

# Media Release

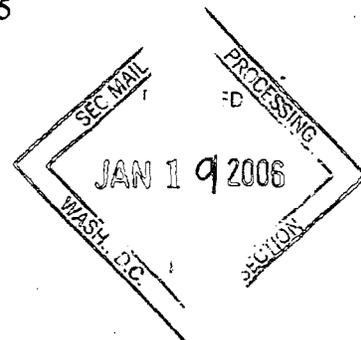


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ROCHE HOLDING 82-3315



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## Roche donates a further 2 million treatment courses of antiviral Tamiflu to the WHO for regional stockpiling

Roche announced today that it will donate another 2 million treatment courses, or 20 million doses, of the antiviral Tamiflu (oseltamivir) to the World Health Organization (WHO). This is addition to previous donations made by Roche in 2004 and in August 2005, and will result in a total of 5.125 million treatment courses being available to the WHO to help people affected by a potential pandemic.

Whilst the donation made last year is stored centrally, these additional 2 million treatment courses will be stored as regional stockpiles in locations to be determined by WHO to serve the needs of developing countries. The regional stockpiles of Tamiflu will be used to reduce morbidity and mortality in the case of an outbreak of avian influenza in humans and prevent the further spread of such an outbreak, in the interest of public health.

"Roche is working as a collaborative and responsible partner with governments and the WHO to assist in pandemic planning, including the stockpiling of Tamiflu. We are pleased to be able to further increase our donation to the WHO and help establish regional stockpiles of Tamiflu", commented William M. Burns, CEO Division Roche Pharma.

"By establishing regional stockpiles of antivirals, developing countries most likely to be affected by avian influenza in humans will be better prepared to rapidly manage outbreaks in the interest of global public health. It is important to emphasize that this and the previous donation(s) do not replace the need for countries to consider the establishment of national antiviral stockpiles as one of a number of measures of national pandemic preparedness consistent with the national priorities of each country", commented Lee Jong-Wook, the Director-General of the World

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## **Health Organization.**

In contrast to the regional stockpiles of Tamiflu, the "rapid response stockpile" of 3 million courses of Tamiflu treatment donated by Roche to the WHO in August 2005, will be used exclusively at the site of outbreak of a pandemic in an attempt to contain or slow its spread.

### **A comprehensive production network**

In order to increase the availability of Tamiflu to meet the growing demand as pandemic planning continues, Roche has taken significant steps to increase manufacturing capacity, doubling production capacity in 2004 and 2005 and will have the capacity to produce over 300 million treatments of Tamiflu annually by 2007 - more than a ten fold increase over the capacity in 2004. Roche has established close relationships with 50 external suppliers and the supply chain in place exceeds our current orders from Governments. Roche is now in a position to have a back-up supply in case of emergency and companies identified to take the capacity further will allow Roche's supply network to respond to future demands from governments. Furthermore Roche has granted sublicenses to manufacture oseltamivir to a Chinese and an Indian pharmaceutical manufacturer.

### **About pandemics and H5N1**

Influenza pandemics occur approximately every 40 years, and experts caution that it is a case of when, not if, the next pandemic will strike. The H5N1 avian influenza strain originating in Asia is considered by experts to be the most likely source of the next pandemic. Tamiflu is designed to be active against all clinically relevant influenza viruses, including H5N1, and data suggest it could be effective against any mutating strain of the virus- the key to a pandemic. An orally administered treatment, Tamiflu is systemically active, and can protect against the virus at all sites in the body.

### **About Tamiflu (oseltamivir)**

Tamiflu is designed to be active against all clinically relevant influenza viruses and key international research groups have demonstrated, using animal models of influenza that Tamiflu is effective against the avian H5N1 strain circulating in the Far East.<sup>3</sup>

It works by blocking the action of the neuraminidase (NAI) 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 delivers:

- 38 percent reduction in the severity of symptoms<sup>1</sup>
- 67 percent reduction in secondary complications such as bronchitis, pneumonia and

sinusitis in otherwise healthy individuals <sup>2</sup>

- 37 percent reduction in the duration of influenza illness<sup>5,3</sup>
- 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<sup>4</sup>

In children, Tamiflu delivers:

- 36 percent reduction in the severity and duration of influenza symptoms<sup>5</sup>
- 44 percent reduced incidence of associated otitis media as compared to standard care<sup>6</sup>

As with any antiviral, a theoretical potential exists for an influenza virus to emerge with decreased sensitivity to a drug. Extensive monitoring, by Roche and the independently established Neuraminidase Inhibitor Susceptibility Network (NISN) measured the incidence of resistance to NAIs. From around 4000 patients treated with Tamiflu resistance was encountered in 0.4 per cent in adults and 4 per cent in children aged one to 12. This resistant virus was found to be less virulent than the wild type virus and did not affect the course of the illness.

