Durata Therapeutics Announces NDA Submission for Dalbavancin for the Treatment of Patients With Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

CHICAGO, Sept. 26, 2013 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX), an emerging specialty pharmaceutical company, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of dalbavancin for the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible Gram-positive microorganisms, including MRSA (methicillin resistant Staphylococcus aureus).

"We are pleased to be another step closer to offering dalbavancin for the treatment of patients with acute bacterial skin and skin structure infections," said Paul R. Edick, Durata Therapeutics Chief Executive Officer. "Dalbavancin is our first product candidate, and this milestone demonstrates our company's commitment to improving patients' lives by addressing the growing demand for therapeutics to treat acute illnesses and infectious diseases."

The submission is based on the entire data set from Durata Therapeutics' clinical development program, including positive results from two Phase 3 trials DISCOVER 1 and DISCOVER 2, as well as a previous Phase 3 study (VER-009). Both DISCOVER 1 and DISCOVER 2 trials were conducted under a Special Protocol Assessment (SPA) with the FDA.

In November 2012, the FDA designated dalbavancin as a Qualified Infectious Disease Product (QIDP). The QIDP provides Durata Therapeutics priority review by the FDA, eligibility for fast-track status, and extension of statutory exclusivity periods for an additional five years upon FDA approval of the product.

"Currently available treatments for ABSSSI have limitations, especially in today's health
care environment, so the development of new antibiotics is imperative," said David Andrew Talan, MD, FACEP, FIDSA Chairman, Department of Emergency Medicine and Faculty, Division of Infectious Diseases. "If approved by the FDA, dalbavancin, with its once-weekly 30-minute intravenous doses, may help facilitate an important shift in treatment from the hospital to ambulatory settings."

ABOUT ABSSSI

For the six month period of January to June 2010, a projected 9.2 million patients were treated in U.S. hospitals for infections of any type, and nearly 17 percent of the diagnostic category presentations were for skin and skin structure infections (SSSIs). Of these presentations for SSSI, approximately 74 percent were disease types included in ABSSSI. This category of infection increased by 176 percent from 1997 to 2009 in hospitalized patients. The majority of skin and soft tissue infections in hospitalized patients are caused by Staphylococcus aureus, and approximately 59 percent of these infections are estimated to be caused by MRSA in the U.S. Effective early treatment of ABSSSI is critical to prevent wound expansion and to avoid lengthy and costly hospital stays. Failure to successfully treat ABSSSI may result in hospital readmissions. Under the new health care reform laws, hospitals may incur financial penalties for preventable hospital readmissions, including unresolved infections.

ABOUT DURATA THERAPEUTICS, INC.

Durata Therapeutics, Inc. is a pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses. Durata has completed two global Phase 3 clinical trials with its lead product candidate, dalbavancin, for the treatment of patients with acute bacterial skin and skin structure infections, or ABSSSI.

FORWARD-LOOKING STATEMENTS

Statements contained in this press release contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts,
contained in this press release, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements in this press release include statements about the FDA approval of dalbavancin and the potential impact of dalbavancin’s dosing schedule on hospital costs and readmissions. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the "Risk Factors" section of our most recent quarterly report on Form 10-Q, which is on file with the SEC and is also available on our website. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our views change. Therefore, you should not rely on these forward-looking statements as representing our views as of any date subsequent to today.


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