

*Bristol-Myers Squibb*  
*Global Access  
Program*

Access to HIV/AIDS Medicines  
Through Science, Commitment and Compassion



Bristol-Myers Squibb

## *The Need for Expanded Access – The Bristol-Myers Squibb Perspective*

**A**t Bristol-Myers Squibb, we have long understood the need to act forcefully against the HIV/AIDS pandemic – alone and in partnership with others. This extremely complex public health problem has a host of psychological, social, ethical, cultural, economic and political implications. Over time, a common vision, focused on expanding sustainable access to HIV treatment and care, will help yield significant results. While no one company or organization can single-handedly meet the many challenges before us, each must do its part.

Bristol-Myers Squibb's effort to address the global HIV/AIDS pandemic is best demonstrated through its own focus on leadership in science, on an enduring commitment to expand access to treatment and care for HIV/AIDS patients and on programs that exhibit compassion.



## Science

From the earliest days of the pandemic, Bristol-Myers Squibb has remained one of the leading companies in the world developing and distributing advanced treatments for HIV/AIDS. Today, Bristol-Myers Squibb is the first and only pharmaceutical company with oral treatments in all three classes of HIV medications. In 2003, the company received regulatory approval for *REYATAZ*<sup>®</sup> (atazanavir), the first protease inhibitor to be approved by the U.S. Food and Drug Administration for once-daily administration. Our other antiretroviral agents include three nucleoside analog reverse transcriptase inhibitors – *ZERIT*<sup>®</sup> (stavudine), *VIDEX*<sup>®</sup> (didanosine) and *VIDEX EC*<sup>®</sup> (didanosine) – and one non-nucleoside reverse transcriptase inhibitor – *SUSTIVA*<sup>®</sup> (efavirenz).

Though great progress has been made, there is still no known cure for this virus today. Existing treatment regimens may be complicated, and the emergence of resistance underscores the importance of continuing the search for innovative treatments. That is why research in virology has remained a top priority for Bristol-Myers Squibb. The company's Pharmaceutical Research Institute is currently conducting more than 100 clinical trials around the world with HIV drugs. And it has several compounds in active development that seek new approaches to interfere with the virus including an attachment inhibitor that blocks virus entry to the host cell, currently in Phase II trials, and an integrase inhibitor in earlier development.



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Medicines developed by research-based pharmaceutical companies have transformed the prognosis for those stricken by HIV/AIDS. Yet more than 90% of people living with HIV are in developing countries that have limited resources and infrastructure to purchase and apply these therapies. Therefore Bristol-Myers Squibb remains committed to working in partnership with governments and others to find sustainable solutions to provide access to our medications to those most in need.

There are no simple answers to this complex public health problem. Simply providing medications at low cost, or even at no cost, will not alleviate all the suffering. Medications must be distributed effectively to those most in need; they must be administered appropriately within the context of a viable health care delivery infrastructure; and they must be part of a larger overall effort that includes prevention, education, destigmatization and economic development. Funding has grown in the global community with the introduction of the Global Fund to Fight AIDS, Tuberculosis and Malaria and The U.S. Emergency Plan for AIDS Relief.

Ultimately, successfully containing HIV/AIDS will require an ongoing commitment by national governments, adequate funding of carefully developed and integrated national policies and strategies, and the involvement of both the private and public sectors – all working in partnership against this terrible disease. The Accelerating Access Initiative and the company's own Global Access program, described here, are further demonstrations of the company's commitment to sustainable access and the company's own efforts to make a difference.

## *The Accelerating Access Initiative and the Bristol-Myers Squibb Global Access Program*

To help increase access to HIV/AIDS care and treatment in developing countries, in May 2000, the company joined with other research-based pharmaceutical companies that now also include Abbott Laboratories, Boehringer-Ingelheim, F. Hoffmann-La Roche, Gilead Sciences, GlaxoSmithKline and Merck & Co., and with five United Nations organizations, to establish the Accelerating Access Initiative (AAI).

In partnership with the UN AIDS Secretariat, WHO, UNICEF, the UN Population Fund and the World Bank, the AAI has focused on developing countries, initially in sub-Saharan Africa where nearly 70% of those living with HIV/AIDS are located, as well as in the rest of Africa. Its aims include:

- accelerate sustained access and increased use of appropriate, good quality interventions for prevention, treatment and care
- foster new alliances in both the public and private arena
- respond to specific needs of individual countries, with respect to human rights, equity, transparency and accountability

The initiative provides an important framework that brings together critical partners – national governments, international organizations, pharmaceutical companies, people living with HIV/AIDS, and community-based and nongovernmental organizations – to find sustainable solutions for access to quality medicines and care. Six essential principles have guided the development and implementation of the program:

