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HELINN GRANTS TO DARA EXCLUSIVE U.S. COMMERCIAL RIGHTS TO GELCLAIR[®], AN FDA-CLEARED ORAL GEL FOR THE TREATMENT OF ORAL MUCOSITIS

Gelclair[®] Strengthens DARA's Growing Portfolio of In-licensed Oncology and Oncology Supportive Care Products

LUGANO, Switzerland and RALEIGH, N.C., USA, September 13, 2012 – The Helsinn Group of Switzerland announced today that it has entered into an exclusive agreement with [DARA BioSciences, Inc.](#) (Nasdaq: DARA) for U.S. commercial rights to Gelclair[®]. Gelclair[®] is an FDA-cleared product indicated for the treatment of oral mucositis. DARA plans to launch Gelclair[®] in the first quarter of 2013.

Oral mucositis is a painful inflammation and ulceration of the surface of the mouth and throat, which can result from a variety of cancer treatments. Gelclair[®] is a topical gel used to coat and protect the oral cavity to reduce pain.

David J. Drutz, MD, DARA's Chief Executive Officer, stated, "The exclusive agreement with Helsinn for rights to commercialize Gelclair[®] is a significant milestone that provides us with an important commercial product in an area of significant medical need. Hundreds of thousands of cancer patients suffer from oral mucositis each year." Dr. Drutz continued, "Helsinn

offers DARA a respected partner with extensive experience in the oncology supportive care market. Our joint undertaking also provides the potential opportunity for a meaningful and long-term commercial and developmental relationship between our two companies."

HELINN Group Chief Executive Officer, Riccardo Braglia, said "We are excited to have a partner, in DARA, who has the same commitment to the oncology supportive care market as we do. We believe DARA will support Gelclair[®] with the programs necessary to ensure health care providers and patients have this valuable product available as part of their treatment regimen. The shared vision of both HELINN and DARA provides a sound foundation for a successful, long-term collaboration."

About oral mucositis

The American Cancer Society estimates that approximately 400,000 patients annually will experience oral mucositis as a result of cancer treatment. The National Cancer Institute estimates that almost 100



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percent of patients receiving radiation therapy for head and neck cancers experience oral mucositis, as do 80 percent of patients undergoing hematopoietic stem cell transplantation and 40 percent of patients receiving standard-dose chemotherapy.

The consequences of mucositis are far-reaching and include pain, difficulty swallowing, interruption of chemotherapy or radiation treatment, administration of narcotics, hospitalization and, in the most severe cases, reliance on parenteral nutrition.

Gelclair[®] provides a synergistic fit within DARA's oncology supportive care portfolio. DARA's three FDA-approved/cleared products ([Bionect[®]](#), [Soltamox[®]](#) and Gelclair[®]), and a fourth, [gemcitabine](#), due for ANDA submission by end of 2012, are focused on the needs of oncology patients. DARA licensed all four agents this year as part of its strategy to build a portfolio of niche opportunity products for the oncology and oncology supportive care markets.

DARA increased its focus in oncology treatment and supportive care products through its January 2012 acquisition of Oncogenerix, Inc. In June 2012, DARA launched its first product, Bionect, a topical

treatment for skin irritation and burns associated with radiation therapy. It is preparing for the launch of Soltamox, the first and only FDA-approved oral liquid formulation of tamoxifen citrate, a widely used therapy for the prevention and treatment of breast cancer. Its product portfolio also includes [KRN5500](#), a novel therapy under development for the treatment of neuropathic pain in patients with cancer, a condition with no current adequate therapy.

About Helsinn Group

HELSINN is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and the United States. HELSINN's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in therapeutic niche areas. Helsinn is an important player in cancer supportive care. HELSINN Group in-licenses early-to-late stage new chemical entities, completes their development through the performance of pre-clinical /clinical studies and Chemistry, Manufacturing, and Control (CMC) development, and files and attains their market approvals worldwide. HELSINN's products are out-licensed to its network of



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local marketing and commercial partners, selected for their deep in-market knowledge and know-how whom HELSINN assists and supports by providing a full range of product and scientific management services, including commercial, regulatory financial, legal, and medical marketing advice. The active pharmaceutical ingredients and the finished products are manufactured according to the highest quality, safety, and environmental standards at HELSINN's GMP facilities in Switzerland and Ireland and supplied worldwide to its customers. Further information on HELSINN Group is available at www.helsinn.com.

About DARA BioSciences, Inc.

DARA is a specialty pharmaceutical company focused on the development and commercialization of oncology treatment and supportive care products. DARA increased its focus in oncology through its January 2012 acquisition of Oncogenex, Inc., which holds the exclusive U.S. marketing rights to Soltamox[®], a novel oral liquid formulation of tamoxifen citrate which is widely used in the treatment and prevention of breast cancer. Soltamox is the only FDA approved oral liquid version of tamoxifen citrate and fulfills a vital clinical need for patients who cannot tolerate

existing solid tablet formulations of this drug. DARA plans to begin marketing Soltamox in the U.S. later this year. Additionally, in June 2012 DARA launched its first product, Bionect[®], a topical treatment for skin irritation and burns associated with radiation therapy.

Prior to acquiring Oncogenex, DARA was focused on the development of a cancer-support therapeutic compound, KRN5500, for the treatment of neuropathic pain in patients with cancer. This product is an excellent fit with DARA's strategic oncology focus, has successfully completed a Phase IIa study, and has been designated as a Fast Track Drug by the United States Food and Drug Administration. DARA is working with the National Cancer Institute (NCI) to design an additional clinical trial under joint DARA-NCI auspices while considering further Phase 2 development.

In addition to its oncology products, DARA's pipeline includes DB959, a novel, non-TZD dual delta/gamma, PPAR agonist for the treatment of type 2 diabetes and dyslipidemia. DARA has completed Phase I testing of DB959 and is presently pursuing opportunities to out-license this product.

DARA also has rights to other PPAR and DPPIV-inhibitor compounds for which it



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intends to seek out-licensing or partnering opportunities.

For more information please visit the web site at www.darabio.com.

Safe Harbor Statement

All statements in this news release that are not historical are forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended. Such forward-looking statements are subject to factors that could cause actual results to differ materially for DARA from those projected. Those factors include risks and uncertainties relating to DARA's ability to timely commercialize and generate revenues or profits from Bionect®, Soltamox® or other products given that DARA only recently hired its initial sales force and DARA's lack of history as a revenue-generating company, FDA and other regulatory risks relating to DARA's ability to market Bionect, Soltamox® or other products in the U.S. or elsewhere, DARA's ability to develop and bring new products to market as anticipated, DARA's current cash position and its need to raise additional capital in order to be able to continue to fund its operations, the current regulatory environment in which DARA develops and sells its products, the market

acceptance of those products, dependence on partners, successful performance under collaborative and other commercial agreements, competition, the strength of DARA's intellectual property and the intellectual property of others, the potential delisting of DARA's common stock from the NASDAQ Capital Market, risks and uncertainties relating to DARA's ability to successfully integrate Oncogenerix and other risk factors identified in the documents DARA has filed, or will file, with the Securities and Exchange Commission ("SEC"). Copies of DARA's filings with the SEC may be obtained from the SEC Internet site at <http://www.sec.gov>. DARA expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in DARA's expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based. DARA BioSciences and the DARA logo are trademarks of DARA BioSciences, Inc.

Source: Helsinn Group and DARA BioSciences, Inc.



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