on Janssen’s phase 3 ORION study. With this approval, patients will have the option to self-administer their treatment in a simple and more convenient way.”

Tremfya® (guselkumab) has been approved in the U.S., Canada, the European Union, and several other countries for the treatment of adults with moderate to severe plaque psoriasis and in Japan for the treatment of various forms of psoriasis, psoriatic arthritis, and palmoplantar pustulosis. The agent is currently being investigated in clinical studies in several indications, including plaque psoriasis, pediatric psoriasis, psoriatic arthritis, Crohn’s disease, hidradenitis suppurativa, and ulcerative colitis. More information about guselkumab clinical studies is available on clinicaltrials.gov.

Further information can be found in a press release issued by Janssen on February 27, 2019.

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.

This communication contains certain forward-looking statements concerning the MorphoSys group of companies, expectations regarding the U.S. FDA approval of Tremfya® (guselkumab) One-Press, a single-dose, patient-controlled injector for adults with moderate-to-severe plaque psoriasis, clinical results of a phase 3 ORION study evaluating the safety and efficacy of Tremfya® administered with One-Press in patients with moderate to severe plaque psoriasis, expectations regarding the convenience of the self injection for patients as well as expectations regarding the clinical development of guselkumab (Tremfya®) including the treatment of plaque psoriasis, psoriatic arthritis, Crohn’s disease, hidradenitis suppurativa, and ulcerative colitis and MorphoSys’s eligibility to receive milestone payments and royalties on net sales of Tremfya. 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 U.S. FDA approval of Tremfya® (guselkumab) One-Press, a single-dose, patient-controlled injector for adults with moderate-to-severe plaque psoriasis, clinical results of a phase 3 ORION study evaluating the safety and efficacy of Tremfya® administered with One-Press in patients with moderate to severe plaque psoriasis, expectations regarding the convenience of the self injection for patients as well as expectations regarding the clinical development of guselkumab (Tremfya®) including the treatment of plaque psoriasis, psoriatic arthritis, Crohn’s

disease, hidradenitis suppurativa, and ulcerative colitis and MorphoSys's eligibility to receive milestone payments and royalties on net sales of Tremfya 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 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.

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