The greatest use of Tamiflu today is in Japan. To illustrate this, there were an estimated 16 million influenza infections in Japan over the 2004/2005 influenza season. Roche estimates that around 6 million of those individuals infected with the influenza virus received Tamiflu. Even with this degree of usage, resistance appears very infrequent.

#### **Avian Influenza and Pandemics**

Most avian influenza viruses are not infectious to humans, but, should an avian and a human influenza virus co-infect a human or a pig, the virus strains can join, mutate and create a completely new virus, which may be transmissible from animals to humans, and from humans to humans. Such a strain would be entirely new in composition, so vaccines developed and administered to date to protect humans during seasonal epidemics, would be ineffective against this new strain, leaving the population vulnerable to infection. Experts believe the next influenza pandemic could result from such a mutation of virus strains.

#### **World Health Organisation**

One of WHO's recommendations as part of its Pandemic Preparedness Plan is that countries establish stockpiles of antiviral treatments, which are effective against all strains of the influenza virus. The Pandemic Preparedness Plan, along with details of the countries that have implemented national plans, can be viewed at:

[http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_EDC\\_99\\_1/en/](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_EDC_99_1/en/)

## 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 disease, 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 medicines for cancer and transplantation and a market leader in virology. Roche employs roughly 65,000 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 ([www.roche.com](http://www.roche.com)).

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## 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\\_mbrtamiflu04e.pdf](http://www.roche.com/med_mbrtamiflu04e.pdf)
- About Influenza: [www.roche.com/med\\_mbrinfluenza05e.pdf](http://www.roche.com/med_mbrinfluenza05e.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/fs205/en/](http://www.who.int/mediacentre/factsheets/fs205/en/)

## Roche Group Media Office

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

- 1 Treanor JJ et al. Efficacy and safety of the oral neuraminidase inhibitor oseltamivir in treating acute influenza: a randomized, controlled trial. *JAMA*:283;2000 1016-24
- 2 Kaiser et al. Impact of Oseltamivir treatment on influenza-related lower respiratory tract complications and hospitalisations. *Arch Intern Med*(2003) 1672-163:1667 .
- 3 Nicholson KG et al. Efficacy and safety of oseltamivir in treatment of acute influenza: a randomised controlled trial. *Lancet* 1850-365:1845 ;2000
- 4 Welliver R. W. et al. Effectiveness of oseltamivir in preventing influenza in household contacts: a randomized controlled trial. *JAMA* 2001 ,Feb 14; 285(6): 748-754
- 5 Whitley RJ, Hayden FG et al; Oral oseltamivir treatment of influenza in children. *Pediatr Infect Dis J*:20 ;2000 122-133
- 6 Roche data on file, 2003

## *International media*



Basel, 5 January 2006

### **Invitation to the 2006 Annual Media Conference Wednesday, 1 February 2006, 10.00 am, in Basel**

Ladies and Gentlemen,

We take pleasure in inviting you to Roche's Annual media conference in Basel to present our Group sales and profit figures for 2005. We look forward to welcoming you at the Roche campus on 1 February. Please use the entrance to Building 52 (high-rise). A media package will be waiting for you at the Welcome Desk from 09.00 am onwards, and the conference starts at 10.00 am. Our Annual Report and other background material will also be available. As in the past, press room facilities including phones, fax machines and e-mail connections will be provided. The Annual Report and a media release will also be available on the Internet ([www.roche.com](http://www.roche.com)) from 7:00 am onwards.

The conference will be held primarily in German. Simultaneous interpretation into French and English will be provided throughout the conference. The event will also be broadcast on the Internet.

Please assist us with our preparations by completing and returning the enclosed registration form by January 20, 2006.

Yours sincerely,

A handwritten signature in dark ink, appearing to read "D. Piller", written over a dotted grid background.

**Daniel Piller**  
Head, Roche Media Office

**Enclosures: Registration form and information for attendees**

## Information for attendees, Annual Media Conference, 1 February 2006

- Place** Enter through Building 52/high-rise, Grenzacherstrasse 124, Basel.
- Programme (CET)**
- |               |  |
|---------------|--|
| 07:00         | Media release                              |
|               | Annual Report on Internet                  |
| 09:00         | Media package available                    |
|               | Coffee and croissants served in the foyer  |
| 10:00 - 10:50 | Conference                                 |
|               | Speeches and presentations on the Internet |
| approx. 10:50 | Questions and answers                      |
| approx. 11:30 | Conference ends                            |
|               | Standing buffet lunch                      |
| 11:30 - 12:45 | Interviews                                 |
- Fax/e-mail** Press room facilities are provided in Building 71 in Room 6 (includes fax and e-mail connections) and Room 11.
- Refreshments** Following the conference you are invited to a standing buffet lunch.
- How to get here**

By car

Leave the motorway at the Grenzach/Wyhlen exit, then head for Wettsteinplatz. Please use the visitors' car park in Peter Rot-Strasse (turn right at the end of the Roche campus).

