DARA BioSciences' KRN5500 Granted Orphan Drug Designation by FDA for Treatment of Multiple Myeloma

Second Orphan Drug Designation Received in 2014 for Key Development Asset

RALEIGH, NC -- (Marketwired) -- 06/16/14 -- 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 the experimental compound KRN5500 for the treatment of multiple myeloma.

KRN5500 is a novel, intravenous, non-opioid, non-narcotic compound currently in Phase 2 clinical development. Earlier this year, KRN5500 received orphan status to be developed for the parenteral treatment of painful, chronic, chemotherapy-induced peripheral neuropathy (CCIPN) that is refractory to conventional analgesics in patients with cancer. In 2011, the FDA designated KRN5500 as a Fast Track program which expedites the development pathway and consideration for priority review. Orphan Drug Designation provides DARA with seven years market exclusivity from the time of approval, tax credits, and the waiver of PDUFA filing fees, as well as access to federal grants.

"This second orphan drug designation for our key development asset KRN5500 allows us to approach the actual treatment of multiple myeloma, whereas the CCIPN designation is specific to neuropathy. It is noteworthy in this regard that up to 20% of myeloma patients have intrinsic peripheral neuropathy, an incidence that increases to the range of 75% in patients treated with neurotoxic drugs such as thalidomide or bortezomib. We believe this myeloma-specific orphan designation enhances both the viability and the future market opportunity for this valuable pipeline product," said David J. Drutz, M.D., Chief Executive Officer and Chief Medical Officer of DARA BioSciences.

The favorable consideration of myeloma as an orphan indication for KRN5500 was supported by a comprehensive publication in 2012 by an independent group of academic investigators, which demonstrated its therapeutic potential in both in vitro and in vivo experiments in which KRN5500, a spicamycin derivative, exhibited anti-myeloma effects through impairing both myeloma cells and osteoclasts.

Dr. Drutz continued, "We greatly appreciate the expeditious review and approval of this additional KRN5500 orphan designation application by the FDA's Office of Orphan Product Development, which provides an important step towards the potential treatment of multiple..."
myeloma and one of its major complications. This second orphan drug designation underscores the value of this asset and strengthens DARA's resolve and positioning in the ongoing pursuit of partnering opportunities to assist in funding the clinical advancement and development pathway of KRN5500."

Multiple myeloma is a hematologic cancer (or cancer of the blood) and the second most common blood cancer after non-Hodgkin's lymphoma. The American Cancer Society estimates that more than 24,000 new cases of the disease will be diagnosed in 2014. The FDA grants orphan drug designation to therapeutics intended to treat diseases that affect fewer than 200,000 people in the United States.

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 both Soltamox® (tamoxifen citrate) oral solution and Gelclair®. 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%).

Soltamox® (tamoxifen citrate) oral solution, the only liquid form of tamoxifen, is indicated for the treatment of metastatic breast cancer, the adjuvant treatment of node-positive breast cancer in postmenopausal women, the reduction in risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), and for the reduction of the incidence of breast cancer in women at high risk for breast cancer. 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 coumadin-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 Boxed Warning:
**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.

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](http://www.Gelclair.com) and [www.Bionect.com](http://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 two separate Orphan Drug Designations for the treatment of multiple myeloma and for the treatment of painful, chronic chemotherapy-induced peripheral neuropathy that is refractory to conventional analgesics (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, Gelclair and Bionect, this specialized oncology supportive care sales team also provides 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 press release that are not historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, and are subject to risks and uncertainties. Forward-looking 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 for DARA from those projected. Important 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 ability to realize the desired benefits of Orphan Drug Designation and Fast Track designation for KRN5500, 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, DARA's current cash position and its need to raise additional capital in order to be able to continue to fund its operations, DARA's ability to raise sufficient capital and on favorable terms and the stockholder dilution that may result therefrom, the current regulatory environment in which DARA 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, 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.

All forward-looking statements are expressly qualified in their entirety by this cautionary
notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Media Contact:
David Connolly
LaVoieHealthSciences
617-374-8800, Ext. 108
dconnolly@lavoiegroup.com

Corporate Contact:
Jim Polson
FTI Consulting
312 553 6730
Jim.polson@fticonsulting.com

Source: DARA BioSciences, Inc.