

## Shire Executes Agreement to Divest DERMAGRAFT®

**DUBLIN, Ireland, January 17, 2014** – Shire plc (LSE: SHP, NASDAQ: SHPG), the global specialty biopharmaceutical company, today announced that it has entered into a definitive agreement pursuant to which it has sold its DERMAGRAFT assets to Organogenesis Inc. DERMAGRAFT is a living skin substitute indicated for use in the treatment of full-thickness diabetic foot ulcers and is approved for use in the US and Canada. Going forward Organogenesis will assume all financial and management responsibility for DERMAGRAFT.

Flemming Ornskov MD, Chief Executive Officer of Shire commented: “Following the new strategy we outlined during the first half of last year, Shire has had a renewed focus on operational discipline. As such, we have been prioritizing investments that are of the greatest strategic, clinical and commercial value to our Company. DERMAGRAFT no longer meets these criteria and this divestment will allow us to focus our resources on other projects. Due to the recent Medicare ruling regarding reimbursement for DERMAGRAFT, the business environment has changed, and the prospects for the product have reduced significantly. We believe the best path forward for the patients who benefit from DERMAGRAFT is to transfer it to new ownership in order to provide continued care and availability of their treatment.”

### Transaction Details

The DERMAGRAFT assets that have been sold to Organogenesis comprise the key operating assets relating to the development, manufacture and sale of the DERMAGRAFT product. These assets include intellectual property relating to DERMAGRAFT including patents, trademarks and know-how; regulatory filings and registrations relating to DERMAGRAFT; certain manufacturing plant, equipment and materials; DERMAGRAFT product inventory and accounts receivable. These assets had a value of \$683 million in Shire’s September 30, 2013 balance sheet. Shire is generally retaining legacy liabilities relating to the DERMAGRAFT business, including the previously announced Department of Justice investigation relating to the sales and marketing practices of Advanced Biohealing, Inc (now known as Shire Regenerative Medicine, Inc.).

Shire will receive no upfront payment from Organogenesis but is entitled to receive up to \$300 million cash in total milestone payments should Organogenesis meet certain annual net sales targets between now and 2018<sup>(1)</sup>. Shire will record a loss on disposal and associated impairment charges of approximately \$650 million in the fourth quarter of 2013, which will be excluded from Non GAAP earnings.

DERMAGRAFT operations will be reported as discontinued in Shire’s fourth quarter and full year earnings for 2013. The US GAAP operating loss from DERMAGRAFT operations in the nine months ended September 30, 2013 amounted to \$324 million including the impairment of goodwill (\$192 million recorded in Q1 2013). On a Non GAAP basis for the same period the operating loss for Dermagraft operations was \$81 million.

In advance of its Full Year 2013 earnings release scheduled for February 13, 2014 Shire will issue a further press release providing historical quarterly analysis for 2012 and 2013 restated to show the DERMAGRAFT operations as discontinued.

Lazard and Davis Polk & Wardwell LLP acted as advisors to Shire.

**Reference:**

(1) The annual net sales targets range from as low as \$70 million in calendar years 2014 and 2015 to as high as \$250 million. For the purposes of determining the reported loss on disposal, the fair value of these contingent payments is estimated at approximately \$30 million.

**For further information please contact:****Investor Relations**

Eric Rojas [erojas@shire.com](mailto:erojas@shire.com) +1 781 482 0999

Sarah Elton-Farr [seltonfarr@shire.com](mailto:seltonfarr@shire.com) +44 1256 894157

**Media**

Jessica Mann [jmann@shire.com](mailto:jmann@shire.com) +44 1256 894 280

Gwen Fisher [gfisher@shire.com](mailto:gfisher@shire.com) +1 484 595 9836

**NOTES TO EDITORS**

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

Our strategy is to focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs.

We provide treatments in Neuroscience, Rare Diseases, Gastrointestinal, Internal Medicine and Regenerative Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas.

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

**About Dermagraft**

DERMAGRAFT is a cryopreserved human-fibroblast –derived dermal substitute; it is composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. 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. The most frequently reported adverse events experienced by patients in the DERMAGRAFT group of the pivotal registration trial (terms  $\geq$  5%) included infection, accidental injury, skin dysfunction/blister, flu syndrome, osteomyelitis, surgeries involving study ulcer, wound enlargement/skin ulcer, cellulitis and peripheral edema/localized swelling. Refer to DERMAGRAFT Directions for Use for more information.

## **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.