



April 18, 2011 11:43 UTC

Durata Therapeutics Initiates Phase 3 Study of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections

FDA Has Provided Special Protocol Assessment Agreement for Pivotal Clinical Study

MORRISTOWN, N.J.--([BUSINESS WIRE](#))-- Durata Therapeutics today announced the Company initiated a global, pivotal, Phase 3 study (DISCOVER-1) of its lead product, dalbavancin, a long-acting, intravenous (IV) lipoglycopeptide for the treatment of acute bacterial skin and skin structure infections (abSSSI). The pivotal study is being conducted under a Special Protocol Assessment (SPA) agreed upon with the U.S. Food and Drug Administration (FDA).

Paul R. Edick, Chief Executive Officer of Durata, commented, "We are very pleased to begin this pivotal clinical study for dalbavancin, which Durata acquired in December 2009. The data from this trial, supplemented by a previously completed, large Phase 3 study, will provide the basis of our overall clinical program, leading to our regulatory submission to the FDA. The SPA agreement is an important element in this, since it maps out a clearly defined path forward, concurrent with the FDA's process of finalizing its guidelines for antibiotic development for acute bacterial skin and skin structure infections. We look forward to continued momentum in our program in the near term."

John E. Edwards, Jr., M.D., Chief, Division of Infectious Diseases, Harbor/UCLA Medical Center, Professor of Medicine, David Geffen School of Medicine at UCLA, said, "New antibiotics with activity against resistant staphylococci are critically needed. Antibiotic resistance is a growing concern; for instance, community-acquired methicillin-resistant *Staphylococcus aureus* (MRSA) has now become a common cause of community-acquired soft tissue infections at many clinical care centers. Physicians need new products so that we can address the increasing threat to health of patients both inside and outside the hospital setting."

The pivotal, Phase 3 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.

Durata's Chief Medical Officer, Michael Dunne, M.D., stated, "Dalbavancin is one of the most advanced of the next-generation lipoglycopeptides, in the same class as vancomycin. In a previous, Phase 3 study, dalbavancin met its primary endpoint for the treatment of complicated skin infections. Due to its unique features and PK profile, dalbavancin offers the significant convenience of once-a-week dosing and short, 30-minute infusion time. Furthermore, the safety profile of dalbavancin already has been established in extensive previous clinical development work in over 1300 patients. Based on these characteristics and our expectations for the pivotal program, we believe this product has the potential to set the bar for activity against important Gram-positive bacterial infections, including those due to MRSA."

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. The Company also has two antibiotic programs in earlier-stage, preclinical research.

Durata's senior leadership has substantial experience at leading healthcare companies, including in medical affairs, operations and manufacturing and with 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.

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