
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES
EXCHANGE ACT OF 1934**

For the month of July 2021

Commission File Number: **001-37384**

GALAPAGOS NV

(Translation of registrant's name into English)

Generaal De Wittelaan L11 A3 2800 Mechelen, Belgium

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

The information contained in this Report on Form 6-K, including Exhibit 99.1, except for the quote of Dr. Walid Abi-Saab contained in Exhibit 99.1, is hereby incorporated by reference into the Company's Registration Statements on Forms F-3 (File No. 333-230639) and S-8 (File Nos. 333-204567, 333-208697, 333-211834, 333-215783, 333-218160, 333-225263, 333-231765 and 333-249416).

On July 14, 2021, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

[\(c\) Exhibit 99.1. Press release dated July 14, 2021](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GALAPAGOS NV
(Registrant)

Date: July 14, 2021

/s/ Xavier Maes
Xavier Maes
Company Secretary

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 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.

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.glp.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

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with GLPG3970 may not be completed in the currently envisaged timelines or at all, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support registration or further development of GLPG3970 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties and that Galapagos' estimations regarding its GLPG3970 development program and regarding the commercial potential of GLPG3970 as well as regarding its Toledo platform, may be incorrect, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2020 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.

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

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