Galapagos and MorphoSys announce initiation of the IGUANA Phase 2 clinical trial with MOR106 in atopic dermatitis patients

Mechelen, Belgium and Planegg/Munich, Germany; 1 May 2018; 22.01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) and MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) announced today that the first patient has been screened in IGUANA, a Phase 2 study with MOR106, an investigational antibody directed against IL-17C, in atopic dermatitis patients.

IGUANA – A MOR106 Phase 2 trial
At least 180 patients with moderate-to-severe atopic dermatitis (AD) are planned to be treated over a 12-week period with one of three different doses of MOR106 (1, 3 or 10 mg/kg) or placebo using two different dosing regimens in this Phase 2 trial in multiple centers across Europe. The placebo controlled, double-blind study will evaluate the efficacy, safety and pharmacokinetics (PK) of MOR106. Dosing at 2 or 4-week intervals will be evaluated over the 12-week treatment period, followed by a 16-week observation period. The primary objective will be assessed by the percentage change from baseline in Eczema Area and Severity Index (EASI) score at week 12.

"Moderate-to-severe AD 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 safe and efficacious treatment options and we are looking forward to further developing MOR106 for these patients in the Phase 2 trial we have now initiated together with our partner Galapagos.”

“The IGUANA trial is aimed at providing a robust dataset on MOR106 in atopic dermatitis patients. We look forward to seeing what this IL-17C mechanism of action can bring to a larger trial population for longer treatment duration,” said Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos.

MOR106 was generated using MorphoSys’ 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.

About MOR106 results of a Phase 1 study in atopic dermatitis (AD)
Clinical data of a MOR106 Phase 1 trial in AD patients were presented at the American Academy of Dermatology (AAD) conference in February 2018 in San Diego. After 4 infusions in weekly intervals, an improvement of at least 50% in the Eczema Area and Severity Index (EASI-50) was observed in 83% of patients (5 out of 6) at week 4 at the highest dose level of MOR106. The onset of activity occurred within two to four weeks, depending on the dose administered. Pooled data across all dose cohorts showed that AD patients treated with MOR106 achieved an EASI improvement compared to baseline of 58%, 62%, 72%, and 64% at week 4, 8, 12, and 14, respectively. For patients receiving placebo, the EASI improvement was 32%, 40%, 38%, and 50%. MOR106 was generally well tolerated in this trial. Any adverse drug reactions observed in relation to MOR106 were mild-to-moderate and transient in nature. No serious adverse events or infusion-related reactions were recorded (Thaći et al., 2018, AAD).
About atopic dermatitis
Atopic dermatitis (AD), the most severe and common type of eczema, is a chronic relapsing inflammatory skin disease that causes severe itch, dry skin and rashes, predominantly on the face, inner side of the elbows and knees, and on hands and feet. Scratching of the affected skin leads to a vicious cycle causing redness, swelling, cracking, scaling of the skin and an increased risk of bacterial infections. Lichenification, thickening of the skin, is characteristic in older children and adults. The National Eczema Association estimates that AD affects over 30 million Americans or up to 25% of children and 2-3% of adults. 60% of AD patients are diagnosed in the first year of life, and 90% of patients have a disease onset before age five. Symptoms commonly fade during childhood, however, approximately 10-30% of the patients will suffer from AD for life. A smaller percentage first develop symptoms as adults.

About IL-17C
IL-17C is a cytokine that is broadly expressed in human skin pathologies and is described as an important modulator of the innate immune system of the skin, distinct from other members of the IL-17 cytokine family. IL-17C plays a crucial role in human inflammatory conditions, including skin diseases.

About MOR106 and the antibody collaboration of Galapagos and MorphoSys
MOR106 is an investigational fully human IgG1 monoclonal antibody designed to selectively target IL-17C, currently being developed for treatment of inflammatory diseases. MOR106 arises from the strategic discovery and co-development alliance between Galapagos and MorphoSys, in which both companies contribute their core technologies and expertise. Galapagos has provided the disease-related biology including cellular assays and targets discovered using its target discovery platform. MorphoSys has contributed its Ylanthia antibody technology to generate fully human antibodies directed against the target and contributes full CMC development of this compound. Galapagos and MorphoSys equally share research and development costs, as well as all future economics.

About MorphoSys
MorphoSys is a late-stage, biopharmaceutical company devoted to the development of innovative and differentiated therapies for patients suffering from serious diseases. Based on its technological leadership in generating antibodies, MorphoSys, together with its partners, has developed and contributed to the development of more than 100 product candidates, of which 28 are currently in clinical development. This broad pipeline spans MorphoSys’s two business segments: Proprietary Development, in which MorphoSys invests in product candidates for its own account, and Partnered Discovery, in which product candidates are developed exclusively for a variety of Pharma and Biotech partners. In 2017, Tremfya® (guselkumab), marketed by Janssen, became the first therapeutic antibody based on MorphoSys’s proprietary technology to receive marketing approval for the treatment of moderate-to-severe plaque psoriasis in the United States, the European Union and Canada. MorphoSys is listed on the Frankfurt Stock Exchange under the symbol MOR. For regular updates about MorphoSys, visit http://www.morphosys.com.

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About Galapagos
Galapagos (Euronext & NASDAQ: GLPG) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action. Galapagos’ pipeline comprises Phase 3 through to discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has
delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic pulmonary fibrosis and atopic dermatitis. Galapagos is focused on the development and commercialization of novel medicines that will improve people’s lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 634 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at [www.glpg.com](http://www.glpg.com).

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**Galapagos forward-looking statements**

This release may contain forward-looking statements pertaining to Galapagos, including, among other things, statements regarding Galapagos’ strategic ambitions, the mechanism of action and potential safety and efficacy of MOR106, or regarding the timing, progress and/or results of clinical trials with MOR106, and the potential commercialization of MOR106, if approved. 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 Galapagos’ expectations regarding its 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 Galapagos’ ongoing and planned clinical research program 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 partner for MOR106, MorphoSys), 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.