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Pfizer Will Withdraw Global Marketing Applications for Dalbavancin to Conduct a New Trial

Monday, September 08, 2008 - 11:02pm

(BUSINESS WIRE)--Pfizer Inc today announced it will globally withdraw all dalbavancin marketing applications for the treatment of complicated skin and skin structure infections in adults, including the U.S. new drug application (NDA) and the European marketing authorization application (MAA).

Following feedback from regulatory authorities, the company plans to conduct an additional Phase 3 clinical trial with dalbavancin for the treatment of adults with complicated skin and skin structure infections caused by Gram-positive bacteria, including MRSA (methicillin resistant *Staphylococcus aureus*). The global multi-center study will generate additional clinical data to support planned future regulatory submissions. A pediatric program with dalbavancin is also planned.

“After careful consideration of feedback and ongoing dialogue with regulatory authorities, Pfizer has decided to study dalbavancin further in patients with complicated skin and skin structure infections,” said Dr. Mark Kunkel, Pfizer’s Global Medical Therapeutic Area Leader for Anti-infectives and HIV. “Dalbavancin represents a potential important treatment advance and Pfizer is committed to ongoing research of its use in patients who suffer from serious skin infections, including those caused by MRSA.”

Dalbavancin, a member of the glycopeptide class of antibiotics, represents an important addition to Pfizer’s broad portfolio of antibacterial products and product candidates. Dalbavancin was acquired by Pfizer in September 2005 as part of its acquisition of Vicuron Pharmaceuticals, Inc.

Pfizer has a long history of developing new medicines for treating infectious diseases and remains committed to providing physicians with this important new treatment option. FDA-approved products, including Pfizer’s ZYVOX® (linezolid IV/Oral), are currently available for the treatment of complicated skin infections caused by MRSA.

MRSA is a virulent and potentially deadly bacterium, and MRSA infections caused by this bacterium are on the rise in hospitals, long-term care facilities and within communities. MRSA is resistant to many classes of commonly used antibiotics and can cause several types of infections, with skin infections being the most common. The Infectious Diseases Society of America (IDSA) has included MRSA on a reported Hit List of top-priority, dangerous drug-resistant microbes that require additional research and new treatments**.**

DISCLOSURE NOTICE: The information contained in this release is as of September 9, 2008. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, Dalbavancin, including its potential benefits and plans for future regulatory submissions, that involves substantial risks and uncertainties.

Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; the results of the planned additional Phase 3 clinical trial; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for Dalbavancin as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in its reports on Form 10-Q and Form 8-K.

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