Galapagos announces start of Phase 2 study with selective TYK2 inhibitor, GLPG3667, in patients with active systemic lupus erythematosus

- **GLPG3667 is an investigational, novel, oral, reversible, and selective tyrosine kinase 2 (TYK2) inhibitor**
- **GLPG3667 is currently in development for the treatment of inflammatory and auto-immune diseases and is in Phase 2 for dermatomyositis**

Mechelen, Belgium; 28 August 2023, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the first patient was randomized in GALACELA, a Phase 2 systemic lupus erythematosus (SLE) trial with GLPG3667.

The GALACELA Phase 2 trial (NCT05856448) is a randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of GLPG3667 in adults with active SLE. A once-daily oral administration of GLPG3667 or placebo will be investigated in approximately 140 adult patients with SLE for 32 weeks. The primary endpoint is the proportion of patients who achieve the SLE responder index (SRI)-4 response at Week 32. The secondary efficacy endpoints are the proportion of patients who achieve the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) response at Week 32, proportion of patients with >=50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) score at Week 16, proportion of patients who achieve Lupus Low Disease Activity State (LLDAS) at Week 32 and change from baseline in the 28-joint count for tender, swollen, and tender and swollen (active) joints at Week 32.

“We are proud to have reached this important milestone in our journey to improve the lives of patients living with autoimmune diseases. Although significant progress has been made in the management of SLE over the past decade, flares, morbidity, and mortality continue to remain a significant concern and quality of life is poor among patients living with SLE,” said Daniele D’Ambrosio, MD, PhD, Therapeutic Area Head Immunology, at Galapagos. “We are excited about GLPG3667’s potential to make a meaningful difference for people living with SLE and look forward to advancing this candidate medicine in clinical development.”

GLPG3667 is an investigational drug and is not approved by any regulatory authority. Its efficacy and safety have not been established or fully evaluated by any regulatory authority.

About systemic lupus erythematosus (SLE)
SLE is a chronic, inflammatory, autoimmune disease affecting nearly every organ system and thereby one of the most heterogeneous illnesses treated by physicians[1]. The pathogenesis of SLE is characterized by a global loss of self-tolerance with activation of autoreactive T and B cells. This leads to the production of pathogenic autoantibodies that primarily target a variety of nuclear antigens, deposit in tissues and activate complement, resulting in organ damage. SLE affects women more frequently than men and is more prevalent and severe (with higher disease activity and more damage accrual) in non-Caucasian populations (Hispanics, African descendants, and Asians)[2]. SLE has periods of relatively stable disease followed by flares that may induce irreversible organ damage. Despite best practice, most patients accrue irreversible

organ damage within 7 years of diagnosis. SLE has no cure and current treatment options are associated with partial efficacy and/or substantial toxicities. New treatments may help to fulfill the current unmet medical needs among patients.

About Galapagos

Galapagos is a fully integrated biotechnology company united around a single purpose: to transform patient outcomes through life-changing science and innovation for more years of life and quality of life. We focus on the key therapeutic areas of immunology and oncology, where we have developed deep scientific expertise in multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to commercialized programs and our first medicine for rheumatoid arthritis and ulcerative colitis is currently available in Europe and Japan. For additional information, please visit www.glpg.com or follow us on LinkedIn or Twitter.

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Forward-looking statements

This press release includes forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but not always, made through the use of words or expressions such as "start," "potential," "remains," "develop," advance," "continue," "will," "can," "forward," and "improve," as well as similar expressions. Forward-looking statements contained in this press release include, but are not limited to, statements regarding the preliminary, interim and topline data from our studies, including, without any limitation, the GALACELA study, and all other analyses related to GLPG3667 or our immunology portfolio, statements regarding our plans and strategy with respect to GLPG3667 or our immunology portfolio, including, without any limitation, the GALACELA study, statements regarding the expected timing, design and readouts of the GALACELA study, including the recruitment for trials and timing for topline results, and statements regarding our R&D and regulatory outlook. Any forward-looking statements in this press release are based on our management's current expectations and beliefs, and are not guarantees of future performance. Forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause our actual results, performance or achievements to be materially different from any historic or future results, performance or achievements expressed or implied by such statements. These risks, uncertainties and other factors include, without any limitation, the risk that ongoing and future clinical studies (including the GALACELA study) may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties associated with competitive developments, clinical trials, recruitment of patients, product development activities and regulatory approval requirements (including, without any limitation, that data from ongoing and planned clinical research programs, including, without any limitation, the data from the ongoing GALACELA study, may not support further development or registration due to safety, efficacy, or other reasons, or that data readouts in the future may not reflect interim data results), the inherent risks and uncertainties associated with target discovery and validation or drug discovery and development activities, the risks related to our reliance on collaborations with third parties, and the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan. A further list and description of these risks, uncertainties and other factors can be found in our filings and reports with the Securities and Exchange Commission ("SEC"), including in our most recent annual report on Form 20‑F filed with the SEC, as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future. Given these risks and uncertainties, the reader is advised not to place any undue reliance on forward-looking statements. In addition, even if our results, performance or achievements are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. These forward-looking statements speak only as of the date of publication of this press release. We expressly disclaim any obligation to update any forward-looking statements in this press release, unless required by law or regulation.

[1] Rees, F. et al., (2017). The worldwide incidence and prevalence of systemic lupus erythematosus: a systematic review of epidemiological studies. Rheumatol. Oxf. Engl., 56(11), 1945–1961.
[2] González, L. A. et al (2013). Ethnicity in systemic lupus erythematosus (SLE): its influence on susceptibility and outcomes. Lupus, 22(12), 1214–1224.