

Galapagos announces start of Phase 2 study with selective TYK2 inhibitor, GLPG3667, in patients with dermatomyositis

- 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, if approved, has the potential to be the first selective oral TYK2 inhibitor in dermatomyositis

Mechelen, Belgium; 23 May 2023, 22:01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) today announced that the first patient was dosed in GALARISSO, the Phase 2 dermatomyositis (DM) trial with GLPG3667.

The GALARISSO Phase 2 trial ([NCT05695950](https://clinicaltrials.gov/ct2/show/study/NCT05695950)) is a randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of GLPG3667. A daily oral administration of GLPG3667 150mg or placebo will be investigated in approximately 62 adult patients with DM over 24 weeks. The primary endpoint is the proportion of patients with at least minimal improvement in the signs and symptoms of DM at Week 24 according to the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) criteria.¹

“We remain committed to delivering transformational medicines to patients living with severe immunological disorders and are pleased to further advance our novel, orally administered TYK2 inhibitor, GLPG3667, into Phase 2 development in dermatomyositis,” said Daniele D’Ambrosio, MD, PhD, Therapeutic Area Head, Immunology, at Galapagos. “Dermatomyositis is a debilitating inflammatory disease marked by muscle weakness and a distinctive skin rash that can severely impact patients’ daily lives. There is a significant unmet need for effective and convenient treatment options for patients living with this rare disease, and we hope that our novel drug-candidate can help address this need and improve patient outcomes.”

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 dermatomyositis

Idiopathic inflammatory myopathies (IIM) are a heterogeneous 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.² 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

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 Goshi R, et al. Quality of life in dermatomyositis. *J Am Acad Dermatol.* 2011 Dec;65(6):1107-16.

common causes of death.³ 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.⁴ 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 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 a 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 available in Europe and Japan. For additional information, please visit www.glp.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 are not always, made through the use of words or phrases such as “will,” “can,” “commit,” “deliver,” “potential,” “remains,” “advance,” and “improve,” as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements related to our plans and strategy with respect to GLPG3667, including our planned Phase 2 clinical development in dermatomyositis with GLPG3667 and, the GALARISSO study, statements in relation to the envisaged timelines for the GALARISSO study, statements regarding patient enrollment for the Phase 2 program with our TYK2 inhibitor product candidate, GLPG3667, and statements regarding the timing or likelihood of approval for our product candidate, GLPG3667, for DM. Any forward-looking statements in this release are based on our management’s current expectations and beliefs and are not guarantees of future performance. Forward-looking statements 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 forward-looking statements. These risks, uncertainties and other factors include, without limitation, the risk that the clinical study with GLPG3667 for DM, GALARISSO, and any future clinical studies with GLPG3667 may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties associated with competitive developments, clinical trial and product development activities, including with respect to the GALARISSO study, risks related to regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support registration of GLPG3667 due to safety, efficacy or other reasons), risks related to our reliance on collaborations with third parties, the risk that our estimations regarding our GLPG3667 development program and regarding the commercial potential of GLPG3667 may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will need to revise our business plan, and risks related to the ongoing COVID-19 pandemic, as well as those risks and uncertainties identified in our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (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 such 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

³ Marie I. et al. Morbidity and mortality in adult polymyositis and dermatomyositis. *Curr Rheumatol Rep.* 2012 Jun;14(3):275-85.

⁴ DeWane ME, et al. Dermatomyositis: Clinical features and pathogenesis. *J Am Acad Dermatol.* 2020 Feb;82(2):267-281.

publication of this release. We expressly disclaim any obligation to update any such forward-looking statements in this release unless required by law or regulation.