DARA BioSciences' KRN5500 Receives Orphan Drug Designation From FDA

Novel Non-Opioid Therapeutic in Phase 2 to Treat Chronic Chemotherapy-Induced Peripheral Neuropathy; Existing FDA Fast Track Designation

RALEIGH, NC -- (Marketwired) -- 02/25/14 -- DARA BioSciences, Inc. (NASDAQ: DARA), an oncology supportive care specialty pharmaceutical company dedicated to providing healthcare professionals a synergistic portfolio of medicines to help cancer patients adhere to their therapy and manage side effects arising from their cancer treatments, today announced the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to KRN5500 for the parenteral treatment of painful, chronic, chemotherapy-induced peripheral neuropathy that is refractory to conventional analgesics. KRN5500 is a novel, non-opioid, non-narcotic intravenous product currently in Phase 2 clinical development.

"We are absolutely thrilled to receive Orphan Drug Designation, and appreciate the hard work of the FDA's Office of Orphan Product Development over the many months in reviewing and ultimately approving the KRN5500 application for orphan designation. We believe this Orphan Drug Designation will expedite the development of KRN5500 for patients with cancer who suffer from chronic neuropathic pain brought on by potent chemotherapeutic agents," said David J. Drutz, M.D., Chief Executive Officer and Chief Medical Officer of DARA BioSciences. "KRN5500, is a candidate to treat chronic neuropathic pain induced by chemotherapy, and fits perfectly into our corporate strategy of providing clinicians and patients with access to a synergistic portfolio of oncology supportive care products."

With the orphan drug designation, DARA is committed to evaluating various funding sources for the clinical advancement of KRN5500. The FDA grants orphan drug designation to therapeutics intended to treat diseases that affect fewer than 200,000 people in the U.S. Importantly, this provides DARA with seven years market exclusivity, tax credits, and the waiver of PDUFA filing fees, as well as access to federal grants.

In 2011, FDA designated the development of KRN5500 for the treatment of chemotherapy induced peripheral neuropathy as a Fast Track program. Fast Track designation allows for increased contact with the Review Division in the form of meetings and written correspondence, and consideration for priority review.

"Both Fast Track and Orphan Drug Designations are important drivers of KRN5500's developmental program which will be extremely helpful as we move forward with clinical trials," said Chris Clement, Chief Operating Officer of DARA BioSciences.

About DARA BioSciences, Inc.

DARA BioSciences Inc. of Raleigh, North Carolina, is an oncology supportive care pharmaceutical company dedicated to providing healthcare professionals a synergistic portfolio of medicines to help cancer patients adhere to their therapy and manage side effects arising from their cancer treatments.

DARA holds exclusive U.S. marketing rights to Soltamox® (tamoxifen citrate) oral solution, the only
liquid form of tamoxifen, used for the treatment and prevention of breast cancer. Soltamox offers a choice to patients who prefer or need a liquid form of tamoxifen. Tamoxifen is indicated for the treatment of ductal carcinoma in situ (DCIS); as adjuvant treatment of node-positive breast cancer; in the treatment of metastatic breast cancer; and for breast cancer risk reduction in high risk women. Currently, there are more than 1.8 million prescriptions of tamoxifen written on an annual basis in the United States. Between 30 and 70 percent of patients fail to complete their prescribed course of treatment, thereby diminishing its benefits in reducing the risk of breast cancer recurrence.

**Tamoxifen Important Safety Information**

Tamoxifen citrate is contraindicated in women who require concomitant coumarin-type anticoagulant therapy, in women with a history of deep vein thrombosis or pulmonary embolus, and in women with known hypersensitivity to the drug or any of its ingredients.

Serious and life-threatening events associated with tamoxifen in the risk reduction setting (women at high risk for cancer and women with DCIS) include uterine malignancies, stroke and pulmonary embolism.

The most common adverse reactions to tamoxifen treatment are (incidence > 20%) hot flashes, fluid retention, vaginal discharge, vaginal bleeding, vasodilatation, nausea, irregular menses, weight loss, and musculoskeletal events.

Tamoxifen carries the following Black Box Warning:

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**WARNING - For Women with Ductal Carcinoma in Situ (DCIS) and Women at High Risk for Breast Cancer:** Serious and life-threatening events associated with tamoxifen in the risk reduction setting (women at high risk for cancer and women with DCIS) include uterine malignancies, stroke and pulmonary embolism. Incidence rates for these events were estimated from the NSABP P-1 trial (see **CLINICAL PHARMACOLOGY, Clinical Studies, Reduction in Breast Cancer Incidence In High Risk Women**). Uterine malignancies consist of both endometrial adenocarcinoma (incidence rate per 1,000 women-years of 2.20 for tamoxifen vs. 0.71 for placebo) and uterine sarcoma (incidence rate per 1,000 women-years of 0.17 for tamoxifen vs. 0.0 for placebo)*. For stroke, the incidence rate per 1,000 women-years was 1.43 for tamoxifen vs. 1.00 for placebo**. For pulmonary embolism, the incidence rate per 1,000 women-years was 0.75 for tamoxifen versus 0.25 for placebo**. Some of the strokes, pulmonary emboli, and uterine malignancies were fatal. Health care providers should discuss the potential benefits versus the potential risks of these serious events with women at high risk of breast cancer and women with DCIS considering tamoxifen to reduce their risk of developing breast cancer. The benefits of tamoxifen outweigh its risks in women already diagnosed with breast cancer.

