

Galapagos' GLPG0634 shows excellent efficacy and safety in rheumatoid arthritis Phase II study

- **Statistically significant improvement already seen in four weeks:**
 - **83% of patients showed improvement in ACR20 score**
 - **half of treated patients went into remission or showed a low disease activity**
- **Unique and clean safety profile: neither anemia nor increase in LDL/cholesterol observed**
- **First JAK1 selective compound to demonstrate clinical efficacy**
- **Achievement of 2011 revenue and profit guidance depends on partnering of the program**

Webcast press conference presentation at 15.00 Central European Time (CET)/9:00 AM EST, www.glpq.com, call number +32 2290 1608

Mechelen, Belgium; 22 November 2011– Galapagos NV (Euronext: GLPG) announced that its JAK1 inhibitor, GLPG0634, achieved the primary endpoint of significant improvement in the signs and symptoms of rheumatoid arthritis (RA). GLPG0634 is a selective inhibitor of JAK1 (Janus kinase 1) being developed for inflammatory conditions, such as rheumatoid arthritis (RA).

Efficacy results at week four

	Placebo n=12	GLPG0634			Pooled vs. placebo
		100 mg BID n=12	200 mg QD n=12	Pooled n=24	
ACR20 (%)	33.3	91.7	75.0	83.3	p=0.0067
ACR50 (%)	8.3	58.3	25.0	41.7	p=0.0591
ACR70 (%)	0	25.0	16.7	20.8	ns
DAS28 (change)	- 0.20	- 2.98	- 2.28	- 2.63	p<0.0001
CRP (change, mg/L)	21.9	- 13.8	- 35.0	- 24.4	p<0.0001

In this four week, Proof-of-Concept trial in 36 RA patients, GLPG0634 was administered in two dosage arms of 200 mg: one group taking a once-daily dose (QD), and the other taking twice-daily doses of 100 mg (BID). GLPG0634 met the primary endpoint of significant improvement in

ACR20¹ response rate and showed impressive results in secondary efficacy endpoints: ACR50, ACR70, DAS28² and CRP (C-reactive protein). GLPG0634 was well-tolerated, with all patients completing the trial and no safety signals reported. No anemia or increases in lipids (LDL or cholesterol) were observed in this trial. No severe adverse events were reported in patients receiving GLPG0634.

"We noticed a rapid and remarkable response for the RA patients participating in this trial, with no treatment-emergent safety signals arising," said Minodora Mazur, MD, PhD, *Professor Internal Medicine & Rheumatology, State Medical and Pharmaceutical University "Nicolae Testemitanu"* and Principal Investigator for the trial. "Patients did very well while on therapy – in fact, many reported significant improvements after one week of treatment."

"Despite the short duration of the trial, GLPG0634 shows one of the highest initial response rates ever reported for rheumatoid arthritis treatments. If this efficacy and safety profile is maintained in longer treatment studies, GLPG0634 has the potential to become a blockbuster treatment for RA and other inflammatory diseases," said Piet Wigerinck, *Senior Vice President Development of Galapagos*.

"Galapagos identified the JAK1 target with its proprietary target discovery platform back in 2003, well before JAK inhibitors were evaluated clinically. Since then, we have developed the target all the way into GLPG0634. This clearly demonstrates the power of our target and drug discovery capabilities and validates our innovative approach," said Onno van de Stolpe, *CEO of Galapagos*.

Galapagos plans to initiate an extended dose-range finding study for GLPG0634 in the first half of 2012. This will further define the optimal doses for efficacy and safety to be evaluated in longer term studies in patients. GLPG0634 is a fully proprietary program.

Galapagos has given 2011 financial guidance for the Group of €146 million in revenues, a positive operational result and cash flow and a positive net result. This guidance will only be achievable in the event the GLPG0634 program is successfully partnered before year end. Galapagos is in discussions with a number of pharma partners regarding the program, but the Company has not yet decided whether or not to partner, and on which conditions. This important choice will be made with a focus on maximizing the long term value for shareholders.

Conference call and webcast presentation

Galapagos will conduct a conference call today, 22 November 2011, at 15.00 Central European Time (CET)/9:00 AM EST, which will also be webcast ([view webcast](#)). To participate in the conference call or the question and answer session following the presentation, please call +32 2290 1608 ten minutes prior to commencement. The archived webcast also will be available for replay shortly after the close of the call.

Details of the Phase II clinical trial

¹ ACR20 (American College of Rheumatology 20%) response rate signifies a 20% or greater improvement in the number of swollen and tender joints as well as a 20% or greater improvement in three out of five other disease-activity measures.

² DAS28 is an RA Disease Activity Score based on C-reactive protein, tender and swollen joint counts of 28 defined joints and physician's global health assessment; a total score of >5.1 is associated with high disease activity, moderate from 3.2 to 5.1, low disease activity from 2.6, and remission of disease if <2.6.

The clinical Proof-of-Concept Phase II trial (study identifier: NCT01384422, Eudract: 2010-022953-40) for GLPG0634 involved 36 patients with active rheumatoid arthritis, showing an insufficient response to the standard-of-care treatment, methotrexate (MTX). The aim of this study was to evaluate the efficacy and safety of GLPG0634 in patients with active rheumatoid arthritis. Three groups of 12 patients with moderate to severe disease received either a 200 mg once-daily or a 100 mg twice-daily dose regimen of GLPG0634 or placebo, for a period of four weeks, while continuing to take their stable background therapy of MTX and other low-dose anti-inflammatory drugs. The primary efficacy endpoint was the ACR20 response rate, the standard primary endpoint for early RA clinical trials. Secondary endpoints included improvements in ACR50, ACR70 and DAS28 rates. The safety, tolerability, pharmacokinetics and pharmacodynamics of GLPG0634 in RA patients were also evaluated.

About candidate drug GLPG0634

GLPG0634 is an orally-available, novel Janus kinase (JAK) inhibitor with selectivity for JAK1 developed by Galapagos. JAKs are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in rheumatoid arthritis patients. Other nonselective JAK inhibitors have shown long-term efficacy in rheumatoid arthritis trials with an early onset of action. Galapagos aimed to differentiate GLPG0634 from other JAK inhibitors in development by specifically targeting JAK1, a strategy which could result in a cleaner safety profile, as the data of this Proof-of-Concept study supports.

About Galapagos

[Galapagos](#) (Euronext: GLPG; OTC: GLPYY) is a mid-size biotechnology company specialized in the discovery and development of small molecule and antibody therapies with novel modes-of-action. The Company is progressing GLPG0634, as well as one of the largest pipelines in biotech, with seven programs in development and over 50 discovery programs. Through risk/reward-sharing alliances with GlaxoSmithKline, Lilly, Janssen Pharmaceutica, Roche and Servier, Galapagos is eligible to receive up to €2.8 billion in downstream milestones, plus royalties. The Galapagos Group has about 800 employees and operates facilities in six countries, with global headquarters in Mechelen, Belgium. More info at: www.glpq.com

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