Media Release

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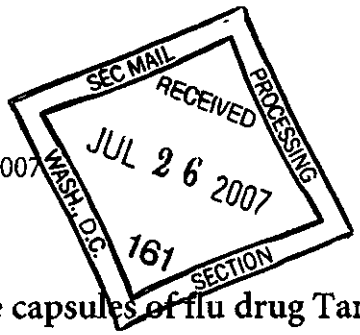
Roche



Basel, 23 July 2007

SUPPL

Smaller size capsules of flu drug Tamiflu receive positive opinion in Europe

30mg and 45mg capsules are convenient alternative to suspension for management of seasonal and pandemic influenza in children

Roche announced today that it has received a positive opinion in Europe from the Committee of Human Medicinal Products (CHMP) recommending marketing authorization for Tamiflu (oseltamivir) capsules of 30 mg and 45 mg doses. Until now, Tamiflu was only available in capsules containing a 75 mg dose of oseltamivir and as a powder for oral suspension. The lower dose capsules provide a convenient alternative for the treatment and prevention of influenza types A and B in patients one year and older. Since the capsules have a longer shelf life than the suspension formulation currently used for children (five years vs. two years), they also offer an improved option for government pandemic stockpiling.

An approval for lower dose capsules was recently granted by the U.S. Food and Drug Administration (FDA).

The application for lower dose capsules was filed in February 2007 based on data already available for the 75 mg capsule. The method of manufacturing will remain the same and the only change will be the size of the capsule and the amount of the active ingredient, oseltamivir, filled into the capsule. The small capsules have longer stability and require considerably less storage space than the currently available paediatric dry suspension. This is critical given the volumes of drug that must be stored and will also facilitate easier distribution in the event of a pandemic.

About Tamiflu

Tamiflu, an oral neuraminidase inhibitor, is designed to be active against all clinically relevant influenza viruses. It works by blocking the action of the neuraminidase enzyme on the surface of the virus. When neuraminidase is inhibited, the virus is not able to spread to and infect other cells in the body. Tamiflu is the only member of the neuraminidase class of drugs approved for use in treatment and prevention of influenza in children 1 to 5 years of age.

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Flu's Impact on Children

Influenza is particularly dangerous for the most vulnerable and this includes young children and infants .Children younger than two years old are as likely as those over age 65 to be hospitalized because of influenza. It is estimated that children are three times more likely to get sick with the flu – on average, one in 10 adults is affected by influenza annually, compared with one in three children. There is a high need for influenza treatments for children as they are more severely affected by seasonal influenza compared to adults.

About Tamiflu (oseltamivir)

Tamiflu delivers:

- 38 percent reduction in the severity of symptoms
- 67 percent reduction in secondary complications such as bronchitis, pneumonia and sinusitis in otherwise healthy individuals
- 37 percent reduction in the duration of influenza illness
- Tamiflu was shown to provide up to 89 percent overall protective efficacy against clinical influenza in adults and adolescents who had been in close contact with influenza-infected patients
- In children, Tamiflu delivers:
- 36 percent reduction in the severity and duration of influenza symptoms
- 44 percent reduced incidence of associated otitis media as compared to standard care

Roche's efforts to support government pandemic stockpiling

The World Health Organization (WHO) advises that stockpiling antivirals in advance is presently the only way to ensure that sufficient supplies are available in the event of a pandemic. Roche has been working closely with WHO and national governments to ensure governments are aware of the importance of stockpiling antivirals in the event of a pandemic situation. Roche has received and fulfilled pandemic orders for Tamiflu totalling 215million treatments from more than 80 countries worldwide. The magnitude of these orders varies with some countries, France, Finland, Iceland, Ireland, Luxembourg, Netherlands, New Zealand, Norway, Switzerland and UK stockpiling or intending to stockpile adequate Tamiflu to cover 20-40% of their population. Few governments to date have stockpiled paediatric antiviral formulations. Roche has also donated 5.125 million courses of Tamiflu treatment to the WHO for international rapid response and regional response to a pandemic influenza strain.

Roche and Gilead

Tamiflu was invented by Gilead Sciences and licensed to Roche in 1996. Roche and Gilead partnered on clinical development, with Roche leading efforts to produce, register and bring the product to the markets. Under the terms of the companies' agreement, amended in November 2005, Gilead participates with Roche in the consideration of sub-licenses for the pandemic supply of oseltamivir. To ensure broader access to Tamiflu for all patients in need, Gilead has agreed to waive its right to full royalty payments for product sold under these sub-licenses.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet at www.roche.com.

Further information

- Roche Health Kiosk on Influenza: www.health-kiosk.ch/start_grip.htm
- More information about Tamiflu: www.roche.com/med_mbtamiflu05e.pdf
- More about the flu: www.roche.com/med_mbinfluenza05e.pdf
- Information from WHO on influenza: www.who.int/csr/disease/influenza/en/
- Information from WHO on avian flu: www.who.int/mediacentre/factsheets/avian_influenza/en/

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Media Release

Basel, 25 July 2007

Actemra monotherapy demonstrates significant clinical benefit in patients with rheumatoid arthritis

- Fourth phase III study with novel interleukin-6 receptor inhibitor meets primary endpoint
- Global regulatory filing on track for late 2007

Roche announced today that AMBITION[1], the study aiming to demonstrate the safety and efficacy of Actemra (tocilizumab) monotherapy, successfully met its primary endpoint[2] in patients with moderate to severe rheumatoid arthritis (RA). This is the fourth study in Actemra's extensive multinational phase III development programme. The study examined the use of Actemra monotherapy against a standard, effective regimen of methotrexate in patients with active RA, including a high proportion of patients with early disease. The data show that a greater proportion of patients treated with Actemra (8mg/kg), achieved a significant improvement in disease signs and symptoms (ACR scores[3]) following 24 weeks of treatment, compared to patients treated with methotrexate alone.

