Press Release

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Shire Regenerative Medicine Initiates Phase 3 Study of ABH001 for Patients with Epidermolysis Bullosa

San Diego, CA – February 8, 2013 – Shire plc (LSE: SHP, NASDAQ: SHPG), today announced the initiation of a Phase 3 study designed to evaluate the efficacy and safety of ABH001, its dermal substitute therapy, for the treatment of non-healing wounds in patients with Epidermolysis Bullosa (EB), a group of rare genetic skin disorders that begin to manifest at birth or early childhood and occur in approximately 19 per 1 million live births in the US. [i]

“People affected by EB suffer skin blisters and almost constant, acute pain and scarring,” said the study’s Principal Investigator, H. Alan Arbuckle, MD, Section Head Pediatric Dermatology Kaiser Permanente Colorado, Wound Care Consultant, Epidermolysis Bullosa Center of Excellence, The Children's Hospital, Aurora Colorado. “The current standard of care is daily wound care, bandaging and pain management. I am excited to be involved in testing the efficacy and safety of ABH001 as a potential treatment option for these patients.”

ABH001 for EB has been granted an orphan drug designation in the US and EU, and has also received Fast Track designation from the US Food and Drug Administration (FDA), which is aimed at facilitating the development and expediting the review of drugs and biologics that fill an unmet medical need. In addition, the European Medicines Agency’s Pediatric Committee has agreed on a pediatric investigation plan for ABH001 for the treatment of EB.

The new Phase 3 study is a multi-site, prospective, randomized, open-label, intra-subject controlled trial evaluating the efficacy and safety of ABH001 to initiate healing and reduce the wound surface area of selected stalled, chronic cutaneous wounds associated with generalized EB. Approximately 20 subjects with generalized EB aged three years and older are planned to enroll in the trial, which is targeted to be conducted in 10 to 15 sites across the US, Europe and Canada. The study will comprise ABH001 applications sufficient to cover the surface area of the wound, applied topically every 4 weeks with protocol-specified dressings until healed or for up to 24 weeks.

“We are excited that Shire Regenerative Medicine has launched this trial,” said Brett Kopelan, Executive Director of the Dystrophic EB Research Association of America (DebRA) and father to a 5-year-old girl with recessive dystrophic EB. “While there is currently no cure for EB, I am encouraged that ABH001 is…targeting the chronic wounds that are the hallmark of this disease. I applaud Shire for pushing this forward and look forward to working closely with them as the trial progresses.”

“We are very eager to begin evaluating ABH001 as a potential wound treatment option for people with EB. We believe it has the potential to initiate and continue wound healing in this patient population,” said Jeff Jonas, MD, President of Shire Regenerative Medicine. “We are committed to developing regenerative medicine solutions that enable people with life-altering conditions to lead better lives, and are encouraged by the fast track and orphan drug designations we have received to further develop this potential therapy for people, most often young children, suffering from this devastating condition.”

Shire is also developing an intravenous protein replacement therapy for the treatment of dystrophic EB, which the company’s Human Genetic Therapies business recently acquired from Lotus Tissue Repair, Inc. Initiation of this pivotal trial of ABH001 for patients with EB

further demonstrates Shire's commitment to developing a portfolio of products targeted toward patients who suffer from this disease.

ABH001 is comprised of allogenic neonatal dermal fibroblasts seeded on a poly(glycolide-co-L-lactide) scaffold, and is currently approved and marketed in the United States as a Class III medical device under the trade name Dermagraft® for the treatment of diabetic foot ulcers.

About Epidermolysis Bullosa (EB)
Epidermolysis Bullosa is a family of genetic skin fragility disorders, primarily clinically characterized by blistering of the skin in response to friction or minor trauma. Although genetically and phenotypically heterogeneous, the common factor in all EB patients is the near constant presence of skin erosions and wounds. Severe forms of EB cause patients to live with constant pain and scarring, and may be fatal.

About ABH001
ABH001 is a tissue-engineered, human fibroblast-derived dermal substitute generated by culturing human neonatal dermal fibroblasts onto a bioabsorbable polyglactin (PGLLA) mesh scaffold. The fibroblasts, which are grown onto the PGLLA mesh, secrete dermal collagen, other extracellular matrix proteins, growth factors, and cytokines, creating a three-dimensional human tissue containing metabolically active living cells. The final product consists of a well-developed dermal matrix and evenly dispersed neonatal dermal fibroblasts.

About Dermagraft
Dermagraft is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. Dermagraft should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. Dermagraft is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts. Dermagraft is contraindicated in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution.

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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.

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[i] Fine J-D, Johnson LB, Suchindran C, Gedde-Dahl T (1999e) The Epidemiology of Inherited Epidermolysis Bullosa: Findings in U.S., Canadian, and European Study Populations. In: Epidermolysis bullosa : clinical, epidemiologic, and laboratory advances, and the findings of the National Epidermolysis Bullosa Registry(Fine, J.-D. and National Epidermolysis Bullosa Registry (U.S.), eds), pp 101-113 Baltimore: Johns Hopkins University Press.