



# Shire to License PF-00547659 from Pfizer, Adding to Established and Leading Gastrointestinal Portfolio

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*PF-00547659 is being evaluated for inflammatory bowel disease and has completed Phase 2 trials*

**Lexington, Massachusetts, US** – June 14, 2016 – Shire plc (LSE: SHP, NASDAQ: SHPG) today announced it has agreed to license global rights to all indications for PF-00547659 from Pfizer Inc. (NYSE: PFE). PF-00547659 is an investigational biologic being evaluated for the treatment of moderate-to-severe inflammatory bowel disease (IBD). PF-00547659 has been evaluated in more than 700 patients in Phase 1 and 2 trials, and Phase 3 trials are expected to begin after consultation with global health authorities. Closing of the transaction is subject to HSR approval.

IBD includes ulcerative colitis (UC) and Crohn's disease (CD), which are serious, chronic diseases characterized by inflammation of the intestine; symptoms include abdominal pain, severe diarrhea, rectal bleeding, fatigue, and weight loss, and can be debilitating. Treatment of IBD focuses on reducing inflammation and associated symptoms through diet and lifestyle changes, pharmacologic therapy, other treatments, or surgery. The prevalence of IBD is estimated to be more than 3.5 million people in the United States, the European Union, and Japan.

“This licensing transaction fits with Shire’s commitment to advancing research and development in select specialty areas, including areas of unmet patient need for gastrointestinal conditions such as IBD,” said Howard Mayer, Head of Clinical Development, Shire. “We look forward to continuing the development of PF-00547659, a

biologic that will benefit from our experience in IBD and across the gastrointestinal space.”

Terms of the deal were not disclosed.

**PF-00547659 and Clinical Development Program** PF-00547659 is a fully-human monoclonal antibody that is designed to directly target a gastrointestinal (GI) endothelial adhesion molecule known as mucosal addressin cell adhesion molecule 1 (MAdCAM-1), that binds to the  $\alpha 4\beta 7$  integrin on lymphocytes (white blood cells).

PF-00547659 has completed Phase 2 clinical trials in UC and CD, known as TURANDOT and OPERA, respectively. TURANDOT met its primary and secondary end points; adult patients with moderate to severe active UC who failed at least one previous treatment who were treated with PF-00547659 showed an increased rate of remission, response, and mucosal healing at week 12, compared to placebo. The most commonly reported adverse events were consistent with the underlying disease.

The safety study TOSCA evaluated PF-00547659 in adult patients with moderate to severe CD with prior treatment with both anti-TNF and immunosuppressants (azathioprine, 6-MP or methotrexate). In patients who received a full induction course of the highest clinical dose of PF-00547659, there was no change in CSF lymphocyte cell count after treatment. Furthermore, in the completed Phase 2 clinical studies, there was no evidence of increased infection, including in MAdCAM-expressing tissues (gastrointestinal tract, nasal tissue, spleen, bladder, uterus and lung), and no progressive multifocal leukoencephalopathy.

Additionally, long-term treatment with PF-00547659 has been evaluated in the completed OPERA II CD study, and is ongoing in the TURANDOT II UC study.

**More About Inflammatory Bowel Disease (IBD)** IBD includes UC and Crohn’s disease. Both conditions often onset during young adulthood and have a relapsing-remitting course, where patients go through quiet periods (remission) and active periods with symptoms (flares). Specific symptoms of IBD vary from patient to patient, and can range from mild-to-moderate and moderate-to-severe. Different treatment options exist for IBD and may include diet and lifestyle changes, pharmacologic therapy, other treatments, or surgery.

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**NOTES TO EDITORS** Shire is the leading global biotechnology company focused on serving people with rare diseases and other highly specialized conditions. We have best-in-class products available in more than 100 countries across core therapeutic areas including Hematology, Immunology, Neuroscience, Lysosomal Storage Disorders, Gastrointestinal / Internal Medicine / Endocrine and Hereditary Angioedema; a growing franchise in Oncology; and an emerging, innovative pipeline in Ophthalmics.

Our employees come to work every day with a shared mission: to develop and deliver breakthrough therapies for the hundreds of millions of people in the world affected by rare diseases and other high-need conditions, and who lack effective therapies to live their lives to the fullest.

[www.shire.com](http://www.shire.com)

**Forward-Looking Statements** Statements included herein that are not historical facts, including without limitation statements concerning future strategy, plans, objectives, expectations and intentions, the anticipated timing of clinical trials and approvals for, and the commercial potential of, inline or pipeline products are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, the following:

disruption from the acquisition and integration of Baxalta Incorporated ("Baxalta") may make it more difficult to conduct business as usual or maintain relationships with patients, physicians, employees or suppliers; the company may not achieve some or all of the anticipated benefits of Baxalta's spin-off from Baxter International, Inc. ("Baxter") and the acquisition may have an adverse impact on Baxalta's existing arrangements with Baxter, including those related to transition, manufacturing and supply services and tax matters; the failure to achieve the strategic objectives with respect to the acquisition of Baxalta may adversely affect the company's financial condition and results of operations; products and product candidates may not achieve commercial success; product sales from ADDERALL XR and INTUNIV are subject to generic competition; the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for the company's products may affect future revenues,

financial condition and results of operations, particularly if there is pressure on pricing of products to treat rare diseases; supply chain or manufacturing disruptions may result in declines in revenue for affected products and commercial traction from competitors; regulatory actions associated with product approvals or changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches; the successful development of products in various stages of research and development is highly uncertain and requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval; the actions of certain customers could affect the company's ability to sell or market products profitably, and fluctuations in buying or distribution patterns by such customers can adversely affect the company's revenues, financial condition or results of operations; investigations or enforcement action by regulatory authorities or law enforcement agencies relating to the company's activities in the highly regulated markets in which it operates may result in significant legal costs and the payment of substantial compensation or fines; adverse outcomes in legal matters, tax audits and other disputes, including the company's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on the company's revenues, financial condition or results of operations; Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect the company's ability to attract and/or retain the highly skilled personnel needed to meet its strategic objectives; failure to achieve the strategic objectives with respect to Shire's acquisition of NPS Pharmaceuticals Inc. or Dyax Corp. ("Dyax") may adversely affect the company's financial condition and results of operations; the company is dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on the company's revenues, financial condition or results of operations; the company may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners; difficulties in integrating Dyax or Baxalta into Shire may lead to the company not being able to realize the expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all; and other risks and uncertainties detailed from time to time in Shire's, Dyax's or Baxalta's filings with the Securities and Exchange Commission, including those risks outlined in "ITEM 1A: Risk Factors" in Shire's and Baxalta's Annual Reports on Form 10-K for the year ended December 31, 2015.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.