

March 10, 2015



# **DARA BioSciences Announces the Acquisition of Exclusive North American Rights to Oravig(R) (Miconazole Buccal Tablets 50mg), From Onxeo S.A.**

**DARA Signs Agreement With Mission Pharmacal to Promote Oravig in the Primary Care Market; DARA to Promote Oravig in the Oncology Market; Deal Significantly Strengthens DARA's Oncology Supportive Care Portfolio**

RALEIGH, NC -- (Marketwired) -- 03/10/15 --

[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 that it has finalized a Commercialization Agreement with Onxeo S.A., an innovative company specializing in the development of orphan oncology drugs, granting DARA the U.S. rights to Oravig<sup>®</sup>, the first and only orally-dissolving buccal tablet approved for oral thrush. DARA has contemporaneously executed a co-promotion agreement with Mission Pharmacal Company, a privately held pharmaceutical company based in San Antonio, Texas, to co-promote Oravig in the primary care market.

Under the terms of the Agreement, DARA will acquire the approved New Drug Application (NDA) and will have the exclusive rights to market and sell Oravig in the United States. DARA also has the right to pursue regulatory approval in Canada which, if granted, would give DARA exclusive rights to market and sell Oravig there. DARA will book all revenues on Oravig and will pay Onxeo S.A. certain milestone payments upon the achievement of defined sales thresholds; DARA has additionally undertaken to complete a pediatric study as part of a post-marketing commitment, which if successful, may provide DARA with both an expanded indication and market size for Oravig.

"We are extremely excited to add an approved, branded, and unique product to our oncology supportive care portfolio," stated Christopher G. Clement, DARA CEO and President. "Combined with our current portfolio of products, Gelclair<sup>®</sup> for oral mucositis and Aquoral<sup>®</sup> for dry mouth, Oravig provides DARA the opportunity to offer a distinctive therapeutic armamentarium for patients suffering from side effects of the oral cavity due to

their cancer treatments. We look forward to promoting this exciting new product in conjunction with our trusted partners at Mission."

There are more than three million prescriptions written in the U.S. annually for oral thrush, with the majority of these written in the primary care segment. In order to maximize the commercial opportunity for Oravig, DARA has signed an agreement with Mission Pharmacal to promote Oravig in the primary care market. DARA currently in-licenses two products from Mission Pharmacal for promotion exclusively within the Oncology market: Aquoral for dry mouth and Ferralet<sup>®</sup> 90 for anemia. Additionally DARA's field sales organization is contracted through Alamo Pharma services, a subsidiary of Mission Pharmacal.

"Our partnership with DARA is extremely important to us," stated Terry Herring, Mission Pharmacal President. "We are committed to providing important products across the various patient populations we serve. Oravig allows Mission to add a significant therapeutic to our primary care division's promoted product portfolio, while further strengthening and expanding upon our existing relationship with the DARA team."

Oravig is an approved product in the U.S. market and was previously promoted by third parties.

"Topical localized therapies for oropharyngeal candidiasis are available; unfortunately these therapies are not optimal due to the need for dosing several times a day, short contact time of the active agent with the oral mucosa, sugar content which can promote yeast growth, unpleasant taste, and difficulty of use in patients with a dry mouth or oral ulceration. Together, these limitations contribute to reduced compliance and efficacy of these topical agents, often necessitating the use of systemic agents which have increased side-effects for patients," stated Dr. Rajesh V. Lalla, Section of Oral Medicine, University of Connecticut Health Center. "Oravig provides an excellent localized therapy solution for the treatment of oropharyngeal candidiasis because Oravig adheres to the oral mucosa and provides sustained local release of miconazole over a period of several hours with just one daily application," Dr. Lalla concluded.

DARA is planning to launch Oravig later this year.

Locust Walk Partners, a transaction advisory firm for the biopharmaceutical industry, served as exclusive advisor to Onxeo.

***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<sup>®</sup> (tamoxifen citrate) oral

solution and Gelclair<sup>®</sup>. DARA licensed the U.S. rights to Soltamox<sup>®</sup> from UK-based Rosemont Pharmaceuticals, Ltd., a U.K. based manufacturer and a subsidiary of Perrigo Company plc, and Gelclair<sup>®</sup> from the Helsinn Group in Switzerland. Under an agreement with Innocutis, DARA also markets Bionect<sup>®</sup> (hyaluronic acid sodium salt, 0.2%).

Soltamox<sup>®</sup> (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 premenopausal 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<sup>®</sup> is an alcohol-free bio adherent 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<sup>®</sup> (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 two Mission Pharmacal products: Ferralet<sup>®</sup> 90 (for anemia), and Aquoral<sup>®</sup> (for chemotherapy/radiation therapy-induced dry mouth).

Important Safety Information and full Prescribing Information for Mission Pharmacal's products may be found at: [www.Ferralet.com](http://www.Ferralet.com) and [www.Aquoral.com](http://www.Aquoral.com).

For more information please visit our web site at [www.darabio.com](http://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 3, 2015, 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<sup>®</sup>, Gelclair<sup>®</sup>, Bionect<sup>®</sup> 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<sup>®</sup>, Gelclair<sup>®</sup>, Bionect<sup>®</sup> 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, 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>. 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.

### **About Onxeo**

Onxeo has the vision to become a global leader and pioneer in oncology, with a focus on orphan or rare cancers, through developing innovative therapeutic alternatives to "make the difference." The Onxeo teams are determined to develop innovative medicines to provide patients with hope and significantly improve their lives. **Key products at advanced development stage are:**

Livatag<sup>®</sup> (Doxorubicin Transdrug<sup>™</sup>): Phase III in hepatocellular carcinoma

Validive<sup>®</sup> (Clonidine Lauriad<sup>®</sup>): Phase II in severe oral mucositis: Positive preliminary top-line results

Beleodaq® (belinostat): registered in the US in peripheral T-cell lymphoma

Loramyc® is marketed through partnership agreements in Europe with the Therabel Group, in Southeast Asia with Handok, in China with SciClone Pharmaceuticals, in Japan with Sosei and in Iran with Shafayab Gostar.

For more information, visit the website [www.onxeo.com](http://www.onxeo.com)

### ***About Mission Pharmacal***

Mission Pharmacal Company is a privately held pharmaceutical company based in San Antonio, Texas. For more than 65 years, the company has been committed to meeting the unique healthcare needs of women throughout all stages of life, pediatric patients, and those persons dealing with urologic and dermatologic conditions. The company has a proven track record of identifying unmet healthcare needs and developing both innovative prescription and over-the-counter products to meet these needs. Using only the purest ingredients and FDA-approved methods of manufacturing, Mission Pharmacal provides physicians and consumers with the highest quality pharmaceutical and dietary supplement products on the market today. Mission Pharmacal is a proud national supporter of the March of Dimes Foundation®, whose mission is to improve the health of babies by preventing birth defects, premature birth, and infant mortality. For more information about the company, visit [missionpharmacal.com](http://missionpharmacal.com).

Source: DARA BioSciences, Inc.

#### **CONTACT**

##### **Corporate Contact:**

Jim Polson

FTI Consulting

312-553-6730

[Jim.polson@fticonsulting.com](mailto:Jim.polson@fticonsulting.com)

##### **Media Contact:**

David Connolly

LaVoie Health Sciences

617-374-8800, Ext. 108

[dconnolly@lavoiegroup.com](mailto:dconnolly@lavoiegroup.com)

Source: DARA BioSciences, Inc.