Galapagos announces first dosing in MANGROVE Phase 2 trial with GLPG2737 in polycystic kidney disease

Mechelen, Belgium; 1 December 2020, 22.01 CET; Galapagos NV (Euronext & NASDAQ: GLPG) announces first dosing in the new 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. The drug candidate or placebo will be administered for 52 weeks in up to 60 ADPKD patients with rapidly progressing disease. Patients will be randomized in a 2:1 ratio of treatment to placebo. Primary objectives of the trial are to assess the growth of total kidney volume over 52 weeks compared to placebo as well as overall safety and tolerability. Secondary measures include renal function, pharmacokinetics, and pharmacodynamics. Recruitment for the MANGROVE trial is planned in 7 countries in Europe.

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

"GLPG2737 presents a potential opportunity for us in ADPKD, a disease with significant unmet need," added Dr. Piet Wigerinck, Chief Scientific Officer of Galapagos. "In MANGROVE we have a clinically meaningful trial that we anticipate will give us new insights into the potential value of CFTR inhibition as a mechanism to treat this serious, rapidly progressing disease."

About ADPKD

Autosomal dominant polycystic kidney disease affects approximately 15 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 (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 late-stage development in multiple diseases. The company's pipeline comprises early discovery through to Phase 3 programs in inflammation, fibrosis, and other indications. Galapagos' 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.

GLPG2737 is an investigational drug and its efficacy and safety have not been established.

For more information about our early clinical programs: www.glpg.com/other-programs
For information about the studies with GLPG2737 in ADPKD (NCT04578548): www.clinicaltrials.gov

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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, efficacy 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 2019 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] U.S. Renal Data System. USRDS 2014 *Annual Data Report*. 2014

[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