By train

	<u>Depart</u>	<u>Arrive</u>
Mannheim - Basel Bad Bf:	06:31	08:47
or:	07:36	09:47
Basel Bad Bf - Mannheim:	12:12	14:22
or:	13:12	15:22
or:	14:12	16:22
Bern - Basel SBB:	08:04	08:59
or:	08:35	09:33
or:	09:04	09:59
Basel SBB - Bern:	12:00	12:56
or:	12:27	13:25
or:	13:00	13:56
or:	13:27	14:25
Zurich HB - Basel SBB:	07:34	08:36
or:	08:02	08:54
or:	08:34	09:36
Basel SBB - Zurich HB	12:07	12:56
or:	12:22	13:26
or:	13:07	13:56
or:	13:22	14:26

Geneva - Basel SBB:	05:36	08:33
or:	06:45	09:33
or:	07:13	09:53
Basel SBB - Geneva:	12:27	15:15
or:	13:05	15:47
or:	13:27	16:15
or:	14:27	17:15
Lausanne - Basel SBB:	06:45	08:51
or:	07:45	09:51
or:	07:20	09:33
Basel SBB - Lausanne:	12:27	14:40
or:	13:27	15:40
or:	14:05	16:15
or:	14:27	16:40

At Basel's SBB station take the no. 2 tram in the direction of Eglisee.  
Get off at Wettsteinplatz and either take bus 31 to Hoffmann-La Roche (second stop in the direction of Hörnl) or walk along the Grenzacherstrasse to Roche (5 minutes).

**Information**

If you have any questions, please contact our Media Office (tel. +41 61 888 8888).

**Cancellations**

If you register for the conference and then find that you will be unable to attend, please notify us by phone.



# Registration form for the Annual Media Conference Basel, 1 February 2006

**Last/first names** \_\_\_\_\_

**Media affiliation** \_\_\_\_\_

**Address** \_\_\_\_\_

\_\_\_\_\_

**Phone** \_\_\_\_\_

**Fax** \_\_\_\_\_

**E-mail** \_\_\_\_\_

- I will be attending the Annual Media Conference on 1 February 2006
- I wish to attend the buffet lunch
- Please send me a press kit

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

Please return your registration form no later than January 20, 2006, addressing it to:

**Roche**  
**Corporate Communications / Media Office**  
**Alice Spinas Building 21/20**  
**CH-4070 Basel, Switzerland**

Or send it by fax to: +41 61 888 27 75

# Media Release

Furnished under Rule 12g3-2(b)  
ROCHE HOLDING 82-3315



Basel, 12 January 2006

## **Roche offers help to local manufacturers to produce HIV medicine for sub-Saharan Africa and Least Developed Countries**

**New Technology Transfer Initiative announced**

Today Roche pledged further help to tackle HIV/AIDS in the world's poorest and hardest hit countries. As part of its new Technology Transfer Initiative, Roche announced that it will expand its current activities within sub-Saharan Africa and the world's Least Developed Countries by providing local manufacturers with the technical expertise required to produce generic HIV medicines. These countries cover 69% of all people living with HIV/AIDS in the world. The model for the transfer of expertise will be based upon the processes to manufacture the HIV protease inhibitor medicine, saquinavir, recommended by the World Health Organization as a second line treatment in resource limited settings.

William M. Burns, CEO Division Roche Pharmaceuticals, stated, "With international funding now available, Africa will be the world's biggest user of HIV medicine. We have taken this unique step, which is unlike any initiative undertaken by Roche, to help ensure that the right medicines in the right formulation are available locally. We want to use the knowledge we have developed to help strengthen local manufacturing capability and hope to help as many manufacturers as possible in these hardest hit countries by sharing our knowledge, so that they can learn and benefit from our technology."

A new Roche team is being established and the full team will be fully operational from the second quarter of 2006. The team will be based in part on the ground in Africa, as much of the knowledge and skill sharing will be undertaken onsite, at the local manufacturer's production facilities, and in part at the global headquarters in Basel, Switzerland.

With the growing scale up effort resulting in increased access to first line treatment in resource

limited settings, such as sub-Saharan Africa, the need and subsequently the demand for second line treatments will continue to grow. As a result, increasing manufacturing knowledge and capacity within these regions could play a vital role in treatment delivery.

#### **About Roche's Technology Transfer Initiative**

Manufacturers in sub-Saharan Africa and the Least Developed Countries wishing to produce generic saquinavir for use in these countries will not be required to apply for a voluntary licence, as Roche has committed as part of its global policy not to enforce the patents it holds on HIV medicines within these regions. Interested manufacturers should contact the Project Manager, Technology Transfer Initiative at the Roche Kenya office: [info.aidstechtransfer@roche.com](mailto:info.aidstechtransfer@roche.com).