- political commitment by governments
- strengthened national health care capacity and infrastructure
- multisectoral involvement
- efficient, reliable and secure distribution systems
- significant additional funding
- continued investment in R&D, consistent with international agreements on intellectual property protection

## Progress to Date

As a founding partner of the AAI, Bristol-Myers Squibb's response, through its own Global Access Program, has been significant:

- Beginning in March 2001 and continuing today, Bristol-Myers Squibb made two antiretrovirals (ARVs) – *VIDEX* and *ZERIT* – available in sub-Saharan Africa at a price that reflects no profit to the company. This offer has been extended to national governments as well as to NGOs and other private organizations, including major employers in sub-Saharan Africa, which can deliver clinically appropriate ARV therapy and maintain effective, secure distribution systems to ensure that treatment gets to patients.
- Also in March 2001, the company announced that it would ensure that its patents do not prevent inexpensive HIV/AIDS therapy in sub-Saharan Africa.
- From July 2005, Bristol-Myers Squibb has made *VIDEX EC* available in sub-Saharan Africa at a no-profit price.
- Bristol-Myers Squibb has offered substantial discounts and price reductions to developing countries in other regions – including Central and Latin America, the Caribbean, the former Soviet Union and northern Africa – that have well defined National HIV Action Plans. In many of these countries, the need is great, the impact of the epidemic is devastating and national resources to pay for treatments are minimal.
- In Haiti, an agreement with Partners-in-Health, a Harvard University-affiliated NGO, has enabled the purchase of *VIDEX* and *ZERIT* at no-profit prices.

The estimated number of HIV-positive people in developing countries receiving treatment through the AAI companies has increased to more than 380,000 by December 2004. This is a 40 percent increase over 2003 with over 100,000 people being initiated on treatment in 2004. Nevertheless, millions are still without treatment, and in absolute terms the number of people receiving treatment in developing countries remains small. The AAI recognizes the need for multiple options, given the complexities of HIV/AIDS care and treatment, including the need for efforts to simplify HIV treatment regimens.

While the larger goal of providing treatment to the millions who need it is still to be achieved, the encouraging news is that a framework for doing so has been established, progress has been made, and the many barriers to HIV/AIDS treatment and care have been recognized and are, in many ways, beginning to be addressed. Through constructive dialogue, mutual respect and transparency, efforts like the Bristol-Myers Squibb Global Access Program and the AAI have helped move the world from inertia to action. Such efforts have demonstrated that the combination of political will, commitment and partnership are essential to generate and sustain meaningful access to HIV care and treatment in resource-constrained settings.



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## Compassion

In 1999, Bristol-Myers Squibb launched *SECURE THE FUTURE*®, the largest corporate philanthropic effort of its kind, seeking sustainable solutions for women and children infected and affected by HIV/AIDS, by developing and supporting community-based efforts and by building healthcare capacity and infrastructure in southern and West Africa. This \$150 million program operates in ten African countries that have been hard hit by HIV/AIDS. Thus far, it has funded more than 200 projects, including medical research efforts that focus on new approaches to treatment delivery in resource-limited settings and a comprehensive community outreach and education effort that has funded home-based care, care for orphans, income-generation, food security, destigmatization, counseling at the grass-roots level, among others.

It also has spurred the creation of the first pediatric AIDS clinic and now a continental network of five clinics in Africa, located in Botswana, Burkina Faso, Lesotho, Swaziland and Uganda; the creation of the first HIV reference laboratory in Botswana; one of the most widely distributed curriculum on HIV/AIDS for health care professionals; a fast, low cost CD4 test to monitor immune health in people with HIV/AIDS; and a regional institute to foster good governance and program effectiveness for non-governmental organizations.

As part of this program, \$30 million in grants are being used to create six community treatment support sites in southern and West Africa that can serve as models to test how best to combine the delivery of ARV treatments with community-based care and support in resource-limited settings.

To address the need for an immediate increase in health care professional capacity, the Foundation has committed over \$22 million to support the first ever pediatric AIDS corps, which will place 250 American resident pediatricians for at least one year in primary care settings affiliated with the five pediatric AIDS clinics.

Finally, through the Bristol-Myers Squibb Foundation's Global HIV/AIDS Initiative, grants have been made to support community education and health professional training to expand capacity and create sustainable solutions in countries and among populations where the pandemic is emerging, including China, France, Mexico, Russia, Thailand, Ukraine and Vietnam. By working at the community level and involving countries and governments, Bristol-Myers Squibb has developed model programs that can be used around the world.

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**Bristol-Myers Squibb**

*Hope, Triumph and the Miracle of Medicine™*

For Bristol-Myers Squibb, the answers continue to be found in efforts focused on science, commitment and compassion – to fight this global pandemic and to extend and enhance the lives of the people affected and infected by HIV/AIDS around the world.

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