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AbbVie, Galapagos to make drugs for cystic fibrosis mutations

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Singapore: Europe-based Galapagos and AbbVie 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 I 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 pre-determined 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 Mr Onno van de Stolpe, CEO, 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 Dr Jim Sullivan, 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.