Media Release

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Roche and Trimeris announce 24-week results from first Phase III study of HIV fusion inhibitor T-20

Pivotal study meets primary endpoint

Roche and Trimeris, Inc. (Nasdaq: TRMS) today announced positive 24-week results from the first pivotal Phase III study of T-20, the furthest in clinical development of an investigational class of antiretrovirals called fusion inhibitors. The results from this first study (TORO 1: T20-301) as well as the results from a second ongoing study (TORO 2: T20-302) will form the basis of the submission to regulatory authorities.

In the TORO 1 study, T-20 administered in combination with an individualised antiretroviral treatment regimen was shown to provide a significant additional decrease in the amount of virus in the blood as compared to an individualised antiretroviral treatment regimen alone. TORO 1 was conducted in 491 HIV-1 infected patients who were treatment-experienced and/or had documented resistance to each of the three classes of currently available antiretrovirals. At baseline, patients had a median HIV RNA level of over 5 $\log_{10}$ copies/mL and extensive prior exposure to multiple anti-HIV drugs. Patients who received T-20 as part of their combination regimen achieved a reduction in HIV levels of 1.697 $\log_{10}$ copies/mL compared to 0.763 $\log_{10}$ copies/mL for those who were randomised to the control arm, calculated in accordance with the study protocol. The primary efficacy endpoint for the study, the difference in the magnitude of decrease in HIV between the two arms, was 0.934 $\log_{10}$ copies/mL and was statistically significant ($p<0.0001$). Roche and Trimeris expect to present these data in detail at scientific conferences in the next several months.

"These Phase III results demonstrate that T-20 enhanced the activity of combination therapy over 24 weeks," said William M. Burns Head of Pharmaceuticals, Roche. "These results are even better than the positive results of earlier studies had led us to expect, and we are delighted to share this information today."

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"Roche and Trimeris are extremely pleased with the results from this trial. This important milestone brings T-20 one step closer to patients in need of new options to treat their HIV disease," commented Dr. Dani Bolognesi, Chief Executive Officer of Trimeris, Inc.

Safety Results

Through 24 weeks, the incidence of grade 3 and 4 laboratory abnormalities and clinical adverse events was similar between the T-20 and control arms. Additionally, drug discontinuation at 24 weeks was approximately 10% overall and was very similar in both arms. While most patients on the T-20 arm experienced injection site reactions, only 3% of patients discontinued the study as a consequence. Other adverse events (>10%), where the incidence was greater on the T-20 arm than on control, were insomnia, headache, peripheral neuropathy, and dizziness. It was not possible to establish a causal relationship between these other adverse events and T-20.

Study Design

TORO 1 (T-20 vs. Optimised Regimen Only), previously known as T20-301, and TORO 2 (previously known as T20-302) are randomised, open-label trials that enrolled approximately 1,000 patients at 112 centers worldwide. TORO 1 is being conducted in North America and Brazil, while TORO 2 is being conducted in Australia, Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, Switzerland and the United Kingdom. Patients in the trials were treatment-experienced and/or had documented resistance to each of the three classes of currently-available antiretrovirals. In addition, each patient was required to have a plasma HIV-RNA level of greater than 5,000 copies/mL. Patients are expected to undergo treatment for 48 weeks, with an optional 48-week treatment extension.

At entry, genotypic and phenotypic resistance testing was used to aid in the selection of an antiretroviral regimen, consisting of three to five drugs, including if appropriate, up to two newly approved or investigational drugs. After selection of the regimen, patients were randomised 2:1 to receive either the regimen in combination with T-20 or the regimen alone. Patients randomised to T-20 receive T-20 administered as one 90 mg subcutaneous self-injection twice-daily.

Early Access to T-20

In November 2001, Roche and Trimeris announced the initiation of the T-20 open-label safety study (T20-305) to provide T-20 to 450 patients around the world. The study is ongoing and is being conducted in Australia, Brazil, Europe, and North America. An expansion of this trial over the next several months will continue to make T-20 available prior to approval for patients with advanced HIV disease who are unable to construct a viable antiretroviral regimen with currently

approved agents. Additionally, Roche and Trimeris are committed to starting early access programs in the second half of this year when increased drug supply is expected to be available.

Meeting the Growing Need For a New Class of HIV Drugs

One of the biggest challenges facing people living with HIV is resistance to currently available therapies. Thirty to fifty percent of patients are infected with a strain of the virus that has developed resistance to one or more antiretrovirals, thereby reducing the treatment options available to them. Roche and Trimeris are committed to discovering and developing treatments for patients in need of new options and expect to invest approximately half a billion U.S. dollars to bring fusion inhibitors to people living with HIV/AIDS.

Long-Term Commitment to HIV Research and Development

Roche and Trimeris are working together to mobilise the considerable resources required to support the rapid development of T-20, the first member of a new class of investigational anti-HIV drugs known as fusion inhibitors. T-20, currently in Phase III clinical trials, is the furthest along in clinical development in the entry inhibitor class. T-1249, a second generation fusion inhibitor being developed by Roche and Trimeris, is in Phase I/II clinical trials. Unlike existing AIDS drugs that work inside the cell and target viral enzymes involved in the replication of the virus, T-20 inhibits fusion of HIV with host cells before the virus enters the cell and begins its replication process. In June 2001, Roche and Trimeris announced a joint research agreement to identify and develop additional HIV fusion inhibitor peptides.

T-20 has fast track designation from the FDA in the U.S. for the treatment of HIV-infected individuals. Fast track is granted to facilitate the development and expedite the review of applications for drugs that are intended to treat serious or life-threatening disease and that demonstrate the potential to address an unmet medical need.

About Trimeris, Inc.

Trimeris is a development stage, biopharmaceutical company engaged in the discovery and development of novel therapeutic agents that block viral infection by inhibiting viral fusion with host cells. Trimeris' lead product candidate, T-20, which inhibits fusion of the human immunodeficiency virus (HIV) with host cells, is currently in Phase III clinical trials and has received fast track designation from the FDA. Trimeris' second fusion inhibitor product candidate, T-1249, which also inhibits HIV fusion, has received fast track designation from the FDA and is in Phase I/II clinical testing.

For more information on Trimeris, Inc., visit the company's Web site at www.trimeris.com.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life. For more information on Roche and its commitment to research in HIV, visit the: roche-hiv.com website.