

Tibotec recognizes the unparalleled global challenge posed by the HIV/AIDS epidemic and our responsibility to collaborate in the international response to HIV/AIDS, particularly through providing access to our HIV/AIDS medications.

Resistance to HIV/AIDS therapies is an emerging challenge for the estimated



1.5 million patients receiving treatment in the developing world. These patients will need access to new HIV/AIDS therapies active against resistant strains of HIV for the rest of their lives. The Tibotec Global Access Program recognizes this growing challenge and has begun a worldwide access effort for its recently approved antiretroviral PREZISTA[™].

The Tibotec Global Access Program is being developed to make our antiretrovirals available on a sustainable basis to people in need in more than 100 countries.

Program Overview

PREZISTA (darunavir) will be the initial focus of the Tibotec Global Access Program. It is a protease inhibitor, also known as TMC114, and is the first Tibotec antiretroviral medicine to receive regulatory approval. The first approval was received in the USA in June 2006 for treatment-experienced patients.



The Tibotec Global Access Program will include both low-and middle-income countries, where we will make our antiretrovirals available at reduced prices.

For Least Developed Countries and for sub-Saharan Africa in particular, we are actively pursuing licensing and technology transfer agreements.



We are pursuing early filing for registration of PREZISTA in 41 countries. A transparent and realistic filing timetable will be established.

We have requested an Expression of Interest listing in order to apply for World Health Organization prequalification to facilitate rapid access.

Other components of the program include support for healthcare worker and patient education programs, and working with international and national authorities to include HIV/AIDS medications for treatment-experienced patients in treatment guidelines.



41 Countries for Early Filing for Registration

Africa

- Botswana
- Cameroon
- Congo, Dem. Rep.
- Cote d'Ivoire
- Ethiopia
- Ghana

- Kenya
- Lesotho
- Malawi
- Mozambigue
- Namibia
- Nigeria
- Rwanda

- Senegal
- South Africa
- Swaziland
- Tanzania
- Uganda
- Zambia
- Zimbabwe

- Asia Pacific
- China
- India
- Malaysia
- Thailand
- Vietnam

Latin America

- Brazil
- Colombia
- Costa Rica
- Dominican Republic
- Guatemala

- Haiti
- Honduras
- Iamaica
- Peru
- Venezuela

New Europe/ Middle East

- Pakistan Iran
- Kazakhstan • Serbia
- Lebanon Ukraine

As well as our ongoing research and development of new antiretrovirals to treat HIV/AIDS, there are two other Tibotec programs to support the global response to AIDS.

- Tibotec provided a royalty-free license for the antiretroviral TMC120 to the International Partnership for Microbicides (IPM), for development as a vaginal microbicide for HIV/AIDS prevention. Our scientists provide continuing technical advice to IPM.
- Tibotec has developed the anti-fungal TIBOZOLE[™], a miconazole muco-adhesive tablet (MAT) for treatment of oral candidiasis. TIBOZOLE is marketed on a non-profit and cost-recovery basis in the developing world where oral candidiasis is the most common opportunistic infection for people living with HIV/AIDS.



Gen De Wittelaan L 11B 3 2800 Mechelen | Belgium www.tibotec.com email: globalaccess@tibbe.jnj.com