*Updated long-term follow-up data (median length of follow-up is 6.9 years) from NSABP P-1 study. See **WARNINGS, Effects on the Uterus-Endometrial Cancer and Uterine Sarcoma** in Prescribing Information. **See Table 3 under **CLINICAL PHARMACOLOGY, Clinical Studies** in Prescribing Information.

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The full Prescribing Information for Soltamox is available at [www.soltamox.com/prescribing-information](http://www.soltamox.com/prescribing-information).

Gelclair® is an alcohol-free bioadherent oral rinse gel for rapid and effective relief of pain
associated with oral mucositis caused by chemotherapy and radiation treatment. Gelclair should not be used by patients with a known or suspected hypersensitivity to the product or any of its ingredients. DARA licensed the U.S. rights to Soltamox from UK-based Rosemont Pharmaceuticals, Ltd., and Gelclair from the Helsinn Group in Switzerland. Under an agreement with Innocutis, DARA also markets Bionect® (hyaluronic acid sodium salt, 0.2%) a topical treatment for skin irritation and burns associated with radiation therapy, in U.S. oncology/radiology markets. Bionect should not be used by patients with known hypersensitivity to any of its ingredients. For further information on Gelclair and Bionect and the Full Prescribing Information please visit www.Gelclair.com and www.Bionect.com.

DARA is focused on expanding its portfolio of oncology supportive care products in the United States, via in-licensing and/or partnering of complementary late-stage and approved products. In addition, the company wishes to identify a strategic partner for the clinical development of KRN5500, currently in Phase 2 for the treatment of chronic, treatment refractory, chemotherapy-induced peripheral neuropathy (CCIPN). The FDA has designated KRN5500 as a Fast Track Drug, and has granted DARA Orphan Drug Designation for the treatment of CCIPN.

In early 2014, DARA kicked off its new partnership with Alamo Pharma Services, a subsidiary of Mission Pharmacal, in deploying a dedicated 20-person national sales team in the U.S. oncology market. In addition to promoting DARA's products Soltamox (tamoxifen citrate), Gelclair and Bionect, this specialized oncology supportive care sales team also will provide clinicians with access to three Mission Pharmacal products: Ferralet® 90 (for anemia), BINOSTO® (alendronate sodium effervescent tablet indicated for the treatment of osteoporosis), and Aquoral® (for chemotherapy/radiation therapy-induced dry mouth).


For more information please visit our 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, and are subject to risks and uncertainties. These statements are based on the current expectations, estimates, forecasts and projections regarding management's beliefs and assumptions. In some cases, you can identify forward looking statements by terminology such as "may," "will," "should," "hope," "expects," "intends," "plans," "anticipates," "contemplates," "believes," "estimates," "predicts," "projects," "potential," "continue," and other similar terminology or the negatives of those terms. Such forward-looking statements are subject to factors that could cause actual results to differ materially from the expectations described in these forward-looking statements are set forth under the caption "Risk Factors" in DARA's most recent Annual Report on Form 10-K, filed with the SEC on February 4, 2014, and DARA's other filings with the SEC from time to time. Those factors include risks and uncertainties relating to DARA's current cash position and its need to raise additional capital in order to be able to continue to fund its operations; the stockholder dilution that may result from capital raising efforts and the exercise or conversion, as applicable, of DARA's outstanding options, warrants and convertible preferred stock; full-ratchet anti-dilution protection afforded investors in prior financing transactions that may restrict or prohibit DARA's ability to raise capital on terms favorable to the Company and its current stockholders; the potential delisting of DARA's common stock from the NASDAQ Capital Market; DARA's limited operating history which may make it difficult to evaluate DARA's business and future viability; DARA's ability to timely commercialize and generate revenues or profits from Soltamox, Gelclair, Bionect or other products.
given that DARA only recently hired its initial sales force and DARA’s lack of history as a revenue-generating company; DARA’s ability to achieve the desired results from the agreements with Mission and Alamo; FDA and other regulatory risks relating to DARA’s ability to market Soltamox, Gelclair, Bionect or other products in the United States or elsewhere; DARA’s ability to in-license and/or partner products; the current regulatory environment in which DARA sells its products; the market acceptance of those products; dependence on partners and third-party manufacturers; successful performance under collaborative and other commercial agreements; DARA’s ability to retain its managerial personnel and to attract additional personnel; potential product liability risks that could exceed DARA’s liability coverage; potential risks related to healthcare fraud and abuse laws; competition; the strength of DARA’s intellectual property, the intellectual property of others and any asserted claims of infringement, 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.

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