

June 4, 2014



New England Journal of Medicine Publishes Data From Durata Therapeutics' Discover Program

Highlights Potential Change of Treatment Paradigm for ABSSSI Patients

CHICAGO, June 4, 2014 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX) today announced the Phase 3 data from its DISCOVER program evaluating dalbavancin for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults was the subject of an article published in the latest edition of the New England Journal of Medicine (NEJM), "Once-Weekly Dalbavancin versus Daily Conventional Therapy for Skin Infection." The complete article is now available online to subscribers at www.nejm.org and will appear in the June 5th print edition. The article highlights the benefits of dalbavancin and its potential to change the treatment paradigm for ABSSSI patients.

Dr. Michael Dunne, Durata's Chief Medical Officer, said, "Physicians now have an alternative treatment option for patients with acute bacterial skin and skin structure infections which can deliver the efficacy and safety outcomes they expect with existing therapies with the simplicity and convenience inherent in two doses given one week apart."

Helen Boucher, M.D., FACP FIDSA, Director, Infectious Diseases Fellowship Program, Associate Professor of Medicine, Division of Geographic Medicine and Infectious Diseases, Tufts Medical Center, stated, "Dalbavancin has a great likelihood of changing our practice in caring for patients with severe skin infections. It will now be possible to treat once a week instead of several times a day and will potentially remove the need for hospital admission and long-term intravenous catheters," Dr. Boucher said.

Dr. Boucher continued, "The patients in our study were very ill: more than 85 percent had fever at entry and more than half had systemic inflammatory response syndrome. In addition, our patients had large infections with median areas of over 300 square centimeters. Our results establish dalbavancin as an effective therapy and prove non-

inferiority of dalbavancin to vancomycin in the treatment of these serious infections."

The DISCOVER studies are identical multicenter, double-blind, randomized clinical trials that included more than 1,300 adults with ABSSSI from the United States, Europe, Asia and South Africa. In the DISCOVER studies, adult patients were treated for 2 weeks either with intravenous dalbavancin once weekly (1000 mg on Day 1 followed by 500 mg on Day 8) or with intravenous vancomycin (1000 mg or 15 mg/kg every 12 hours, with the option to switch to oral linezolid after 3 days). Dalbavancin achieved its primary endpoint in both the DISCOVER 1 and DISCOVER 2 studies of non-inferiority to vancomycin by demonstrating cessation of spread of the erythema associated with the lesion, as well as the resolution (absence) of fever 48-72 hours following initiation of treatment. The secondary endpoint of clinical success at end of treatment (EOT), the expected primary endpoint for regulatory review in Europe, was also met.

Per pathogen clinical success rates were high and comparable across treatment groups at end-of-therapy and at short-term follow-up.

The rates of serious adverse events and study drug discontinuations for dalbavancin and comparator treated patients were similar. The most commonly reported adverse events for patients treated with dalbavancin in these studies were nausea, diarrhea, headache and pruritus.

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 (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.

ABOUT DALVANCE

DALVANCE is a second generation, semi-synthetic lipoglycopeptide, which consists of lipophilic side-chains attached to glycopeptides. 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 broad range of bacteria, such as *Staphylococcus aureus* (including methicillin-resistant strains) and *Streptococcus pyogenes*, as well as certain other streptococcal species. On May 23, 2014, Durata receive FDA approval for DALVANCE™ (dalbavancin) for injection for the treatment of ABSSSI in

adults.

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.

CONTACT: Investor Relations and Public Affairs Contact
Allison Wey
Durata Therapeutics
Vice President, Investor Relations and Public Affairs
(312) 219-7017
away@duratatx.com

Media Relations Contact
Geoff Curtis
DJE Science
(312) 233-1253
geoff.curtis@djescience.com



Source: Durata Therapeutics, Inc.