

# Media Release



03007462

PROCESSED

APR 01 2003

SUPPL

THOMSON  
FINANCIAL

Basel, 13 February 2003

## Roche updates pricing policy for protease Inhibitor AIDS Drugs within Accelerating Access Initiative

### No profit prices for direct sales of Viracept and Invirase to Least Developed Countries and sub-Saharan Africa

REC'D  
FEB 19 2003  
1086

Following ongoing discussions with partners, Pfizer Inc. and Japan Tobacco Inc., holding the patents for Viracept (nelfinavir), Roche announces an updated policy for its protease inhibitor (PI) drugs Invirase (saquinavir) and Viracept to treat HIV/AIDS across Least Developed Countries and sub-Saharan Africa. The policy aims to further increase access to these WHO defined essential medicines in countries hardest hit by the AIDS pandemic, with substantial price reductions for Viracept.

Key elements of this updated policy include:

- Further reduction in the price of the adult formulation of Viracept to the same "no profit" level previously available for the paediatric formulation and Invirase – now available for direct supplies from Roche headquarters (HQ) in Switzerland to sub-Saharan Africa and UN defined Least Developed Countries
- Clear pricing for direct supplies from Roche HQ to low income and lower middle income countries - as classified by the World Bank
- Reiteration that Roche will not act against infringement of patents Roche holds on HIV/AIDS drugs in sub-Saharan Africa and UN defined Least Developed Countries, nor will Roche file patents on new or investigational HIV/AIDS medications in these countries.

"Our revised policy demonstrates Roche's commitment to the fight against HIV and to further accelerate access to care in these African and Least Developed Countries" stated William M. Burns, Head of Roche Pharma. "The "no profit" prices are designed to facilitate greatest possible access to

*llw*  
3/19

Invirase and Viracept in these hardest hit regions of the world and we will request these governments to eliminate tax and duty mark ups for these essential medicines. While our policy has significantly reduced prices and removed patent issues as barriers to HIV therapy, it would be wrong to suggest that we can solve the problem through these steps alone. Affordability is only one of many barriers to care in developing countries.”

This news represents a significant expansion of Roche's policy since 2000 when Roche joined the Accelerating Access Initiative to increase access to HIV healthcare. As part of that initiative, Roche provided significant reductions on the price of its PIs - with Invirase and Viracept paediatric powder available at no profit across sub-Saharan Africa and the world's Least Developed Countries. In addition Roche is supporting programmes in the region to develop local expertise and provide therapy.

“We are very pleased that our business partners at Roche share our commitment to improving access to HIV/AIDS medicines for patients facing the most difficult economic and health circumstances,” said Pfizer Chairman and Chief Executive Officer Hank McKinnell. “This announcement reconfirms our belief that access to medicines should not be limited by a limited income.”

**Pricing policy - designed to increase access to essential Protease Inhibitors in most needy countries**  
The “no profit” prices for all countries in sub-Saharan Africa and the Least Developed Countries are ex-factory prices direct from Roche's headquarters in Basel Switzerland and are available to Governments, Non Profit Institutional Providers of HIV care and Non-Governmental Organisations (NGOs) in these countries. While the full terms of purchase are posted on [www.Roche-hiv.com](http://www.Roche-hiv.com), the prices available for direct supply from Roche HQ mean that additional costs for freight, import, duty, taxes, distribution and inventory need to be added. The retail prices within these countries will therefore be higher and may vary substantially.

Summary of prices available for direct purchases from Roche Basel, valid as of 1<sup>st</sup> March 2003

Available to	Viracept Price per pack of 270 x 250mg tablets/ CHF	Invirase Price per pack of 270 x 200mg capsules/ CHF
Low income countries and Lower middle income countries - as classified by The World Bank	300.00	300.00
All countries in sub-Saharan Africa and all UN defined Least Developed Countries. These are "no profit" prices.	90.90	95.40

These prices are all quoted ex-factory from Roche Basel in Swiss Francs and will be reassessed on an annual basis in line with costs as long as Roche continues to market these particular products. The prices are listed as direct sales from Roche Basel as only this way can clear and equitable prices be quoted for all the qualifying countries, which would not be possible for national retail prices.

Roche is currently looking into ways of differentiating the packaging of these reduced priced essential medicines to ensure they are only used by those for whom they were purchased and not sold on to other countries.

