

Galapagos and MorphoSys announce initiation of GECKO Phase 2 study with MOR106 in atopic dermatitis patients

Mechelen, Belgium and Planegg/Munich, Germany; 23 April 2019; 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG), MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; NASDAQ: MOR) and Novartis Pharma AG (SIX: NOVN-CH) announced today the initiation of GECKO, a Phase 2 study testing a subcutaneous formulation of MOR106 in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis.

The GECKO trial aims to randomize 60 patients who receive either a dose of MOR106 or placebo subcutaneously for 8 weeks, together with topical steroids, with a 16 week follow-up period. The primary endpoint of GECKO is the incidence of treatment emergent adverse and serious adverse events through day 169.

Pharmacokinetics (PK) and occurrence of anti-drug-antibodies after subcutaneous administration of MOR106 will be assessed as secondary endpoints. In addition, the efficacy of MOR106 will be explored.

Recruitment will take place in the U.S. and Canada, and the study is intended to serve as an IND (investigational new drug) opener with the U.S. FDA.

“With GECKO we aim to explore the effects of the combination of MOR106 with topical steroids, the most frequently prescribed treatment for atopic dermatitis patients today,” said Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos. “This IND opening study extends the development program for MOR106 to the U.S. and Canada, which complements the ongoing clinical evaluations in Europe.”

“Moderate to severe atopic dermatitis is a chronic, debilitating disease affecting millions of patients worldwide,” said Dr. Malte Peters, Chief Development Officer of MorphoSys AG. “We see a clear unmet medical need for additional treatment options. We look forward to further expanding the development program of MOR106 for these patients with the IND opening phase 2 trial we have now initiated together with our partner Galapagos under the global licensing agreement with Novartis.”

About MOR106

MOR106 was generated using MorphoSys’s Ylanthia antibody platform and is based on a target discovered by Galapagos. IL-17C is a cytokine expressed preferentially in the skin and which has been implicated in dermal inflammation and shown to be distinct from other members of the IL-17 cytokine family. MOR106 is the first publicly known human monoclonal antibody directed against IL-17C in clinical development worldwide. MOR106 is an investigational drug and its safety and efficacy have not yet been established. Novartis Pharma AG owns the worldwide, exclusive license for the development and commercialization of MOR106 under an agreement with MorphoSys and Galapagos which became effective on September 10, 2018.

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, the first drug based on MorphoSys’s antibody technology received 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>.

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About Galapagos

Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glp.com.

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Galapagos forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding the mechanism of action and profile of, and timing and results of clinical trials with, and potential commercialization of, MOR106. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, 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 Galapagos' 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 expectations regarding the further development of MOR106 in moderate-to-severe atopic dermatitis, including the intended targeting of IL-17C, as well as Galapagos' expectations regarding the MOR106 development program may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing clinical research programs may not support registration or further development of MOR106 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partners for MOR106, MorphoSys and Novartis), and estimating the commercial potential of MOR106. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission (SEC) filings and reports, including in Galapagos' most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by Galapagos with the SEC. 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. Galapagos 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.