

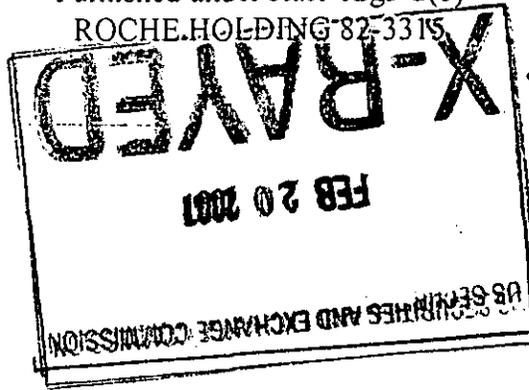
# Media release



Basel, 16. February, 2007

Furnished under Rule 12g3-2(b)

ROCHE.HOLDING 82-3315



## Roche files application in Europe for Tamiflu 30 and 45 mg capsules

Alternative to suspension for seasonal and pandemic use in children

# SUPL

Roche has filed an application with regulatory authorities in Europe requesting an extension of the current Tamiflu license to include smaller capsules of 30 mg and 45 mg in addition to the 75 mg capsule already registered. These lower dosage strengths have been developed mainly for use in children for seasonal and pandemic influenza, as an alternative to the suspension formulation. Tamiflu small capsules would also be useful in the elderly or other adults that have difficulty swallowing the 75 mg capsule. Roche has been granted an accelerated review and is optimistic that

the FDA will complete their evaluation by mid-year.

**PROCESSED**

**FEB 23 2007**

**THOMSON  
FINANCIAL**

An application will also be filed with the Food and Drug Administration (FDA) in the US shortly.

The application was filed based on information 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.

As well as being used to manage seasonal influenza, the 30 mg and 45 mg capsules will be an important component in government pandemic preparedness. They provide:

- A better option for stockpiling for paediatric use, given the longer shelf life compared to paediatric suspension.
- Easier and more convenient dosing by parents. These unit dosing capsules could also allow accurate preparation of an extemporaneous formulation (the contents of the capsules can be used for oral dosing of a solution).

A number of governments have stockpiled Active Pharmaceutical Ingredient (API) as an option, particularly for children, in the event of a pandemic. However the preparation of the API into a drinking solution is logistically more challenging and time consuming than distributing capsules.

Therefore, Roche is now in the process of offering additional services for encapsulating existing API stockpiles, particularly with the new formulations. A number of countries are in discussion regarding this exchange and Finland has already exchanged all of its API for capsules.

#### 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.

#### 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.

#### 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 from more than 75 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. 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 a supplier of innovative 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 a world leader in diagnostics, the leading supplier of drugs for cancer and transplantation, and a market leader in virology. 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 people in 150 countries 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](http://www.roche.com).

All trademarks used or mentioned in this release are protected by law.

#### **Additional information**

- Roche Health Kiosk, Influenza: [www.health-kiosk.ch/start\\_grip.htm](http://www.health-kiosk.ch/start_grip.htm)
- About Tamiflu: [www.roche.com/med\\_mbtamiflu05e.pdf](http://www.roche.com/med_mbtamiflu05e.pdf)
- About influenza: [www.roche.com/med\\_mbinfluenza05e.pdf](http://www.roche.com/med_mbinfluenza05e.pdf)
- WHO: Global influenza programme: [www.who.int/csr/disease/influenza/en/](http://www.who.int/csr/disease/influenza/en/)
- WHO: Avian flu: [www.who.int/mediacentre/factsheets/avian\\_influenza/en/](http://www.who.int/mediacentre/factsheets/avian_influenza/en/)

**Roche Group Media Office**

Telephone: +41 61 688 8888 / Email: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Baschi Dürr
- Daniel Piller (Head Roche Group Media Office)
- Katja Prowald (Head Science Communications)
- Martina Rupp

# Investor Update



Basel, 16 February 2007

## Quick and easy to use cobas h 232 portable cardiac marker system for cardiovascular diagnoses launched

The new portable system is designed for on the spot results – fast diagnosis and fast treatment decisions

Today, Roche Diagnostics announced the launch outside the United States of the cobas h 232 system. This handheld device is for rapid, on-site determination of the important cardiac markers – NT-proBNP, troponin T, CK-MB, myoglobin\* and D-Dimer - in the assessment of symptoms indicative not only of cardiovascular conditions such as acute coronary syndrome (ACS) and heart failure, but also thromboembolic events.

