Galapagos completes patient recruitment for MANGROVE Phase 2 trial with GLPG2737 in polycystic kidney disease

Mechelen, Belgium; 22 November 2021, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) announces completion of recruitment in the MANGROVE Phase 2 trial with investigational CFTR inhibitor GLPG2737 in patients with autosomal dominant polycystic kidney disease (ADPKD).

MANGROVE is a randomized, double-blind, placebo-controlled trial evaluating a once-daily oral dose of GLPG2737 (NCT04578548). The drug candidate or placebo is administered for 52 weeks, followed by an open-label extension period of 52 weeks, in 66 ADPKD patients with rapidly progressing disease. Patients are randomized in a 2:1 ratio of treatment to placebo. Primary objectives of the trial are to assess the effect on growth of total kidney volume over 52 weeks compared to placebo as well as overall safety and tolerability. Secondary objectives include renal function, pharmacokinetics, and pharmacodynamics. Recruitment for the MANGROVE trial was conducted in 7 countries in Europe.

GLPG2737 is a CFTR[1] inhibitor which was observed to be well tolerated by patients in previous clinical trials. It is hypothesized that inhibition of the CFTR channel might reduce cyst growth and kidney enlargement for patients with ADPKD.

Galapagos expects topline results from the MANGROVE Phase 2 trial in the first half of 2023.

"We thank the ADPKD community for participating in the MANGROVE Phase 2 trial with GLPG2737," said Dr. Walid Abi-Saab, Chief Medical Officer of Galapagos. "Polycystic kidney disease patients have a real need for new therapy options. We hope to learn in 2023 from this trial what CFTR modulation may be able to achieve against ADPKD, in our mission to bring new medicines to kidney disease patients."

About ADPKD
Autosomal dominant polycystic kidney disease affects approximately 12.5 million people worldwide and is the fourth leading cause of kidney failure today.[2] Typically with this disease, both kidneys enlarge with fluid-filled cysts, leading to kidney failure for approximately half of patients by the age of 60 and requiring dialysis and possibly kidney transplantation.[3] Patients may also suffer from hypertension, abdominal pain, kidney infections, cyst ruptures, bleeding, and other symptoms impacting quality of life. Other organs may be affected as well. Treatment is aimed at relieving symptoms and controlling the accompanying hypertension. Currently, only one therapy (tolvaptan) is available to slow down the progression of cyst development and renal insufficiency; however, not all patients tolerate this therapy.[4]

About Galapagos
Galapagos NV discovers, develops, and commercializes small molecule medicines with novel modes of action. 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 is available at www.glpg.com.

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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, 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 GLPG2737 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 GLPG2737 due to safety or efficacy concerns or other reasons), Galapagos' reliance on collaborations with third parties, and that Galapagos' estimations regarding its GLPG2737 development program, regarding the potential value of CFTR inhibition as a mechanism to treat ADPKD, and regarding the commercial potential of GLPG2737, 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.

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[1] Cystic Fibrosis Transmembrane Conductance Regulator

[2] Chebib F.T., Torres V.E. Autosomal Dominant Polycystic Kidney Disease: Core Curriculum 2016. *Am J Kidney Dis*. May 2016, 67 (5) 792-810

[3] Parfrey P.S., Bear J.C., Morgan J., Cramer B.C., McManamon P.J., Gault M.H., et al. The diagnosis and prognosis of autosomal dominant polycystic kidney disease. *N Engl J Med.* 1990;323(16):1085–90

[4] Chebib F.T., Perrone R.D., Chapman A.B., Dahl N.K., Harris P.C., Mrug M., et al. A Practical Guide for Treatment of Rapidly Progressive ADPKD with Tolvaptan. *JASN*. October 2018, 29 (10) 2458-2470