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# **Durata Therapeutics Completes Target Enrollment in Phase 3 DISCOVER 1 Clinical Trial Comparing Dalbavancin to Vancomycin and Linezolid in abSSSI Patients**

## **Milestone Achieved On Schedule Through Collaborative Efforts of 92 Study Sites**

MORRISTOWN, N.J.--(BUSINESS WIRE)--Durata Therapeutics (NASDAQ: DRTX) today announced that it has completed its target enrollment for DISCOVER 1 (“**D**albavancin for **I**nfections of the **S**kin **C**ompared to **V**ancomycin at an **E**arly **R**esponse”), one of two ongoing, global, Phase 3 clinical trials of Durata’s lead product candidate, dalbavancin, under investigation for the treatment of acute bacterial skin and skin structure infections (abSSSI).

DISCOVER 1 is a randomized, double-blind, double-dummy trial comparing the efficacy of dalbavancin to a regimen of vancomycin for the treatment of abSSSI. Researchers are comparing two intravenous doses of dalbavancin given one week apart with twice daily vancomycin doses for 14 days. Patients randomized to the vancomycin regimen have an option to switch to oral linezolid after three days of vancomycin treatment.

The protocol design of DISCOVER 1 is consistent with FDA Draft Guidance for Developing Drugs for Treatment of abSSSI. This pivotal study is being conducted pursuant to a special protocol agreement with the U.S. Food and Drug Administration, and is based on scientific advice provided by the European Medicines Agency (EMA).

“We are pleased to have achieved this milestone on schedule, with an open enrollment of less than 18 months, and in under three years since our inception. This accomplishment reflects our strong organizational focus to offer clinicians an important and valuable alternative to currently available Gram-positive intravenous (IV) antibiotic therapies,” said Durata Chief Executive Officer Paul R. Edick.

The primary endpoint of DISCOVER 1 is the early response to therapy measured 48-72 hours after initiation of therapy and determined by the cessation of spread of the erythema (redness) associated with the lesion, as well as the resolution of fever. The study targeted enrollment of 556 patients.

“Durata is conducting this Phase 3 pivotal clinical trial at 92 sites in the United States, Canada and Europe. We greatly appreciate the efforts of the site investigators, and the patients participating in the trial, in helping us reach this milestone within our projected timeframe,” said Durata Chief Medical Officer Michael Dunne, M.D.

Additional information regarding the trial can be found on [clinicaltrials.gov](https://clinicaltrials.gov).

### **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 is currently enrolling and dosing patients in 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.

### **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. 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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