December 11, 2012

Durata Therapeutics Announces Phase 3 Clinical Trial Results for Dalbavancin in the Treatment of ABSSSI

Study Meets Primary Endpoint

Conference Call and Webcast Today at 9:00 A.M. ET to Discuss Results

CHICAGO-- Durata Therapeutics, Inc. (NASDAQ: DRTX) today announced preliminary, top-line results for its DISCOVER 1 ("**D**albavancin for **I**nfections of the **S**kin **CO**mpared to **V**ancomycin at an **E**arly **R**esponse") Phase 3 study of dalbavancin, which is under investigation for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible gram-positive bacteria, including MRSA (methicillin resistant *Staphylococcus aureus)*.

Preliminary top-line data show that dalbavancin achieved its primary endpoint of non-inferiority (10% non-inferiority margin) at 48-72 hours after initiation of therapy, as determined by the cessation of spread of the lesion, as well as the resolution of fever. Researchers were comparing two intravenous (IV) doses of dalbavancin given one week apart with twice-daily vancomycin doses for 14 days. Patients randomized to the vancomycin regimen had an option to switch to oral linezolid after three days of vancomycin treatment. In addition, the key secondary endpoints were supportive of the primary endpoint.

The DISCOVER 1 protocol was conducted pursuant to a special protocol agreement (SPA) with the U.S. Food and Drug Administration (FDA) based on the FDA's Draft Guidance for Developing Drugs for Treatment of ABSSSI. The protocol for the trial was also designed based on scientific advice provided by the European Medicines Agency (EMA). DISCOVER 1 was a randomized, double-blind, double-dummy trial conducted in 573 patients at 92 sites in the United States, Canada, and Europe comparing dalbavancin to a regimen of vancomycin and an option for oral linezolid for the treatment of ABSSSI.

Top-Line Data from DISCOVER 1 Trial

Primary Endpoint, Early Response (48-72 hours)

	Dalbavancin	Vancomycin/Linezolid	Difference in point estimates (95% Confidence Interval)
Early Response (ITT)	239/288 (83.0%)	233/285 (81.8%)	1.2% (-4.9, 7.6)

Secondary Endpoint, End of Treatment, Day 14

	Dalbavancin	Vancomycin/ Linezolid
Clinical Status (CE)	214/246 (87.0%)	222/243 (91.4%)
Clinical Status (ITT)	236/288 (81.9%)	247/285 (86.7%)

ITT = Intent to Treat; CE = Clinically Evaluable

In the clinical trial, the treatment-related adverse event rate for dalbavancin was 12.3% and for vancomycin/linezolid was 18.3%. Adverse events reported in ≥ 3% of patients receiving dalbavancin in this trial were nausea, diarrhea, headache, and pruritus. Discontinuations due to treatment emergent adverse events were 1.8% and 2.1% for dalbavancin and vancomycin/linezolid, respectively. This adverse event profile is consistent with results from prior Phase 3 studies of dalbavancin. Further analyses, including the statistical analyses for the European regulatory submission, remain ongoing.

“We are very pleased with the preliminary results of this trial. There is a significant need for an innovative treatment option for patients suffering with ABSSSI. We anticipate results from our DISCOVER 2 study in the coming months and are proceeding toward submitting to the FDA a New Drug Application for dalbavancin in the first half of 2013,” said Durata Chief Executive Officer Paul R. Edick.

“The development of new products, such as dalbavancin, makes this a very exciting time for patients and healthcare practitioners. Currently available IV treatment options for ABSSSI have limitations, including frequent dosing, antimicrobial resistance, and treatment-limiting adverse events. The potential opportunity to manage more patients more efficiently in ambulatory settings may well be an important advancement for providers of healthcare,” said David Andrew Talan, MD, FACEP, FIDSA, Chairman, Department of Emergency Medicine and Faculty, Division of Infectious Diseases, Olive View-UCLA Medical Center.

“We believe there are approximately 35 million days of IV antibiotic treatment annually in the United States for patients with ABSSSI that are at risk for MRSA, with the majority of these treatments occurring in the hospital setting. Because therapy with dalbavancin would involve an initial dose followed by a second dose one week later, an alternative to hospital admission may become possible for many patients. This change in modality may help reduce the overall cost of treating ABSSSI to the healthcare provider while decreasing the potential spread of MRSA within the healthcare facility,” said Durata Chief Medical Officer Michael Dunne, M.D.

Additional information regarding the trial can be found on clinicaltrials.gov.

Conference Call and Webcast Information

The company will host a conference call today, Tuesday, December 11, 2012 at 9:00 a.m. ET To access the call, please dial 866-632-4021 for participants in the U.S. or Canada and 404-991-3968 for international callers (reference Conference ID 79502265). A replay of the call may be accessed through December 25, 2012 by dialing 800-585-8367 for callers in the U.S. and Canada and (404) 537-3406 for international callers (reference Conference ID 79502265). The conference call will also be webcast live at http://event.on24.com/r.htm?e=554781&s=1&k=657C1386D7A8EC4FF7537AD9D0271CE4.

About Dalbavancin

Dalbavancin is an intravenous antibiotic product candidate under investigation for once-weekly dosing, which we believe may facilitate the treatment of patients with ABSSSI in both the in-patient and out-patient settings, potentially reducing the length of a patient’s hospital stay or avoiding hospital admission altogether, with an impact on the overall cost of care for these patients.

About Durata Therapeutics

Durata Therapeutics is a pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses. Durata has completed its DISCOVER 1 study and enrollment in its DISCOVER 2 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 preliminary top-line results of the DISCOVER I trial, the timing of the filing of a New Drug Application with the U.S. Food and Drug Administration, our estimates regarding the potential market opportunity for dalbavancin and the potential advantages of dalbavancin. 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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