Galapagos Announces Topline Results from Two Phase 3-Enabling Studies with Selective TYK2 Inhibitor GLPG3667 in Dermatomyositis and Systemic Lupus Erythematosus

GLPG3667 met primary endpoint in dermatomyositis study, demonstrating a statistically significant clinical benefit and meaningful improvements on secondary measures of disease activity compared to placebo

In the systemic lupus erythematosus study, GLPG3667 delivered numerical improvements on several secondary endpoints compared to placebo but did not achieve statistical significance in primary endpoint analysis

The safety profile was consistent with previous studies with GLPG3667

Galapagos will evaluate all strategic alternatives, including resumption of its partnering process, to accelerate further development of GLPG3667 in dermatomyositis and potentially other severe auto-immune indications

Mechelen, Belgium; December 18, 2025, 22:01 CET; regulated information – inside information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced the topline results from two Phase 3-enabling studies evaluating the efficacy and safety of GLPG3667, a selective TYK2 inhibitor, in patients with dermatomyositis (DM) (GALARISSO study) and active systemic lupus erythematosus (SLE) (GALACELA study).

The GALARISSO DM study met its primary endpoint, showing that GLPG3667, administered once daily at 150 mg (N=21) in addition to standard-of-care therapy, achieved a statistically significant clinical benefit in the Total Improvement Score (TIS)[1] at Week 24 (p=0.0848; Δ: 14.26), compared to placebo (N=19). The pre-specified threshold of statistical significance was set at 10% (α=0.1). GLPG3667 also showed meaningful clinical improvements compared to placebo on several secondary endpoints of disease activity, including TIS20, TIS40, TIS60 and m-CDASI-A[2]. GLPG3667 demonstrated a favorable safety and tolerability profile throughout the 24-week treatment period.

“The results from the GALARISSO study demonstrate that GLPG3667 has the potential to become an important new treatment option for patients living with dermatomyositis, a debilitating autoimmune disease with limited therapeutic alternatives,” said Prof. Dr. Rohit Aggarwal, University of Pittsburgh Medical Center (UPMC). “Furthermore, the improvements in patients’ disease activity observed in the study are encouraging. We look forward to further analyzing the data, including the long-term follow-up study with GLPG3667 in this indication.”

In the GALACELA SLE study, GLPG3667, administered once daily at 75 mg (N=59) and 150 mg (N= 64) in addition to standard-of-care therapy, the primary endpoint analysis of dose-response on SLE responder index (SRI)-4 at Week 32 did not meet statistical significance. However, GLPG3667 showed numerical improvements over placebo (N=63) on several secondary endpoints, particularly on skin-related outcomes. The safety profile was consistent with previous studies with GLPG3667. The GALACELA study is currently ongoing, and the final Week

[1] *Minimal improvement per ACR/EULAR is defined as a total improvement score (TIS) of >= 20 points. The TIS is a score derived from the evaluation of the results from 6 core set measurements of myositis disease activity.*
[2] *M-CDASI-A: Modified Cutaneous Dermatomyositis Disease Area and Severity Index Activity.*

48 data, expected in the second quarter of 2026, will be essential to assess the totality of the evidence and determine potential next steps for the SLE program.

Commenting on the topline results, Henry Gosebruch, CEO of Galapagos, said: "The positive results from the GALARISSO study in patients with dermatomyositis further validate the anti-inflammatory potential of our selective TYK2 inhibitor, consistent with findings from our earlier Phase 1b psoriasis study and supportive *in vitro* pharmacology. We are encouraged by the favorable safety profile observed to date, which may contribute to the differentiated profile of GLPG3667. As part of our ongoing efforts to maximize the value of this program for both patients and Galapagos, we are evaluating all strategic options. These include resuming potential partnering discussions announced earlier this year to accelerate development in dermatomyositis, as well as exploring opportunities to expand into other severe autoimmune diseases with significant unmet medical need."

The Company aims to present data at an upcoming medical conference.

Gilead agreed to temporarily waive certain rights under the 10-year global Option, License and Collaboration Agreement between Galapagos and Gilead, enabling Galapagos to pursue external partnership opportunities for GLPG3667.

About GLPG3667, the GALARISSO (NCT: 05695950) and GALACELA (NCT: 05856448) studies
GLPG3667 is an investigational reversible and selective tyrosine kinase 2 (TYK2) kinase domain inhibitor currently being evaluated in two Phase 3-enabling studies for dermatomyositis (DM) and systemic lupus erythematosus (SLE).

