

## **DERMAGRAFT® now available in Canada for the treatment of Diabetic Foot Ulcers**

The launch marks the beginning of Shire's Regenerative Medicine business in the country

**Montréal (Québec) – March 25, 2013** – Shire Canada Inc. announced today that DERMAGRAFT (human fibroblast-derived dermal substitute) is now available in Canada for the treatment of diabetic foot ulcers (DFUs) greater than 6 weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.

Health Canada issued a licence for DERMAGRAFT as a class IV medical device designed to be externally applied onto DFUs.

"DERMAGRAFT constitutes a true, additional treatment option to help patients with diabetic foot ulcers," said Dr. Gary Sibbald, MD, FRCPC, MACP, FAAD, M.Ed., MAPWCA, Professor of Medicine and Public Health at the University of Toronto. "DERMAGRAFT can lead to significant improvement in wound closure for stalled healable wounds compared to conventional therapy alone."

One of the most devastating complications of diabetes, DFUs constitute a serious health issue estimated to cost the Canadian healthcare system more than \$150 million annually<sup>i</sup>. In its first and only report to date, the Health Care Innovation Working Group, created by the Council of Federation, identified DFUs as a leading health challenge<sup>ii</sup>.

"We are excited to be bringing DERMAGRAFT to Canada, as we believe it plays an important role in the treatment of DFUs," said Jeff Jonas, MD, President of Shire Regenerative Medicine, Inc, the division of Shire that markets DERMAGRAFT. "This is an important first step for Shire as we continue to build a global business that provides regenerative medicine solutions for people around the world with life-altering conditions."

"The Shire Canada team is pleased to be expanding into a new therapeutic area," added Claude Perron, Vice President and General Manager, Shire Canada Inc. "We hope that Canadian patients and healthcare professionals will benefit from having DERMAGRAFT available as a new therapeutic option to treat DFUs."

### **About DFUs**

DFUs are chronic sores that can develop on the feet of people with diabetes. Among Canadians living with diabetes, up to 15% will experience a DFU in their lifetime<sup>iii</sup>.

### **About DERMAGRAFT**

DERMAGRAFT is approved as a class IV medical device in Canada for the treatment of DFUs. DERMAGRAFT is manufactured from human fibroblast cells derived from donated newborn foreskin tissue. During the manufacturing process, the human fibroblasts are seeded onto a bioabsorbable scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors, and cytokines to create a three-dimensional human dermal substitute containing metabolically active, living cells.

### **Important Safety Information About DERMAGRAFT**

DERMAGRAFT is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than 6 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.

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**Notes to editors**

**SHIRE PLC**

**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.

**"SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

Statements included herein that are not historical facts 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, the Company's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of research, development, approval, reimbursement, manufacturing and commercialization of the Company's Specialty Pharmaceuticals, Human Genetic Therapies and Regenerative Medicine products, as well as the ability to secure new products for commercialization and/or development; government regulation of the Company's products; the Company's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on the Company's products; the Company's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; the Company's ability to obtain and maintain government and other third-party reimbursement for its products; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission.

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iCanadian Association Wound Care website (<http://cawc.net/index.php/public/facts-stats-and-tools/statistics/>)

iiThe Council of the Federation website (<http://www.councilofthefederation.ca/pdfs/Health%20Innovation%20Report-E-WEB.pdf>)

iiiCanadian Association Wound Care website (<http://cawc.net/index.php/public/facts-stats-and-tools/statistics/>)