



## **Durata Therapeutics Initiates Enrollment in DISCOVER-2, Second Phase 3 Study of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections**

**FDA Has Provided Special Protocol Assessment Agreement for Second Study**

## **Durata Also Reaches Milestone Enrolling 20 Percent of Patients in DISCOVER-1 Study**

MORRISTOWN, N.J.--(BUSINESS WIRE)—September 29, 2011 -- Durata Therapeutics today announced the Company has initiated enrollment in a second global, pivotal, Phase 3 study (DISCOVER-2) of its lead product, dalbavancin, a long-acting, intravenous (IV) lipoglycopeptide for the treatment of acute bacterial skin and skin structure infections (abSSSI). Durata's two pivotal studies (DISCOVER-1 and DISCOVER-2) are being conducted under separate Special Protocol Assessments (SPA) agreed upon with the U.S. Food and Drug Administration (FDA).

Durata also announced it has reached 20 percent patient enrollment in the Company's DISCOVER-1 study. Each of the pivotal studies is expected to enroll 556 patients, for a combined total of 1112 patients.

Durata's Chief Medical Officer, Michael Dunne, M.D., stated, "DISCOVER-1 and DISCOVER-2, together with a third, previously reported Phase 3 trial, will constitute a substantial body of safety and efficacy data, with results from over 2000 patients. Upon conclusion of the clinical program, dalbavancin will have a very substantial body of evidence in support of treatment for bacterial skin infections in both the hospital and community settings."

Durata's DISCOVER-2 study is a randomized, double-blind, double-dummy study designed to compare the efficacy and safety of dalbavancin to vancomycin, with patients randomized to vancomycin allowed to switch to oral linezolid after three days of IV vancomycin therapy. The study is expected to enroll approximately 556 patients worldwide. Patients will be randomized to receive either two doses of dalbavancin, each infused over 30 minutes, one week apart from each other, or 10 to 14 days of the comparator regimen. Clinical response will be measured at

48 to 72 hours post study initiation and again at study day 14-15. These measures are consistent with current draft FDA guidance for the development of antibiotics to treat acute bacterial skin and skin structure infections.

Vance G. Fowler Jr., M.D., MHS, Associate Professor, Department of Medicine, Division of Infectious Diseases and International Health, Duke University Medical Center, commented, “According to the Infectious Disease Society of America, an estimated 100,000 hospital deaths a year in the U.S. can be attributed to resistant bacteria, such as methicillin-resistant *Staphylococcus aureus* (MRSA). The threat posed by antibiotic resistance continues to grow, and yet there is a paucity of new antibiotics that are being introduced to fight these infections. Efforts such as those of Durata can be critical to finding new treatments to fill this need.”

“Since Durata’s acquisition of dalbavancin in December 2009, the clinical program has progressed rapidly and has met many important milestones,” stated Paul R. Edick, Chief Executive Officer of Durata. “Both of our pivotal clinical studies are now underway, and we anticipate the same active level of investigator engagement in DISCOVER-2 as we have seen with DISCOVER-1. SPA agreement with the FDA also has been a critical achievement, especially in light of the FDA’s efforts to complete guidelines for abSSSI antibiotic development. In addition, Durata announced successful production of clinical quantities of dalbavancin by two top-tier manufacturers, a key step in ensuring supply of the product. Also, we recently reported we attained worldwide rights for the dalbavancin program, another value inflection point. We are very pleased with our progress and look forward to continued momentum of the program.”

### **About Durata Therapeutics**

Durata Therapeutics is a biopharmaceutical company addressing the growing need for new therapeutics to treat infectious diseases. Durata’s current late-stage clinical product, dalbavancin, is a next-generation lipoglycopeptide with unique features, including convenient, once-a-week dosing. To date, dalbavancin has been shown to be effective and well-tolerated in late-stage clinical trials of patients with skin infections, supported by a promising safety profile based on clinical data in over 1300 patients. Durata has worldwide rights for the development and commercialization of dalbavancin. The Company also has two antibiotic programs in earlier-stage, preclinical research.

Durata’s senior leadership has considerable experience in running healthcare companies and broad expertise in medical affairs, operations, manufacturing and commercialization, including multiple U.S. and global product launches. Durata is supported by a premier team of venture

capital organizations including New Leaf Venture Partners, LLC, Domain Associates, LLC, Aisling Capital, Sofinnova Ventures Inc. and Canaan Partners.

For more information on Durata and the Company's programs, please visit [www.duratatherapeutics.com](http://www.duratatherapeutics.com).

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