

## **AbbVie and Galapagos extend GLPG0634 collaboration to include Crohn's disease**

- **First selective JAK1 inhibitor to enter Phase 2 studies in Crohn's disease**
- **Galapagos to fund and complete Phase 2 study; AbbVie to pay Galapagos \$50 million upon successful completion, expected in 2015**

**North Chicago, USA and Mechelen, Belgium; 17 May 2013 – Galapagos NV (Euronext: GLPG) and AbbVie (NYSE: ABBV) announced today an extension of their GLPG0634 clinical development collaboration to include Crohn's disease. Galapagos will fund and complete a Phase 2 program in Crohn's disease, which is designed to facilitate rapid progression into Phase 3. Upon successful completion of the study, expected in Q2 2015, AbbVie will pay Galapagos \$50 million. The terms of the collaboration extension are in addition to previously agreed upon financial terms. AbbVie will be responsible for funding and performing clinical development beyond Phase 2, and completing regulatory and commercialization activities.**

Galapagos will start an innovative 20-week, Phase 2A/B study with GLPG0634 in 180 patients suffering from Crohn's disease by early 2014. The study will measure both induction of disease remission and early maintenance of its beneficial effects in Crohn's disease, and is expected to read out topline results in Q2 2015. This Phase 2 study in Crohn's will be performed in parallel with the Phase 2B study in rheumatoid arthritis (RA).

Crohn's disease is a serious chronic, inflammatory autoimmune disease of the gastrointestinal (GI) tract that affects millions of people worldwide, including more than one million people in Europe and more than 500,000 people in the U.S. The Janus kinases (JAK) are a family of enzymes that play a key role in the signaling mechanism used by a number of cytokines that are involved in autoimmune diseases. JAK inhibitors, with their immune-modulating effects, have the potential to become an effective treatment option for this disease. By inhibiting JAK1, GLPG0634 blocks signaling for several key pro-inflammatory cytokines such as interleukin 6 (IL-6). Its selective JAK1 inhibition profile avoids inhibition of JAK2 which offers a unique advantage in Crohn's disease. Inhibition of JAK2 has shown anemia and reduced formation of blood cells in clinical studies with other JAK inhibitors, which is a particular concern in patients with inflammatory bowel disease, as blood loss through gastrointestinal bleeding often already causes anemia in these patients. Therefore, GLPG0634 may potentially support a better safety profile than other JAK inhibitors.

"AbbVie supports the start of this innovative study in Crohn's disease with GLPG0634. Our experience within gastroenterology, combined with a novel alternative treatment for this disease may provide a greater benefit to patients in the future," said Scott Brun, M.D., vice president, pharmaceutical development, AbbVie.

"Galapagos and AbbVie are moving forward with GLPG0634, expanding the scope of the development program into inflammatory bowel disease. The innovative Phase 2 program in Crohn's disease is designed to move rapidly into Phase 3 when successful," said Onno van de Stolpe, CEO of Galapagos. "Galapagos is in a strong financial position to fund the Crohn's

program, in addition to the Phase 2b program with GLPG0634 in RA and our other proprietary clinical and pre-clinical programs. Our pipeline continues to mature in stage and scope, now that we have three Phase 2 molecules in five inflammatory indications, all with readouts by mid 2015 or earlier.”

#### **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 signalling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in rheumatoid arthritis patients. JAK inhibitors have shown long-term efficacy in rheumatoid arthritis studies with an early onset of action. GLPG0634 differentiates from other JAK inhibitors in development by specifically targeting JAK1, a strategy which could result in a better efficacy and safety profile. GLPG0634 is a fully proprietary program. Upon successful completion of the Phase 2b studies in RA, AbbVie will license the program and will assume sole responsibility for Phase 3 clinical development and global manufacturing.

#### **About Crohn’s disease**

Crohn’s disease is a type of inflammatory bowel disease in which the well-controlled balance of the intestinal immune system is disturbed. The disease causes ulcerations of the small and large intestines in particular, but may affect any part of the digestive system from mouth to anus. The cause of the disease is unknown, with onset usually between the ages of 15 and 35. Patients suffer from abdominal pain, diarrhea (often bloody), vomiting, fever, and weight loss. There is no cure for Crohn’s disease; treatment options today are restricted to controlling symptoms, maintaining remission, and preventing relapse by the use of drugs that suppress the inflammation or the immune system, antibiotics, and eventually surgical removal of the inflamed bowels. Driven by new therapies in development, Decision Resources estimates that the market for Crohn’s disease treatment will grow from \$3.8 Billion in 2011 to \$5.6 Billion in 2021.

#### **About AbbVie**

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott. The company’s mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world’s most complex and serious diseases. In 2013, AbbVie employs approximately 21,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit [www.abbvie.com](http://www.abbvie.com). Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](https://www.facebook.com/abbvie) or [LinkedIn](https://www.linkedin.com/company/abbvie) page.

#### **About Galapagos**

[Galapagos](http://www.galapagos.com) (Euronext: GLPG; OTC: GLPYY) is specialized in novel modes-of-action, with a large pipeline of four clinical, seven pre-clinical, and 30 discovery small-molecule and antibody programs in cystic fibrosis, inflammation, antibiotics, metabolic disease, and other indications.

[GLPG0634](http://www.galapagos.com) is an orally-available, selective inhibitor of JAK1 for the treatment of rheumatoid arthritis and potentially other inflammatory diseases, about to enter Phase 2b studies in RA and Phase 2 studies in Crohn’s disease. AbbVie and Galapagos signed a worldwide license agreement whereby AbbVie will be responsible for further development and commercialization after Phase 2b. Galapagos has another selective JAK1 inhibitor in Phase 2 in lupus and psoriasis, GSK2586184 (formerly GLPG0778, in-licensed by GlaxoSmithKline in 2012). [GLPG0187](http://www.galapagos.com) is a novel integrin receptor antagonist currently in a Phase 1b patient study in metastasis. [GLPG0974](http://www.galapagos.com) is the first inhibitor of GPR43 to be evaluated clinically for the treatment of IBD; this program is currently in a Proof of Concept Phase 2 study.



The Galapagos Group, including fee-for-service companies [BioFocus](#), [Argenta](#) and [Fidelta](#), has 800 employees and operates facilities in five countries, with global headquarters in Mechelen, Belgium. Further information at: [www.glpj.com](http://www.glpj.com)

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## Galapagos forward-looking statements

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## AbbVie forward-looking statements

*Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in our 2012 Annual Report on Form 10-K/A, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to*

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*forward-looking statements as a result of subsequent events or developments, except as required by law.*