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Teva and Active Biotech to Initiate Pivotal Phase III Trial Program of Oral Laquinimod for Relapsing Multiple Sclerosis

JERUSALEM & LUND, Sweden--(BUSINESS WIRE)--Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech AB (OMX NORDIC: ACTI) today announced that the companies are initiating a clinical Phase III program for laquinimod, a novel once-daily, orally administered immunomodulatory compound for the treatment of relapsing multiple sclerosis (RMS). The studies will now begin following the successful conclusion of a second phase II study and the outcome of discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The companies are to commence two global Phase III trials of laquinimod during this year. The Phase III trials will take place in centers in the United States, Europe, and other locations worldwide, to further confirm the results of the Phase II trials.

"We are extremely excited about initiating the Phase III clinical program for oral laquinimod, as we believe laquinimod is a potential new and convenient treatment option for MS patients," said Shlomo Yanai, President and CEO of Teva Pharmaceutical Industries Ltd. "The accelerated development of oral laquinimod is part of our commitment to MS patients to develop additional improved therapies that combine superior efficacy and excellent safety."

"Laquinimod has the potential to be a novel, orally-administered disease modifying treatment for people suffering from multiple sclerosis," said Sven Andréasson, President and CEO of Active Biotech. "Laquinimod would represent a milestone for patients as it would provide them with an efficacious and safe treatment, as well as a new drug delivery option that is suitable for long-term treatment."

About Phase II Laquinimod Trials

Results from a 36-week, randomized, double-blind, placebo-controlled Phase IIb trial evaluating the effect of oral daily 0.3 and 0.6 mg doses of laquinimod on magnetic resonance imaging (MRI)-monitored disease activity in patients with RRMS were recently presented at the American Academy of Neurology (AAN) Annual Meeting in May, 2007. Data from the trial demonstrated that an oral 0.6 mg dose of laquinimod given daily significantly reduced MRI disease activity by 40 percent in RRMS patients and was well tolerated. In addition, there was a favorable trend towards reducing annual relapse rates, the number of relapse-free patients and time to first relapse compared with placebo. Treatment with both 0.3 and 0.6 mg doses of laquinimod were well tolerated with only some transient and dose-dependent increases in liver enzymes.

A previous 24-week Phase IIa trial conducted by Active Biotech demonstrated that oral 0.3 mg laquinimod given daily was well tolerated and reduced the formation of active lesions in RRMS.