March 31, 2014

FDA Advisory Committee Unanimously Recommends Approval of Dalvance(TM) for the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

CHICAGO, March 31, 2014 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX) announced today that the U.S. Food and Drug Administration's (FDA) Anti-Infective Drugs Advisory Committee voted 12 to 0 that the Company has provided substantial evidence of the safety and effectiveness of its investigational drug, 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). While not bound by the guidance provided by the Committee, the FDA will consider the Committee's deliberations as part of its review of the New Drug Application (NDA) for Dalvance, which was accepted for priority review by the FDA in November 2013 with an action date of May 26, 2014.

"We are pleased with the positive outcome of today's Advisory Committee meeting, and the confidence that was expressed regarding the safety and effectiveness of Dalvance," said Paul R. Edick, Durata Therapeutics Chief Executive Officer. "If approved by the FDA, Dalvance would be the first once-weekly antibiotic for ABSSSI, providing an alternative to current once- or twice-daily treatments. We look forward to continuing to work with the FDA on its evaluation of our product."

A total of 21 clinical trials have been conducted with dalbavancin in the entire clinical program, with the five Phase 3 trials evaluating nearly 3,000 patients. Two Phase 3 trials, DISCOVER 1 and DISCOVER 2 ("**D**albavancin for **I**nfections of the **S**kin **CO**mpared to **V**ancomycin at an **E**arly **R**esponse"), were conducted under a Special Protocol Assessment (SPA) with the FDA and included more than 1,300 patients with ABSSSI.

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.

ABOUT DALVANCE

Dalvance is a second generation, semi-synthetic lipoglycopeptide, which consists of lipophilic side-chains attached to glycopeptides. If approved, Dalvance would be the first drug for ABSSSI requiring only two once-weekly 30-minute intravenous doses (1000 mg on Day 1 and 500 mg on Day 8). Dalvance demonstrates bactericidal activity *in vitro* against a broad range of bacteria, such as *Staphylococcus aureus* (including methicillin-resistant strains) and *Streptococcus pyogenes*, as well as certain other streptococcal species.

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. Durata has completed two global Phase 3 clinical trials with its lead product candidate, Dalvance, under investigation for the treatment of patients with acute bacterial skin and skin structure infections caused by susceptible gram-positive bacteria. 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 FDA's review and approval status of Dalvance and 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.

1. Durata Data on File
2. Wilcox M, Boucher H et al. An Integrated Analysis of the Efficacy of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in the DISCOVER Program. IDWeek Poster #1339 (2013).
3. Discover 1 Preliminary Results (Durata Investor Presentation – Data on File)
4. Discover 2 Preliminary Results (Durata Investor Presentation – Data on File)
5. AMR Hospital Antibiotic Market Guide – Book 2: Diagnosis and Surgery Reports, January 2010 – June 2010.
6. Giuliano C, Kale-Pradhan P, et al. Early Response of Ceftaroline Fosamil in the Treatment of Soft-tissue Infections. Expert Rev Clin Pharmacol. 5(5):509-512 (2012).
7. Moet G, Jones R, et al. Contemporary causes of skin and soft tissue infections in North America, Latin America and Europe: Report from the SENTRY Antimicrobial Surveillance Program (1998-2004). *Diagnostic Microbiology and Infectious Disease*. 57, 7-13 (2007).
8. Moran GJ, Krishnadasan A, Gorwitz RJ et al. EMERGEncy ID Net Study Group. Methicillin-resistant *S. aureus* Infections Among Patients in the Emergency Department. *N. Engl. J. Med*. 355(7), 666–674 (2006).
9. World Health Organization (WHO). Antimicrobial resistance fact sheet. 2013. Available online: http://www.who.int/mediacentre/factsheets/fs194/en/#. Accessed March 2014.
10. Pollack CV et al. Emergency medicine and hospital medicine: a call for collaboration. *American Journal of Medicine*. 2012;125(8):826.e1.
11. Dunne M, Boucher H et al. Microbiologic Analyses of Target Pathogens Identified in the Dalbavancin DISCOVER Program. IDWeek Poster #1338 (2013).

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