FDA Approves Durata Therapeutics' DALVANCE(TM) for the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Caused by Susceptible Gram-Positive Bacteria, Including MRSA, in Adults

First and Only IV Antibiotic for ABSSSI With Once-a-Week Dosing for Two Weeks

CHICAGO, May 23, 2014 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX) announced today that the U.S. Food and Drug Administration (FDA) has approved DALVANCE™ (dalbavancin) for injection for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible Gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA). DALVANCE is the first and only IV antibiotic approved for the treatment of ABSSSI with a two-dose regimen of 1000 mg followed one week later by 500 mg, each administered over 30 minutes.

"We are proud to bring DALVANCE to market for the millions of Americans who may benefit from an innovative treatment option for ABSSSI in today’s evolving health care environment," said Paul Edick, Chief Executive Officer of Durata Therapeutics. "DALVANCE’s unique dosage regimen offers a new approach to treatment of these serious skin infections by allowing patients, health care professionals and hospitals to move beyond the standard daily or twice-daily IV antibiotic infusions." Mr. Edick continued, "We are executing on all fronts to complete the necessary activities required to launch and ensure success. The time to build out and train a first-class salesforce, complete packaging and final qualification activities keeps us on track to begin shipping in the third quarter."

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 (SSSI). 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.

"Health care providers and hospitals are under enormous pressure to contain costs while still delivering high-quality care that does not compromise patient outcomes," said David Talan, MD, FACEP, FIDSA, Chairman, Department of Emergency Medicine and Faculty, Division of Infectious Diseases, Olive View-UCLA Medical Center. "The approval of DALVANCE is significant in this regard because it allows physicians to provide continuity of care across treatment settings for patients with ABSSSI as it helps reduce, or in some cases, may eliminate, the time patients spend in hospitals by providing an opportunity for care in an ambulatory setting. These outpatient settings may offer a more convenient and potentially less costly treatment experience while still delivering high-quality care and proper follow up."

The entire DALVANCE clinical program encompassed 21 clinical trials with five Phase 3 trials evaluating nearly 3,000 patients. Two Phase 3 trials, DISCOVER 1 and DISCOVER 2 ("Dalbavancin for Infections of the Skin Compared to Vancomycin at an Early Response"), were conducted under a Special Protocol Assessment (SPA) with the FDA and included more than 1,300 patients with ABSSSI. The clinical trials showed DALVANCE was non-inferior to the comparator regimen and met its primary and secondary endpoints of early response, measured at 48 to 72 hours of therapy, and clinical success at the end of treatment in patients with very large skin lesions and high frequencies of fever. DALVANCE was granted priority review as a Qualified Infectious Disease Product (QIDP), in accordance with the Generating Antibiotics Incentives Now (GAIN) Act, which was passed by Congress in 2012 to help make antibiotic development processes smoother.

"A 2013 report from the CDC warned that antimicrobial resistance is one of the most serious health concerns in the U.S., and the FDA recognized the need for new antibiotics by granting DALVANCE priority review with QIDP status," said Michael Dunne, MD, Chief Medical Officer of Durata Therapeutics. "DALVANCE is the first antibiotic approved for ABSSSI under the GAIN Act. It performed very well in clinical trials relative to the current standard, vancomycin, in studies designed to be consistent with guidance provided by the FDA for antibiotic development with efficacy defined by an early response in 48 to 72 hours, as well as clinical success at the end of treatment."

**ABOUT ABSSSI**

There were more than 4.8 million hospital admissions of adults with ABSSSI from 2005
through 2011, which included patients with cellulitis, erysipelas, wound infection and major cutaneous abscess. In fact, hospital admissions for ABSSSI significantly increased by 17.3 percent during this timeframe. The majority of all skin and soft tissue infections in hospitalized patients are caused by streptococci and *Staphylococcus aureus*, and approximately 59 percent of these *S. aureus* infections in the U.S. are estimated to be caused by MRSA. Early and effective treatment of ABSSSI is critical to optimize patient recovery and for certain patients may also help to avoid potentially lengthy and costly hospital stays.

**ABOUT DALVANCE**

DALVANCE is a second generation, semi-synthetic lipoglycopeptide, which consists of a lipophilic side-chain added to an enhanced glycopeptide backbone. DALVANCE is the first and only IV antibiotic approved for the treatment of ABSSSI with a two-dose regimen of 1000 mg followed one week later by 500 mg, each administered over 30 minutes. DALVANCE demonstrates bactericidal activity *in vitro* against a range of Gram-positive bacteria, such as *Staphylococcus aureus* (including methicillin-resistant, also known as MRSA, strains) and *Streptococcus pyogenes*, as well as certain other streptococcal species.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

**WARNINGS and PRECAUTIONS**

Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE; exercise caution in patients with known hypersensitivity to glycopeptides.

Rapid intravenous infusion of glycopeptide antibacterial agents can cause reactions, including flushing of the upper body, urticaria, pruritus and rash.

ALT elevations with DALVANCE treatment were reported in clinical trials.

*Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE. Evaluate if diarrhea occurs.

**ADVERSE REACTIONS**

The most common adverse reactions in patients treated with DALVANCE were nausea (5.5%), headache (4.7%), and diarrhea (4.4%).

**USE IN SPECIFIC POPULATIONS**
In patients with renal impairment whose known creatinine clearance is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis, the recommended two-dose regimen for DALVANCE is 750 mg followed one week later by 375 mg. No dosage adjustment is recommended for patients receiving regularly scheduled hemodialysis, and DALVANCE can be administered without regard to the timing of hemodialysis.

ABOUT DURATA THERAPEUTICS, INC.

Durata Therapeutics is a pharmaceutical company focused on the development and commercialization of new therapeutics for patients with infectious diseases and acute illnesses. For more information about the company, visit www.duratatx.com.

DALVANCE is a trademark of Durata Therapeutics Holding C.V.

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 potential impact of DALVANCE's dosing schedule on patient care. 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 report on Form 10-K, 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.

References

Durata Data on File


Moet G, Jones R et al. Contemporary causes of skin and soft tissue infections in North


Discover 1 Preliminary Results (Durata Investor Presentation – Data on File)
Discover 2 Preliminary Results (Durata Investor Presentation – Data on File)

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Source: Durata Therapeutics, Inc.