January 4, 2013

Durata Therapeutics Meets Primary Endpoints for EMA Review in Phase 3 Clinical Trial

CHICAGO, Jan. 4, 2013 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX) today announced additional 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)*. As reported on December 11, 2012, preliminary top-line data show that dalbavancin achieved its primary endpoint of non-inferiority 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. The subpopulation of patients with MRSA at baseline achieved similar results. The secondary endpoint of clinical success at the end of treatment, the expected primary endpoint for regulatory review in Europe, was also met. Statistical analyses of the results from this secondary endpoint are included below in the updated table of top-line data.

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. 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pursuant to a special protocol agreement (SPA) with the U.S. Food and Drug Administration (FDA) based on the FDA's Draft Guidance for Developing Drugs for Treatment of ABSSSI.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 the DISCOVER 1 Trial

Endpoint	Dalbavancin	Vancomycin/ linezolid	Difference in point estimates (95% Confidence

				interval)
US Primary Endpoint	Early response (48-72 hours)	240/288 (83.3%)	233/285 (81.8%)	1.5% (-4.6, 7.9)
	Patients with MRSA	37/44 (84.1%)	32/39 (82.1%)	

	Endpoint	Dalbavancin	Vancomycin/ linezolid	Difference in point estimates (95% Confidence interval)
EMA Primary Endpoint	Clinical Status (End of Treatment)	214/246 (87.0%)	222/243 (91.4%)	-4.4% (-9.6, 1.6)*
	Patients with MRSA	30/35 (85.7%)	30/31 (96.8%)	
	Investigator Assessment (End of Treatment)	233/246 (94.7%)	237/243 (97.5%)	-2.8% (-6.7, 0.7)

*adjusted for pre-specified baseline variables.

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

"These data are consistent with our previous phase 3 study, VER001-9, which served as the pivotal study in our prior NDA submission and confirm the activity of dalbavancin in the treatment of patients with serious skin infections," said Dr. Michael Dunne, Chief Medical Officer.

Paul R. Edick, Durata's Chief Executive Officer, states, "We anticipate reporting DISCOVER 2 preliminary top-line results this quarter and, along with DISCOVER 1 and the reanalysis of the VER001-9 study, we believe that we have the data we need to re-activate our dalbavancin NDA in the US and file our MAA in the EU with a filing to the FDA in the middle of 2013 and to the EMA at the end of 2013."

About Dalbavancin

Dalbavancin is an intravenous antibiotic product candidate under investigation for once-weekly dosing given twice, 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 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 I trial, the status of the DISCOVER 2 trial, and the content and timing of the filing of a New Drug Application with the U.S. Food and Drug Administration and the content and timing of the filing of an Marketing Authorization Application in the EU, 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
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.