"I am proud that we are now able to offer the easy-to-use, handheld cobas h 232 Point of Care system for cardiovascular diagnosis that offers healthcare professionals in hospitals, as well as general practitioners, access to fast diagnostic results. Patients will benefit from rapid diagnosis and treatment decisions based on the health information provided", states Dr. Volker Pfahlert, Head of Roche Professional Diagnostics, a business area of Roche Diagnostics. "Connected to the cobas IT 1000 data management solution, which serves to collect and analyze the test results, we can allow effective remote management and offer cobas h 232 users further efficiencies in workflows and enhancements in quality assurance – a unique solution from Roche Diagnostics".

With a broad menu covering 5 key cardiac parameters, this portable system is designed to work in different clinical settings. The determination of NT-proBNP in general practice and cardiology can support early diagnosis and exclusion of heart failure easily and rapidly, thus helping practitioners avoid unnecessary and costly referrals. By providing diagnostic information directly on the spot, the cobas h 232 system also aims to facilitate triage and quick treatment decisions for patients presenting with acute symptoms such as chest pain or severe shortness of breath in the emergency room. Patients benefit from earlier interventions that can help save lives, with improved patient management also contributing to lower overall treatment costs.

The cobas h 232 system is a small, self-contained, portable analyzer. It is maintenance-free and

offers different levels of customizable quality control and data management features to meet today's requirements for documentation and quality assurance in Point of Care testing. The cobas h 232 analyzer is designed for use with the pre-calibrated Roche Cardiac single-use test strip assays that are standardized to laboratory reference methods from Roche Diagnostics and clinically validated in a number of trials. Requiring only a single whole blood sample, the cobas h 232 system's touch-screen user interface guides the user during test handling - the test result is provided within minutes.

#### **About Point of Care Testing**

By providing rapid, accurate results at the point of care, Point of Care testing speeds up diagnosis and treatment; improving clinical outcomes and improving workflows by ensuring patients are managed efficiently and more cost-effectively. The rapid results provided by Point of Care testing enable quick referral or initiation of treatment, leading to improved clinical outcomes<sup>1</sup>.

#### **About cobas IT 1000**

The cobas IT 1000 solution is a web based Point of Care Data Management System providing connectivity for devices used for patient bedside testing such as the Accu-Chek Inform, CoaguChek XS Plus and cobas h 232 systems. The cobas IT 1000 solution enables hospitals and hospital networks to manage and control their Point of Care testing program by managing test results, operators, quality controls and instruments.

For more information on the cobas IT 1000 solution please visit:

[www.roche.com/prod\\_diag\\_cobas-it](http://www.roche.com/prod_diag_cobas-it)

#### **About Roche and the Roche Diagnostics Division**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative 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 a world leader in diagnostics, the leading supplier of drugs for cancer and transplantation and a market leader in virology. 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 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai Roche's Diagnostics Division offers a uniquely broad product portfolio and supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information, please visit our website [www.roche.com](http://www.roche.com).

\* Roche Cardiac M assay for use on the cobas h 232 system will be available in the course of Q3/2007.

1- Heidenreich PA. Cost-effectiveness of screening with B-type natriuretic peptide to identify patients with reduced left ventricular ejection fraction. *J Am Coll Cardiol* 2004; 43: 1019-1026.

All trademarks used or mentioned in this release are legally protected.

**Roche IR Contacts:**

Dr. Karl Mahler  
Phone: +41 (0)61 687 85 03  
e-mail: karl.mahler@roche.com

Dianne Young  
Phone: +41 (0)61 688 93 56  
e-mail: dianne.young@roche.com

Dr. Zuzana Dobbie  
Phone: +41 (0)61 688 80 27  
e-mail: zuzana.dobbie@roche.com

Carla Bedard  
Phone: +41 (0)61 687 13 00  
e-mail: carla\_christine.bedard@roche.com

Dr. Nicolas Dunant  
Phone: +41 (0)61 687 05 17  
e-mail: nicolas.dunant@roche.com

**North American investors please contact:**

Thomas Kudsk Larsen  
Phone: +1 973 235 36 55  
Mobile phone: +1 973 393 53 15  
e-mail: thomas\_kudsk.larsen@roche.com

**General inquiries:**

International: +41 (0)61 688 88 80  
North America: +1 973 562 22 33  
e-mail: investor.relations@roche.com

END