GALARISSO is a Phase 3-enabling randomized, double-blind, placebo-controlled, multi-center proof-of-concept study to evaluate the efficacy and safety of GLPG3667. A daily oral administration of GLPG3667 150 mg or placebo is being investigated in adult patients with DM over 24 weeks. At Week 24, patients have been offered the possibility to enter a long-term extension study for an additional 24-week period where they will all receive GLPG3667 150 mg daily (once a day). The primary endpoint is the Total Improvement Score (TIS) at Week 24 according to the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) criteria. The secondary efficacy endpoints at Week 24 are the proportion of patients who achieve at least minimal improvement according to the ACR/EULAR criteria, the change from baseline in Modified-Cutaneous DM Disease Area and Severity Index Activity Score (m-CDASI-A), the change from baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI), and the change from baseline in the Manual Muscle Test (MMT-8).

GALACELA is a Phase 3-enabling randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of GLPG3667 in adults with active SLE. Two once-daily oral doses of GLPG3667 (75 mg and 150 mg) or placebo are being investigated in adult patients with SLE for 48 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 SRI-4 response at Week 48, the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) response at Weeks 32 and 48, proportion of patients with >=50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) score at Weeks 32 and 48, proportion of patients who achieve Lupus Low Disease Activity State (LLDAS) at Weeks 32 and 48 and change from baseline in the 28-joint count for tender, swollen, and tender and swollen (active) joints at Weeks 32 and 48.

About Dermatomyositis (DM)
Idiopathic inflammatory myopathies (IIM) are a heterogenous group of rare autoimmune disorders primarily affecting the proximal muscles. They are characterized by severe muscle weakness, muscle enzyme elevations, inflammation on muscle biopsy, and extra-muscular manifestations. DM is the most common form of IIM and is characterized by inflammatory and degenerative changes of the muscles and skin. Early symptoms of DM include distinct skin manifestations accompanying or preceding muscle weakness. The quality of life (QoL) of patients with DM is impaired due to muscle weakness, pain and skin disease activity.[3] The overall mortality ratio in DM patients also remains three times higher when compared to the general population; with cancer, lung, and cardiac complications and infections being the most common causes of death.[4] DM-specific prevalence has been estimated at one to six per 100,000 adults in the United States, and a recent analysis of 3,067 patients in the Euromyositis registry identified DM in 31% of the sampled patients.[5] DM is a rare disease and with only one currently approved treatment, there is a high unmet need for alternative safe and effective treatment options.

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.[6] 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).[7] 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.

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

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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[3] *Goreshi R, et al. Quality of life in dermatomyositis. J Am Acad Dermatol. 2011 Dec;65(6):1107-16.*
[4] *Marie I. et al. Morbidity and mortality in adult polymyositis and dermatomyositis. Curr Rheumatol Rep. 2012 Jun;14(3):275-85.*
[5] *DeWane ME, et al. Dermatomyositis: Clinical features and pathogenesis. J Am Acad Dermatol. 2020 Feb;82(2):267-281.*
[6] *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.*
[7] *González, L. A. et al (2013). Ethnicity in systemic lupus erythematosus (SLE): its influence on susceptibility and outcomes. Lupus, 22(12), 1214–1224.*

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Forward-looking statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "expect," "plan," "estimate," "will," "continue," "aim," "intend," "future," "potential," "could," "indicate," "forward," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding the GALACELA and GALARISSO Phase 3-enabling studies, statements regarding the expected timing, design and readouts of the GALACELA and GALARISSO studies, and statements regarding the potential benefits of GLPG3667. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause Galapagos' actual results to be materially different from those expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that preliminary or interim clinical results may not be replicated in ongoing or subsequent clinical trials, the risk that ongoing and future clinical studies with GLPG3667 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 development program may not support registration or further development of GLPG3667 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties, and that Galapagos' estimations regarding its GLPG3667 program and regarding the commercial potential of GLPG3667 may be incorrect, as well as those risks and uncertainties identified in Galapagos' Annual Report on Form 20-F for the year ended 31 December 2024 filed with the U.S. Securities and Exchange Commission (SEC) and its 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, unless specifically required by law or regulation.