Pfizer Receives Approvable Letter from FDA for Dalbavancin

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(BUSINESS WIRE)--Pfizer Inc today announced that it has received an approvable letter from the U.S. Food and Drug Administration (FDA) issued for dalbavancin HCl, Pfizer's once-weekly two-dose antibiotic under FDA review for the treatment of adult patients with complicated skin and skin structure infections, including those caused by methicillin-resistant Staphylococcus aureus (MRSA).

The FDA recently published a draft guidance on studies designed to show non-inferiority as a basis for approval of antibacterial drug products and has requested that Pfizer provide additional data with regard to dalbavancin. Pfizer is working with the FDA to respond to these new requirements.

Separately, the FDA approvable letter refers to deviations from current good manufacturing practices (cGMP) at a third-party manufacturer, not specifically related to dalbavancin. The third-party manufacturer is working with the FDA to resolve outstanding manufacturing issues.

Pfizer is also addressing a question from the FDA regarding length of storage time following reconstitution of dalbavancin.

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 for

skin infections caused by MRSA. FDA-approved products, including Pfizer’s ZYVOX® (linezolid IV/Oral), are currently available for the treatment of complicated skin and skin structure infections caused by MRSA.

MRSA is a virulent and potentially deadly bacterium, and MRSA infections 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 December 21, 2007. 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 that involves substantial risks and uncertainties regarding a product candidate that is under review by the United States Food and Drug Administration (FDA), including its potential benefits. Such risks and uncertainties include, among other things, whether and when the FDA will approve the product candidate, the FDA’s decisions regarding labeling and other matters that could affect its availability or commercial potential, as well as competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its reports on Form 10-Q and Form 8-K.

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