# AbbVie and Galapagos to Co-Develop Cystic Fibrosis Therapies

Galapagos to host webcast presentation today at 15.00 CET/ 9 am ET/ 6 am PT

NORTH CHICAGO, III. and MECHELEN, Belgium, Sept. 24, 2013 -- Galapagos NV (Euronext: GLPG) and AbbVie (NYSE: ABBV) announced today that they have entered into a global alliance to discover, develop and commercialize novel potentiator and combination therapies in cystic fibrosis (CF), an inherited chronic disease that affects 70,000 people worldwide.

AbbVie and Galapagos will work collaboratively to contribute technologies and resources in order to develop and commercialize oral drugs that address the main mutations in CF patients, including F508del and G551D. The goal of the collaboration is to identify compounds that correct defects in expression of (corrector) and/or increase the activity (potentiator) of the main mutations in the cystic fibrosis transmembrane regulator (CFTR) protein, including the F508del mutation, which is the most common with 90 percent prevalence among patients with CF.

In the alliance, AbbVie and Galapagos will develop potentiators and correctors discovered by Galapagos and expand the range of molecules, with the aim to initiate Phase 1 clinical studies at the end of 2014. Following successful clinical development and regulatory approval, AbbVie will be responsible for commercial activities, with Galapagos retaining exclusive rights in China and South Korea and co-promotion rights in Belgium, the Netherlands, and Luxembourg.

Under the terms of the agreement, AbbVie will make an initial upfront payment of \$45 million to Galapagos for rights related to the global alliance. Upon successful completion of predetermined success milestones, AbbVie and Galapagos will share responsibility and funding for Phase III clinical development. Galapagos is eligible to receive up to \$360 million in total additional payments for developmental and regulatory milestones, sales milestones upon the achievement of minimum annual net sales thresholds and additional double-digit royalty payments on net sales.

"Galapagos is very pleased to join forces with AbbVie in this exciting new area of CF. Our programs in CF show promise. Partnering with AbbVie allows us to ramp up our commitment significantly, share development risk and expertise, and increase our chances of bringing best-in-class therapies to CF patients," said Onno van de Stolpe, chief executive officer, Galapagos.

"We're pleased to enhance our partnership with Galapagos to include research in cystic fibrosis, a debilitating disease with significant unmet medical need. Our knowledge of the patient experience, combined with innovative advances in the understanding of disease etiology, offers the potential for new transformational treatments," said Jim Sullivan, Ph.D., vice president, pharmaceutical discovery, AbbVie.

Galapagos initiated its research in CF in 2005 as part of a collaboration with the Cystic Fibrosis Foundation. In 2010, Galapagos decided to pursue CF as the first orphan disease in which the company is attempting to discover, develop and launch its own medicines. Galapagos has developed small molecule therapies that can restore the function of the defective CF protein (CFTR). The first pre-clinical candidate is expected to be nominated this year, with the first clinical trials starting at the end of 2014.

#### Webcast presentation

Galapagos will hold an audio webcast presentation for journalists, analysts, and investors today at 15.00 CET/9 am ET /6 am PT, viewable at <a href="https://www.glpg.com">www.glpg.com</a>.

# **About Cystic Fibrosis**

Cystic fibrosis (CF) is a hereditary disease of the entire body which leads to severe disability and early death in many cases. Symptoms include frequent lung infections, sinus infections, poor growth, and diarrhea. The cause is a defect in the gene which encodes for cystic fibrosis transmembrane conductance regulator (CFTR), a protein which regulates components of sweat, mucus, and digestive juices. CF affects approximately 70,000 people worldwide. Patient symptoms are treated with antibiotics and other medicines. There currently is no cure for the disease, and the predicted median age of survival is in the late 30s.

#### 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 <a href="https://www.abbvie.com">www.abbvie.com</a>. Follow <a href="mailto:@abbvie">@abbvie</a> on Twitter or view careers on our <a href="mailto:Facebook">Facebook</a> or <a href="mailto:LinkedIn">LinkedIn</a> page.

## **About Galapagos**

<u>Galapagos</u> (Euronext: GLPG; OTC: GLPYY) is specialized in novel modes-of-action, with a large pipeline of four clinical, six pre-clinical, and 20 discovery small-molecule and antibody programs in CF, inflammation, antibiotics, metabolic disease, and other indications.

AbbVie and Galapagos signed an agreement in CF where they work collaboratively to develop and commercialize oral drugs that address two mutations in the CFTR gene, the G551D and F508del mutation. In the field of inflammation, AbbVie and Galapagos signed a worldwide license agreement whereby AbbVie will be responsible for further development and commercialization of <a href="GLPG0634">GLPG0634</a> after Phase 2B. GLPG0634 is an orally-available, selective inhibitor of JAK1 for the treatment of rheumatoid arthritis and potentially other inflammatory diseases, currently in Phase 2B studies in RA and about to enter Phase 2 studies in Crohn's disease.

The Galapagos Group, including fee-for-service companies <u>BioFocus</u>, <u>Argenta</u> and <u>Fidelta</u>, has 800 employees and operates facilities in five countries, with global headquarters in Mechelen, Belgium. Further information at: <u>www.glpg.com</u>

## Galapagos forward-looking statements

This release may contain forward-looking statements, including, without limitation, statements containing the words "believes," "anticipates," "expects," "intends," "plans," "seeks," "estimates," "may," "will," "could," "stands to," and "continues," as well as similar expressions. Such forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions, performance or achievements expressed or implied by such forward-looking statements. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless required by law or regulation.

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

SOURCE: AbbVie

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