#### **About the countries invited**

Interested manufacturers in the following countries are invited to contact Roche to discuss the Technology Transfer Initiative: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Botswana, Burundi, Cambodia, Cameroon, Congo, Côte d'Ivoire, Cape Verde, Central African Republic, Chad Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana Gambia, Guinea, Guinea-Bissau, Haiti Kenya, Kiribati, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritius Mauritania, Mozambique, Myanmar, Namibia, Nigeria Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Seychelles Senegal, Sierra Leone, Solomon Islands, Somalia, South Africa, Swaziland Sudan, United Republic of Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, Zambia Zimbabwe.

#### **About Roche's patent and pricing policy**

In addition to its Technology Transfer Initiative, Roche will maintain its current pricing and patent policy for the developing world. No patents for any of Roche medicines – across all disease areas – will be filed in the world's Least Developed Countries (LDCs), as defined by the UN. Roche will not file patents on new HIV/AIDS medicines in Least Developed Countries or sub-Saharan Africa. Roche will not take action in these countries against the sale or manufacture of generic versions of HIV medicines for which Roche still holds patents. Generic versions of such HIV medicines can therefore be produced in LDCs and sub-Saharan Africa without the need for a voluntary or compulsory licence. Roche makes its HIV protease inhibitors Invirase and Viracept available at no profit prices for direct supplies from Roche Basel to LDCs and sub-Saharan Africa.

#### **About Roche**

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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. Roche employs roughly 65,000 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).

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**Further information**

- Roche & HIV/AIDS: [www.roche-hiv.com](http://www.roche-hiv.com)
- Access to Roche's medicines: [www.roche.com/sus\\_med.htm](http://www.roche.com/sus_med.htm)

**Roche Group Media Office**

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## Media Release



Basel, 12 January 2006

### **Roche's rapid sepsis test now available in the European Union**

**LightCycler SeptiFast Test is self declared for CE Mark – faster results in diagnosis of "blood poisoning"**

Roche today announced that its new LightCycler SeptiFast Test has received CE Mark ("Conformité Européenne"), allowing Roche Diagnostics to sell the test for diagnostic use in the European Union. The LightCycler SeptiFast Test can rapidly and reliably detect and identify 25 different sepsis-causing pathogens – including bacteria and fungi – which cause approximately 90 percent of all sepsis cases. This new test opens up a whole new dimension in sepsis diagnosis as rapid initiation of targeted treatment is crucial in this condition.

Over 18 million cases of severe sepsis occur each year. According to epidemiological studies, severe sepsis accounts for up to 135,000 European and 215,000 American deaths each year. In Germany, severe sepsis accounts for up to 60,000 deaths each year, a figure that makes this condition the third leading cause of death in Germany after coronary heart disease and acute myocardial infarction. Despite improvements in its medical management, sepsis still constitutes one of the greatest challenges in intensive care medicine.

Micro-organisms responsible for causing sepsis are traditionally detected in hospital laboratories with the aid of microbiological culture methods which are very time-consuming, generally taking from two to five days to complete, and up to eight days for the diagnosis of fungal infections. By contrast, the LightCycler SeptiFast Test offers the advantage of being able to detect and identify the sepsis pathogens in less than 6 hours – an important time saving for targeted medical treatment. Only after pathogens are correctly identified can targeted therapy using a specific antibiotic begin.

"We are very pleased that we can offer physicians this new test and support their efforts to fight this life-threatening infection. Combining the latest PCR technology and our know-how in molecular

diagnostics has allowed us to rapidly develop this potentially life-saving test. I am confident that many patients will greatly benefit from it," states Severin Schwan, CEO Division Roche Diagnostics and Member of the Corporate Executive Committee of Roche.

#### **About the LightCycler SeptiFast Test**

The LightCycler SeptiFast Test can detect several pathogens simultaneously from just one blood sample. Three millilitres of whole blood are sufficient – even if the collected sample only contains minute quantities of pathogen DNA. It can even be used to identify bacteria that have already been treated with antibiotics and that therefore would not be detectable by traditional culture methods. The test operates on the basis of the Polymerase Chain Reaction (PCR). This method is used to copy repeatedly specific sequences from the genetic material of the pathogen (deoxyribonucleic acid, DNA) so that even small initial quantities can be clearly identified. From the technical standpoint, the LightCycler SeptiFast Test is implemented on the LightCycler 2.0 and is characterized by the MGRADE quality of its reagents. Practically speaking, these are free of any contamination with microbial genetic material that would compromise the reliability of the results. Additional information is available on the Internet at [www.roche-diagnostics.com/press\\_lounge/sepsis.html](http://www.roche-diagnostics.com/press_lounge/sepsis.html).

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#### **Further information**

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