DARA BioSciences Completes Breast Cancer CAPTURE Registry

CAPTURE: COMPLIANCE AND PREFERENCE FOR TAMOXIFEN REGISTRY -- Provides Important New Insight into Aspects of Tamoxifen Therapy Adherence; 626 Patients Enrolled in Cancer Centers Nationwide

RALEIGH, NC -- (Marketwired) -- 12/03/13 -- 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, announced completion of CAPTURE (Compliance and Preference for Tamoxifen Registry).

A total of 626 women who had been prescribed and were taking tamoxifen therapy for breast cancer completed the CAPTURE survey, providing investigators with valuable insight into adherence to prescribed tamoxifen treatment; patient preference for a liquid formulation of tamoxifen; and prevalence of difficulties in swallowing among breast cancer patients taking tamoxifen tablets. CAPTURE was initiated earlier in 2013 subsequent to DARA's commercialization of Soltamox® (tamoxifen citrate) oral solution as the only FDA-approved liquid formulation of tamoxifen citrate in the United States. DARA and CAPTURE investigators anticipate presenting these data at upcoming oncology conferences in 2014.

"We expect data generated from the CAPTURE registry will enable physicians to provide a more comprehensive clinical assessment, thereby improving patient long-term adherence to tamoxifen therapy based on specific patient parameters," said David J. Drutz, MD, CEO and CMO of DARA BioSciences. "DARA initiated CAPTURE to illustrate our commitment to the enhancement of oncology supportive care. By working with investigators and their clinical teams at 17 participating oncology centers across the country, we are confident that CAPTURE will help advance clinical practice to maximize adherence to long-term tamoxifen therapy."

The American Society of Clinical Oncology recently updated its guidelines, recommending that increasing duration of tamoxifen therapy (20mg per day for 10 years) should be discussed as an option to reduce the risk of estrogen receptor (ER) positive breast cancer. Based on the updated guidelines, long term adherence is of utmost importance to support the best possible therapeutic outcomes.
"Understanding key drivers for patients' long-term tamoxifen adherence is of the utmost significance," stated Professor Stefan Glück MD, PhD, FRCPC, Sylvester Distinguished Professor, Department of Medicine, Division of Hematology/Oncology, Sylvester Comprehensive Cancer Center and a member of the CAPTURE Scientific Steering Committee. "CAPTURE will provide the oncology community important information that positively will affect tamoxifen prescribing habits and long-term patient adherence."

Soltamox® offers an alternative (oral liquid) form of delivery previously not available to patients and prescribing physicians, and is bioequivalent to, and indicated for the same FDA approved indications as the tablet form of tamoxifen.

The oncology centers that participated in the registry include Advanced Medical Specialties, Blood and Cancer Center of East TX, Breastlink Medical Group, Cancer Care Centers of South Texas, Cancer and Hematology Centers of Western Michigan, Cedars Sinai Medical Group, Florida Cancer Center, Highlands Oncology Group, Holy Cross Hospital-Bienes Cancer Center, La Grange Oncology Associates, MacNeal Hospital, Memorial Cancer Institute, Oncology Consultants, Tennessee Oncology, PLLC, Sylvester Comprehensive Cancer Center, Weiss Memorial Hospital, and West Suburban Medical Center.

Dr. Drutz concluded, "DARA is working with the oncology community to contribute to the improvement of patient care in a meaningful way. DARA will continue our efforts to support advancement of patient care by providing both patients and health care practitioners with novel therapies, supportive programs, and clinical opportunities such as CAPTURE."

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. Important Safety Information and the complete Black Box Warning may be found at: http://soltamox.com/prescribing-information.

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. 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. 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. 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 DARA is seeking orphan status for the treatment of CCIPN.

In 2014, DARA kicks 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 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 March 28, 2013, DARA’s most recent Quarterly Report on Form 10-Q, filed with the SEC on November, 13, 2013, and DARA’s other filings with the SEC from time to time. Those factors include risks and uncertainties relating to 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, 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, 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.

Media Contact:
David Connolly
LaVoie Group
617-374-8800 ext. 104
dconnolly@lavoiegrou.com

Investor Contact:
Jenene Thomas
DARA BioSciences
908-938-1475
jthomas@darabio.com

Source: DARA BioSciences, Inc.