In low income and lower middle income countries where there is a local Roche affiliate, the company is taking action to align Viracept prices from these local affiliates to a maximum of CHF 420 per pack of 270 x 250mg tablets. The retail prices within these countries will be higher and may vary significantly depending on nationally mandated distribution and retail margins. Local supply conditions across upper middle and high income countries remain unchanged.

The "no profit" prices direct from Roche Basel are the lowest prices at which the products can be provided in a sustainable manner. They do not reflect research or development costs, marketing costs, distribution costs or company overheads. In order to achieve the lowest price level for Viracept

in line with this "no profit" price, Roche's licensing partners Agouron/Pfizer and Japan Tobacco, who hold the patent rights of Viracept, have agreed to waive all royalties on the sales of the product in qualifying countries.

#### **Roche in HIV**

Roche is at the forefront of efforts to combat HIV infection and AIDS, committed since 1986 to groundbreaking research and development of innovative new drugs and diagnostic technology. Saquinavir was the first Protease Inhibitor (PI) and was first introduced by Roche in 1995 in the US.

As a consequence of Roche's continuous research and development, the combination of boosted saquinavir with zidovudine (1000/100 mg twice daily) has shown encouraging results in the MaxCmin 1 trial with high efficacy and an excellent safety and tolerability profile. Saquinavir/zidovudine was approved in the EU in August 2002. Viracept (nelfinavir), another PI is supplied by Roche outside the US and Canada. In first-line HIV therapy, Viracept delivers consistent long-term efficacy and safety. When used first line, Viracept also allows the subsequent use of both NNRTIs and other PIs for most patients due to its unique resistance pattern.

#### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups. The company's two core businesses in pharmaceuticals and diagnostics provide innovative products and services that address prevention, diagnosis and treatment of diseases, thus enhancing people's health and quality of life. The two core businesses achieved a turnover of 19.3 billion Swiss Francs in the first three quarters of 2002 and employed about 57,000 people worldwide. All trademarks used or mentioned in this release are legally protected.

Please see [www.Roche-hiv.com](http://www.Roche-hiv.com) for full terms and conditions

#### **Notes to editors**

The Following Countries are Designated by the United Nations as Least Developed:  
Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea Bissau, Haiti, Kiribati, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Senegal, Sao Tome and Principe, Sierra Leone, Solomon Islands, Somalia, Sudan, Togo, Tuvalu, Uganda, Tanzania, Vanuatu, Yemen and Zambia.

Additional countries in sub-Saharan Africa not covered by UN list of Least Developed Countries for which the lowest level, no profit prices apply:

Botswana, Cameroon, Congo, Gabon, Ghana, Ivory Coast, Kenya, Mauritius, Namibia, Nigeria, South Africa, Swaziland and Zimbabwe.

Low-income economies - source World Bank classification of economies <sup>1</sup>

<http://www.worldbank.org/data/databytopic/class.htm>

Armenia, Azerbaijan, Georgia, India, Indonesia, Korea Dem. Rep., Kyrgyz Republic, Moldova, Mongolia, Nicaragua, Pakistan, Tajikistan, Ukraine, Uzbekistan, Vietnam.

Lower-middle-income economies <sup>1,2</sup>

Albania, Algeria, Belarus, Belize, Bolivia, Bosnia and Herzegovina, Bulgaria, China, Colombia, Cuba, Dominican Republic, Ecuador, Egypt, El Salvador, Fiji, Guatemala, Guyana, Honduras, Iran, Iraq, Jamaica, Jordan, Kazakhstan, Latvia, Lithuania, Macedonia FYR, Marshall Islands, Micronesia Fed. Sts, Morocco, Papua New Guinea, Paraguay, Peru, Philippines, Romania, Russian Federation, Sri Lanka, St. Vincent and the Grenadines, Suriname, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkmenistan, West Bank and Gaza, Yugoslavia Fed. Rep.

<sup>1</sup> Those not otherwise classified as "Least Developed" by the United Nations.

<sup>2</sup> Other than those already listed above in the list of sub-Saharan countries where no profit prices apply.

For further information on WHO defined essential medicines see:

<http://www.who.int/medicines/organization/par/edl/eml.shtml>