



Galapagos and MorphoSys report first promising signs of clinical activity in a Phase 1 study with IL-17C antibody MOR106 in atopic dermatitis patients

- Generally well-tolerated with no clinically relevant safety signals in Phase 1 study
- At the highest dose level, 5 out of 6 patients (83%) reached an improvement of at least 50% in atopic dermatitis symptoms (EASI-50) by week 4
- Results support progression to Phase 2 study
- GLPG's 3<sup>rd</sup> novel mechanism to show promising patient results
- MOR106 is the first human monoclonal antibody against IL-17C in clinical development worldwide

Mechelen, Belgium and Planegg/Munich, Germany; 27 September 2017; 7.30 CET – Galapagos NV (Euronext & NASDAQ: GLPG) and MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) today announced Phase 1 results with their joint investigational antibody program MOR106 directed against IL-17C in patients with moderate-to-severe atopic dermatitis (AD). MOR106 was generated using MorphoSys's Ylanthia antibody platform and is based on a target discovered by Galapagos. IL-17C is a cytokine which has been related to dermal inflammation and shown to be distinct from other members of the IL-17 cytokine family.

The Phase 1 study was a randomized, double-blind, placebo-controlled trial, evaluating single ascending doses (SAD) in healthy volunteers, and multiple ascending doses (MAD) in patients with moderate-to-severe atopic dermatitis. MOR106 was administered as an intravenous infusion. The primary objective of the Phase 1 study was to evaluate the safety and tolerability of MOR106. The study's secondary objective was to characterize the pharmacokinetic (PK) profile of MOR106 in patients. Exploratory objectives to measure early signs of efficacy were also included in the MAD part of the study. 24 patients, diagnosed with moderate-to-severe atopic dermatitis, received four weekly infusions of either placebo or MOR106 in a 1 to 3 ratio of placebo to MOR106. Patients were followed for 11 weeks after the last infusion.

Galapagos and MorphoSys previously disclosed that the SAD "healthy volunteer" part of the Phase 1 study reported generally favorable safety findings. In the MAD portion in patients, all adverse drug reactions observed were mild-to-moderate and transient in nature and did not lead to clinically relevant safety signals. No serious adverse events (SAEs) and no infusion-related reactions (IRRs) were recorded. MOR106 reported a favorable PK profile with dose-dependent exposure and a half-life in patients in line with what was observed in healthy volunteers.

Even though the study was not statistically powered to show differences in efficacy between treatment groups, at the highest dose level of MOR106, in 83% of patients (5 out of 6) an improvement of at least 50% in signs and symptoms of atopic dermatitis measured by the Eczema Area and Severity Index (EASI-50) was recorded at week 4. The onset of activity was rapid and occurred within few weeks and was maintained for over 2 months after the last treatment. Among patients receiving placebo, in 17% of patients (1 out of 6) an EASI-50 improvement was seen at week 4.

"Moderate-to-severe atopic dermatitis is a chronic, debilitating disease affecting millions of patients worldwide with a clear unmet medical need for safe and efficacious treatments. In this Phase 1





study MOR106 was observed to be generally well-tolerated, with a favorable PK profile. In addition, we have seen first very promising signs of clinical activity, with a response sustained for months after stopping treatment," said Professor Diamant Thaçi MD, Direktor Institut für Entzündungsmedizin Universitätsklinikum Schleswig-Holstein Campus Lübeck and Independent Advisor for the study. "There is plenty of room in the clinicians' armamentarium for new treatments in this field, so I very much look forward to working further on the evaluation of this investigational compound and its potential role in treating atopic dermatitis."

"Following JAK1 and autotaxin, IL-17C is the third mechanism out of our proprietary target discovery platform for which we are excited to pursue clinical development, underlining extracellular mechanisms of action as a new area of development for us," said Dr. Piet Wigerinck, CSO of Galapagos. "We are very pleased with the outcome of this initial patient study with the first novel mechanism antibody directed against IL-17C in the Galapagos pipeline. The Phase 1 results of MOR106 support its progression into Phase 2 development in patients. In parallel, we will evaluate the switch to subcutaneous administration."

"We are delighted with these first Phase 1 clinical results from our joint antibody program with Galapagos in patients with moderate-to-severe atopic dermatitis. MOR106 is MorphoSys's fifth program in Morphosys' proprietary development portfolio and the first antibody from our Ylanthia technology platform in the clinic. These data further encourage us to develop MOR106 as a potential novel biologic therapy for patients suffering from this severe disease with high medical need together with our partner Galapagos", commented Dr. Malte Peters, Chief Development Officer of MorphoSys AG.

Galapagos and MorphoSys intend to present the clinical data from this study with MOR106 at a future medical conference.

## **About Atopic Dermatitis**

Atopic dermatitis, also known as atopic eczema, is a chronic pruritic (itching) inflammatory skin disease that most frequently starts in early childhood, often persists into adulthood, but may also have an adult onset. According to GlobalData, there were 35 million atopic dermatitis patients in the US, the major EU nations and Japan in 2016, approximately 25 million of which were estimated to be moderate-to-severe cases. The main features of atopic dermatitis are the impairment of the skin barrier and dysfunction of the immune system accompanied with dry skin and severe pruritus that is associated with cutaneous hyperactivity to various environmental stimuli. The pruritus (itching) may lead to sleep loss, anxiety, depression and impaired social life and is therefore considered as highest therapeutic need in atopic dermatitis.

## **About IL-17C**

IL-17C is a cytokine that is broadly expressed in human skin pathologies and is a checkpoint in innate skin immunology, 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

MOR106 is an investigational human IgG1 monoclonal antibody currently being developed for treatment of inflammatory diseases. It is the first publicly disclosed human monoclonal antibody designed to selectively target IL-17C in clinical development worldwide. 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 provides the disease-related biology including cellular assays and targets discovered using its target discovery platform. MorphoSys contributes its Ylanthia antibody technology to generate fully human antibodies directed





against the target and contributes full CMC development of this compound. Galapagos and MorphoSys will continue to co-develop MOR106 further in the clinic.

## About MorphoSys

MorphoSys's mission is to make exceptional, innovative biopharmaceuticals to improve the lives of patients suffering from serious diseases. Innovative technologies and smart development strategies are central to our approach. Success is created by our people, who focus on excellence in all they do, collaborate closely across disciplines and are driven by a desire to make the medicines of tomorrow a reality. Success benefits all of our stakeholders. Based on its proprietary technology platforms, particularly in the field of fully human therapeutic antibodies, MorphoSys, together with its partners, has built a therapeutic pipeline of more than 110 programs in R&D, around a quarter of which is currently in clinical development.

In its proprietary development segment, MorphoSys, alone or with partners, is developing new therapeutic candidates, mainly focusing on cancer and inflammation. In its partnered discovery segment, MorphoSys uses its technologies to discover new drug candidates for pharmaceutical partners and participates from the programs' further development success, through success-based payments and royalties. 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. Galapagos has demonstrated proof of platform with filgotinib targeting JAK1 in inflammatory conditions (collaboration with Gilead), GLPG1690 targeting autotaxin in IPF, and MOR106 targeting IL-17C in atopic dermatitis (collaboration with MorphoSys). 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 550 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia. More information at www.qlpq.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 the mechanism of action and safety and efficacy profile of MOR106, or regarding the timing, progress and/or results of clinical studies with MOR106. Galapagos cautions the reader that forward-looking statements are not quarantees 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 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.