

Galapagos demonstrates early clinical activity with SIK2/3 inhibition in inflammation

- **Biologic effect of salt inducible kinase (SIK) mechanism in first patient studies supports further progression of Toledo portfolio**
- **SIK2/3 inhibitor GLPG3970 generally safe and well-tolerated**
- **Study in psoriasis patients shows improvement in PASI score at Week 6**
- **Study in ulcerative colitis (UC) patients shows signs of biologically important effects; does not translate to signal on Mayo score at Week 6**
- **No signal observed in rheumatoid arthritis (RA) study at Week 6**

Mechelen, Belgium; 14 July 2021; 22.01 CET; regulated information – Galapagos NV (Euronext & Nasdaq: GLPG) reports topline results with GLPG3970 in three patient studies. GLPG3970, the first product candidate from a broad portfolio of SIK inhibitor compounds, provides clinical data supporting the role of SIK inhibition in inflammation. SIK is a novel target class discovered by Galapagos.

Galapagos evaluated GLPG3970, a proprietary salt inducible kinase (SIK) 2/3 inhibitor, in three randomized, placebo-controlled, double-blind studies: a Phase 1b study in patients with moderate to severe psoriasis and two Phase 2a studies in patients with moderate to severely active UC and RA. GLPG3970 or placebo were administered orally once-daily for 6 weeks. Main objectives were to evaluate the safety and tolerability of GLPG3970 as well as early signs of biologic and clinical effect.

Across the three studies, GLPG3970 was generally safe and well tolerated. There were no deaths nor serious adverse events, and the majority of treatment emergent adverse events (TEAEs) were mild or moderate in nature.

CALOSOMA study: Phase 1b trial in psoriasis

This study randomized 26 patients with moderate to severe psoriasis in a 3:2 ratio, GLPG3970 to placebo. Two out of 15 patients discontinued in the treatment arm (COVID-19 and pruritus) versus 1 out of 11 on placebo (psoriatic arthropathy).

At Week 6, four out of 13 patients on GLPG3970 had a PASI¹ 50 response, defined as at least a 50% improvement of baseline PASI, compared to none on placebo. Specifically, the four responders achieved 50%, 50%, 56%, and 77% improvement in their PASI scores from baseline, reaching statistical significance compared to placebo (p=0.002) at Week 6. Positive signals of clinical effect were also consistently observed for other endpoints, including affected Body Surface Area and physician and patient global assessment, versus placebo at Week 6.

SEA TURTLE study: Phase 2a trial in UC

This study randomized 31 biologic-naïve patients with moderate to severely active UC in a 2:1 ratio, GLPG3970 to placebo. One out of 21 patients discontinued in the active treatment arm (COVID-19) versus one out of 10 on placebo (QT abnormality at baseline).

At Week 6, positive signals were observed in patients on GLPG3970 on objective parameters such as endoscopy, histology, and fecal calprotectin. These findings did not translate in a differentiation from

¹ Psoriasis Area and Severity Index; an index used to express the severity of psoriasis. It combines the severity (erythema, induration and desquamation) and percentage of affected area

placebo on change from baseline total Mayo Clinic Score in this 6-week study (GLPG3970 -2.7, placebo -2.6). Seven out of 18 patients on GLPG3970 who underwent endoscopy at Week 6 met the criteria for Endoscopic Improvement, defined as a score of 0 or 1 on the endoscopic response score, compared to one out of 9 patients on placebo. The robustness of these signals will be further examined when additional efficacy and biomarker data become available later this year.

LADYBUG study: Phase 2a trial in RA

This study randomized 28 patients with moderate to severely active RA and an inadequate response to methotrexate in a 3:2 ratio, GLPG3970 to placebo. Three out of 16 patients discontinued in the treatment arm (COVID-19, ALT increase and physician decision) versus 2 out of 12 on placebo (COVID-19).

At Week 6, patients on GLPG3970 showed no differentiation from placebo on change from baseline DAS28 (CRP)² response (GLPG3970 -1.29, placebo -1.24), nor on the majority of other efficacy endpoints.

Further development of Toledo product portfolio

GLPG3970 is the first compound from Galapagos' broad portfolio of novel molecules to provide clinical evidence for the potential role of SIK inhibition in inflammation. Biomarker data from these signal-finding studies with GLPG3970 will be further analyzed for signature profiles. Our aim with the Toledo program is to explore this novel mode of action fully and bring forward improved molecules directed toward SIK2/3 as well as other SIK selectivity profiles. Galapagos currently has two compounds exhibiting SIK2/3 inhibition in preclinical development.

"We are excited to demonstrate, for the first time, important biologic and clinical effects with a SIK inhibitor in patients with inflammatory conditions. This is a major achievement when working on a novel mode of action target class. The CALOSOMA trial in psoriasis patients indicates clear proof of activity and the SEA TURTLE trial in ulcerative colitis patients provides encouraging results that support further development with Toledo compounds with improved pharmacology. In addition, these studies in patients confirm the safety and tolerability profile previously observed in healthy volunteers," said Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos. "The GLPG3970 broad dataset is an important step forward, and we aim to apply key learnings from these studies to the further development of our Toledo portfolio of SIK inhibitors."

Galapagos intends to submit study outcomes with GLPG3970 for publication at scientific conferences and in peer-reviewed medical journals.

About Toledo

"Toledo" is an extensive program with a novel target class, SIK, whose potential role in inflammation was discovered by Galapagos. The Toledo program aims to treat a broad range of autoimmune conditions with important unmet medical needs. The Toledo platform delivers small molecule inhibitors of SIK targets with different selectivity profiles. The most advanced compound, SIK2/3 inhibitor GLPG3970, has shown immunomodulatory activity *in vitro* preclinically and *ex vivo* clinically with what Galapagos believes is a dual mode of action characterized by enhanced transcription of anti-inflammatory cytokines and inhibited transcription of pro-inflammatory cytokines. SIK inhibition has previously shown encouraging preclinical activity in a range of inflammatory disease models.

GLPG3970 is an investigational drug and not approved by any regulatory authority. Its efficacy and safety have not been established.

² DAS28 is a RA Disease Activity Score based on a calculation that uses tender and swollen joint counts of 28 defined joints, the physician's global health assessment and a serum marker for inflammation, such as C-reactive protein. DAS28 (CRP) includes the C-reactive protein score calculation

About Galapagos

Galapagos NV (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, several of which show promising patient results and are currently in clinical development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis, 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.glpg.com.

This press release contains inside information within the meaning of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation).

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Galapagos Forward-Looking Statements

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