

## Shire Acquires Premacure AB

Deal Enhances Shire's Late-Stage Pipeline with the Acquisition of a Phase II Protein Replacement Therapy Being Investigated for the Prevention of Retinopathy of Prematurity

**Lexington, MA, US – March 12, 2013** – Shire plc (LSE: SHP, NASDAQ: SHPG), announces that it has acquired Premacure AB of Uppsala, Sweden, a privately held biotechnology company developing a protein replacement therapy, currently in Phase II development, for the prevention of retinopathy of prematurity (ROP). ROP is a rare and potentially blinding eye disorder that primarily affects premature infants and is one of the most common causes of visual loss in childhood. Currently, only symptomatic treatment is available for ROP. Shire will purchase Premacure for an upfront payment and certain contingent payments based on the achievement of pre-specified development and commercial milestones. This acquisition underscores and expands Shire's commitment to bringing innovative therapies to patients with rare disorders worldwide.

During normal gestation, the developing fetus is reliant on certain growth factors from the maternal serum; full term babies can produce these growth factors on their own. In preterm infants (born before 31 weeks of gestation), the early separation from the maternal circulation results in a loss of specific growth factors, such as insulin-like growth factor 1 (IGF-1), that are believed to result in lifelong complications, including ROP.

This acquisition allows Shire HGT to enter a new therapeutic area – neonatology – while maintaining its focus on developing novel therapies for the treatment of rare diseases with high unmet medical need. With the acquisition of Premacure, Shire HGT will continue the ongoing Phase II study, the primary goal of which is to restore the IGF-1 levels in the preterm infant to those found during normal in utero development.

"ROP is a devastating eye disorder that can severely impact preterm infants for the rest of their lives," said Flemming Ornskov, MD, CEO Designate, Shire. "This investigational protein has the potential to provide a first-in-class treatment that may minimize the development and impact of complications arising from ROP. We will build on the work that Premacure has done and will apply Shire's proven ability in developing protein replacement therapies for rare disorders to bring this much needed therapy to the market."

"The acquisition of Premacure by Shire further underscores the potential to change the long-term outlook for preterm infants with ROP and their families," said Jan Borg, founding CEO of Premacure. "We are excited that this program will become part of the innovative pipeline at Shire and believe that their experience and resources may accelerate the development of a product that seeks to prevent some of the devastating long-term consequences of ROP."

Premacure AB is a private company launched in 2006 by entrepreneurs and internationally recognized clinicians in the area of neonatology.

### About ROP

Retinopathy of Prematurity (ROP) is a potentially blinding eye disorder that primarily affects premature infants weighing less than 2 pounds (about 1kg) who are born before 31 weeks of gestation (a full term pregnancy has a gestation of 38–42 weeks). The smaller a baby is at birth, the more likely that baby is to develop ROP. This disorder, which usually develops in both eyes, is one of the most common causes of visual loss in childhood and can lead to lifelong vision impairment and blindness.

In the US and EU, there are approximately 87,000 and 54,000 premature infants (born) born annually. Each year approximately 14,000–16,000 preterm infants in the US are affected by some degree of ROP. In 1,100–1,500 of these infants the ROP is severe enough to require medical treatment, and consequently 400–600 infants become legally blind.

### **About Insulin-Like Growth Factor 1**

IGF-1 is primarily produced by the liver and supports normal childhood growth and development. Administration of IGF-1 to premature infants, as a substitute for the maternal and endogenous source, allows for the establishment of a physiological level of the hormone comparable to that present in utero. Such a treatment is believed to promote normal development and thereby prevent the development of complications of ROP.

Premacure initiated the clinical development of the preventative treatment with a formulation of recombinant human IGF-1 combined with a recombinant version of its naturally occurring binding protein, insulin-like growth factor-1 binding protein-3 (IFGBP3).

A Phase I clinical trial was conducted and results showed that the levels of IGF-1 were increased to within physiological levels and that administration of the investigational protein to preterm infants is generally well tolerated. A Phase II, safety and efficacy multi-centre clinical trial has started in Sweden and is on-going.

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#### **Notes to editors**

**Shire enables people with life-altering conditions to lead better lives.**

Through our deep understanding of patients' needs, we develop and provide healthcare in the areas of:

- Behavioral Health and Gastro Intestinal conditions
- Rare Diseases
- Regenerative Medicine

as well as other symptomatic conditions treated by specialist physicians.

We aspire to imagine and lead the future of healthcare, creating value for patients, physicians, policymakers, payors and our shareholders.

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## **FORWARD - LOOKING STATEMENTS - "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

Statements included in this announcement that are not historical facts are forward-looking statements. 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, that:

- Shire's products may not be a commercial success;
- revenues from ADDERALL XR are subject to generic erosion;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payors in a timely manner for Shire's products may impact future revenues and earnings;
- Shire relies on a single source for manufacture of certain of its products and a disruption to the supply chain for those products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis;
- Shire uses third party manufacturers to manufacture many of its products and is reliant upon third party contractors for certain goods and services, and any inability of these third party manufacturers to manufacture products, or any failure of these third party contractors to provide these goods and services, in each case in accordance with its respective contractual obligations, could adversely affect Shire's ability to manage its manufacturing processes or to operate its business;
- the development, approval and manufacturing of Shire's products is subject to extensive oversight by various regulatory agencies and regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the actions of certain customers could affect Shire's ability to sell or market products profitably and fluctuations in buying or distribution patterns by such customers could adversely impact Shire's revenues, financial conditions or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire's activities in the highly regulated markets in which it operates may result in the distraction of senior management, significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire's ability to obtain, maintain, enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire's revenues, financial condition or results of operations;

and other risks and uncertainties detailed from time to time in Shire's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K.