Media Release

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European Price Announced for AIDS Drug Fuzeon

Fuzeon to be available under special pre-licence sales programmes at commercial price level

Roche today announced that they will make the investigational HIV drug Fuzeon (enfuvirtide, formerly known as T-20) available at a daily treatment price of 52.- Euros to EU countries that elect to undertake a pre-licence special access programme before approval is granted. The initiation of special license sales programmes will ensure that supplies of Fuzeon are made available as soon as possible for patients living in the shadow of multi-drug resistance.

Fuzeon is currently being reviewed by the European CPMP for licence approval. Special access programmes are expected to begin in the near future as more drug becomes available and these programmes will complement Early Access Programmes which are already ongoing as part of the clinical studies in a number of EU countries.

“This price reflects the structural complexity of Fuzeon and its highly sophisticated manufacturing process,” said William M. Burns, Head of Roche Pharmaceuticals. "Fuzeon is the most clinically advanced agent of the fusion inhibitors, a completely new class of drugs. With its unique mechanism of action, Fuzeon represents the first significant breakthrough in HIV therapy since 1996.”

Roche has pledged that this special access programme price will be close to the future commercial price. However on a country level, local retail prices will vary according to local conditions such as trade margins and taxes. In the US, pending approval of Fuzeon by the FDA, the price will be communicated at launch. Submissions for marketing authorisations for Fuzeon have been submitted in the European Union, Australia, Canada, Switzerland and the US.

F. Hoffmann-La Roche Ltd CH-4070 Basel Corporate Communications Tel. 061 - 688 88 88
Fax 061 - 688 27 75
http://www.roche.com

Fuzeon is the front-runner in a new class of HIV medications known as fusion inhibitors. Fuzeon's mechanism of action is not comparable to any existing HIV drugs. Unlike existing anti-HIV drugs that work inside the cell, it is designed to block HIV from entering healthy human immune cells and is active against strains of HIV that have become resistant to currently available medications. Fuzeon offers a new hope to patients living with multi-drug resistant HIV or who are intolerant to current anti-HIV drug classes.

Fuzeon was studied in two large, international phase III studies. These studies confirmed the activity of Fuzeon against drug resistant forms of the virus and that treatment-experienced patients receiving Fuzeon plus an individualised regimen of standard anti-HIV drugs were twice as likely to achieve undetectable levels of HIV in the blood (less than 400 copies/mL) as patients who received an individualised drug regimen without Fuzeon.

Fuzeon is one of the most complex and challenging molecules ever chemically manufactured by the pharmaceutical industry at large scale, requiring 45kg of raw materials for 1kg of Fuzeon, and more than 100 production steps.

A total of 420 individual components are provided in each one month treatment pack of Fuzeon. These comprise vials of Fuzeon, vials of sterile water for injection, alcohol swabs, syringes with retractable needles for reconstitution and syringes with retractable needles for injection.

"Fuzeon is unlike any of the existing HIV drugs in terms of complexity, cost of production and mode of administration," said Dr. Dani Bolognesi, CEO of Trimeris, co-developer of Fuzeon. "For these reasons it is necessary to price Fuzeon differently from conventional HIV medications."

Notes to editors

Resistance to HIV drugs

It is estimated that in a single untreated person the virus can mutate to form around a billion new and potentially different versions of HIV every day. The incidence of drug resistant HIV among already treated patients is increasing at a disturbing rate. It was recently reported in one study that up to 78 percent of patients in North America are infected with a strain of the virus that has developed resistance to one or more anti-HIV drug.

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 ritonavir (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/r 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. Fuzeon and T-1249 are being co-developed by Roche and Trimeris.

Roche is a committed partner of the Accelerating Access Initiative to increase access to HIV care in sub-Saharan Africa and the world's Least Developed Countries. For more information on Roche policy and pricing of HIV protease inhibitors for these regions and research in HIV, visit www.roche-hiv.com.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals and diagnostics. Roche's innovative products and services address prevention, diagnosis and treatment of diseases, thus enhancing people's well being and quality of life.

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