February 25, 2013

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

DISCOVER 2 Study Meets Primary & Secondary Endpoints

Conference Call and Webcast Today at 8:30 A.M. EST to Discuss Results

CHICAGO, Feb. 25, 2013 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX) today announced preliminary, top-line results for its DISCOVER 2 ("**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 methicillin resistant *Staphylococcus aureus* (MRSA). DISCOVER 2 results follow the recent release of data from DISCOVER 1, which also met its primary and secondary endpoints.

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 trial assessed as a secondary outcome measure the non-inferiority of clinical response at the end of treatment in clinically evaluable patients. Dalbavancin also achieved this secondary endpoint.

The DISCOVER 2 study 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pursuant to a special protocol agreement (SPA) with the U.S. Food and Drug Administration (FDA) based on the FDA's Draft Guidance for Developing Drugs for Treatment of ABSSSI.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 2 was a randomized, double-blind, double-dummy trial conducted in 739 patients at 139 sites in the United States, Europe, Asia and South Africa comparing dalbavancin to a regimen of vancomycin (with an option to switch to oral linezolid) for the treatment of ABSSSI.

Top-line Data from the DISCOVER 2 Trial

	Endpoint	Dalbavancin	Vancomycin/ linezolid	Difference in point estimates (95% Confidence interval)
FDA Primary Endpoint	Early response 48-72 hours	285/371 (76.8%)	288/368 (78.3%)	-1.5% (-7.4, 4.6)
	>20% reduction in lesion size	325/371 (87.6%)	316/368 (85.9%)	1.7% (-3.2, 6.7)
FDA Secondary Endpoint (EMA Primary Endpoint)	Clinical Status [1] End of Treatment	303/324 (93.5%)	280/302 (92.7%)	0.8% (-3.3, 4.9)
	Investigators' assessment	314/324 (96.9%)	290/302 (96.0%)	0.9% (-2.2, 4.1)

[1]Pre-specified adjustment to the confidence interval by important baseline variables

In this clinical trial, the drug-related treatment-emergent adverse event rate for dalbavancin was 12.2% and for vancomycin/linezolid was 10.1%. The most commonly reported adverse events for dalbavancin in this trial were nausea, diarrhea, vomiting, pruritus and headache. Discontinuations due to treatment emergent adverse events were 2.4% and 1.9% for dalbavancin and vancomycin/linezolid, respectively. This adverse event profile is consistent with results from prior Phase 3 studies and DISCOVER 1. Additional analyses of the data are ongoing.

"The treatment of serious skin infections remains a challenge for the healthcare provider," said Mark Wilcox, MD., Head of Microbiology for the Leeds Teaching Hospitals and Professor of Medical Microbiology at the University of Leeds, UK. "These promising results from DISCOVER 2 provide evidence of dalbavancin's role as a safe and effective treatment option for cellulitis, major abscess and wound infections while also being more convenient for patients and potentially more cost-effective for healthcare systems."

"We are very excited with the positive top-line results of the DISCOVER 2 trial as they were consistent with all the prior studies done with dalbavancin," said Durata Chief Executive Officer Paul R. Edick. "With the completion of both of our Phase 3 studies, we are on track to submit our NDA with the FDA in mid-year and the MAA with the EMA at year-end 2013."

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

Conference Call and Webcast Information

The company will host a conference call today, Monday, February 25, 2013 at 8:30 AM EST. 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 10797012). A replay of the call may be accessed through March 11, 2013 by dialing 800-585-8367 for callers in the U.S. and Canada and 404-537-3406 for international callers (reference Conference ID 10797012). The conference call will also be webcast live at http://event.on24.com/r.htm?e=585599&s=1&k=6492106EF6010A225EBAAFE767CD2860.

The webcast will as well be available on the Investor Relations section of the Company's website at www.duratatherapeutics.com.

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 now 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.

The Durata Therapeutics, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=16463

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 2 trial, the timing of the filing of a New Drug Application with the U.S. Food and Drug Administration and a Marketing Authorization Application with the EMA, 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.

CONTACT: Investor Relations and Public Affairs Contact
Allison Wey
Durata Therapeutics, Inc.
Vice President, Investor Relations and Public Affairs
312-219-7017
awey@duratatherapeutics.com

Media Relations Contact
Jed Weiner
White Oak Communications, Inc.
847-392-4186
jed.weiner@comcast.net

Source: Durata Therapeutics, Inc.