"This is the first multinational phase III trial using Actemra monotherapy. The trial demonstrates Actemra's safety and efficacy, reinforcing the role of IL-6 receptor inhibition in RA" said William M. Burns, CEO Pharmaceuticals Division of Roche. "These exciting data support Actemra's potential as a new future therapy for RA patients."

The study, together with data from the previous three international studies, will form the basis of the regulatory filing for marketing approval later this year.

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About the AMBITION study

The AMBITION trial is a two-arm, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of Actemra (8 mg/kg) compared to methotrexate in RA patients. Patients received either Actemra intravenously (8 mg/kg) every four weeks plus placebo capsules weekly or placebo infusions every four weeks plus methotrexate weekly. The study included 673 patients at 252 trial sites in 18 countries, including the United States.

Previous and ongoing studies

The AMBITION trial is one of five phase III clinical studies designed to evaluate Actemra as a potential new treatment for RA. Three of the phase III trials – OPTION[4], TOWARD[5] and RADIATE[6] – are completed and have reported meeting their primary study endpoints. At the European Congress of Rheumatology meeting in June, data results from the OPTION trial demonstrated that treatment with Actemra plus methotrexate resulted in a significant improvement in RA symptoms in patients who had an inadequate response to methotrexate. An additional phase III trial evaluating Actemra in RA is ongoing; the two-year study, called LITHE, is expected to report later in 2008. Data from the AMBITION study will be submitted for presentation at future international scientific meetings.

About Actemra

Actemra is the first humanised interleukin-6 (IL-6) receptor inhibiting monoclonal antibody and represents a novel mechanism of action to treat RA, a disease with a high unmet medical need. The overall safety profile observed in the global studies of Actemra is consistent and Actemra is generally well tolerated. The most frequent adverse events reported have included upper respiratory tract infections, headache, nasopharyngitis and hypertension. As with other biological disease modifying anti-rheumatic drugs (DMARDs), serious infections have been reported in some patients treated with Actemra.

Roche and Chugai are collaborating on a phase III clinical development programme in RA running outside Japan, with more than 4000 patients enrolled in 41 countries including several European countries and the USA. In Japan, Actemra was launched in June 2005 as a therapy for Castleman's disease and in April 2006 filed for the additional indications of rheumatoid arthritis and systemic-onset juvenile idiopathic arthritis.

About rheumatoid arthritis

Rheumatoid arthritis is a progressive, systemic autoimmune disease characterized by chronic inflammation of multiple joints and fatigue as well as the possibility of osteoporosis, anaemia, and lung, skin and liver effects. This inflammation causes pain, stiffness and swelling, resulting

in loss of joint function due to destruction of the bone and cartilage, often leading to progressive disability. Further, as chronic inflammation continues, there may be shortening of life expectancy as a result of effects on major organ systems. After 10 years, less than 50% of patients can continue to work or function normally on a day to day basis. RA affects more than 21 million people worldwide.

About Roche in rheumatoid arthritis

One of the most important drivers for growth at Roche over the next few years is expected to be the company's emerging franchise in autoimmune diseases with rheumatoid arthritis as the first indication. Following the launch of MabThera® (rituximab) there are a number of projects in development, potentially allowing Roche to build on further opportunities. MabThera is the first and only selective B-cell therapy for RA, providing a fundamentally different treatment approach by targeting B cells, one of the key players in the pathogenesis of RA. Actemra is Roche's second novel medicine and is a humanised monoclonal antibody to the interleukin-6 (IL-6) receptor, inhibiting the activity of IL-6 , a protein that plays a major role in the RA inflammation process. Actemra is the result of research collaboration by Chugai and is being co-developed globally with Chugai. Additional projects creating a rich pipeline include compounds in Phase I, II and III clinical trials. Notably, ocrelizumab, a humanised anti-CD20 antibody, has entered phase III development for RA.

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Further information

- Roche & Autoimmune diseases: www.roche.com/med_events_mb1106

References:
[1]AMBITION refers to Actemra versus Methotrexate double-Blind Investigative Trial In mONotherapy trial
[2]The proportion of patients who achieved ACR20 at week 24
[3]The ACR response is a standard assessment used to measure patients' responses to anti-rheumatic therapies, devised by the American College of Rheumatology (ACR). It requires a patient to have a defined percentage reduction in a number of symptoms and measures of their disease. For example, a 20%, 50% or 70% level of reduction (the percentage of reduction of RA symptoms) is represented as ACR20, ACR50 or ACR70. An ACR70 response is exceptional for existing treatments and represents a significant improvement in a patient's condition.
[4]OPTION refers to the TOcilizumab Pivotal Trial in Methotrexate Inadequate respONders
[5]TOWARD refers to Tocilizumab in cOmbination With traditional DMARD therapy
[6]RADIATE refers to Research on Actemra Determining efficacy after Anti-Tnf FailurEs

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