

Merck and Bristol-Myers Squibb License New AIDS Drugs to IPM for Development as Microbicides to Protect Women from HIV

New Nature study shows potential of “entry inhibitor” compounds as HIV prevention tool

Contacts:

IPM: Victor Zonana, +1-917-497-3939, vzonana@ghstrat.com, www.ghstrat.com
Annmarie Leadman, +1-301-346-2506, aleadman@ipm-microbicides.org

Merck: Christopher Loder, +1-908-423-3786, Christopher_loder@merck.com

BMS: Rebecca Taylor, +1-609-252-4476, rebecca.taylor@bms.com
Laura Hortas, +1-609-252-4587, laura.hortas@bms.com

New York – In a first-of-its-kind joint announcement, two of the world’s leading pharmaceutical companies, Merck & Co., Inc. and Bristol-Myers Squibb have each announced today that they have signed separate license agreements with the International Partnership for Microbicides (IPM) to develop new antiretroviral compounds as potential microbicides to protect women from HIV. Under the two separate agreements, Merck and Bristol-Myers Squibb will each grant the non-profit group a royalty-free license to develop, manufacture and distribute their compounds for use as microbicides in resource-poor countries.

Announced on the eve of the TIME Global Health Summit, this agreement marks the first time a pharmaceutical company has licensed an anti-HIV compound for development as a microbicide when the class of drugs is so early in development. The compounds are part of a new class of antiretrovirals known as “entry inhibitors.” Some of the compounds bind directly to HIV; others bind to the CCR5 receptor. They are designed to prevent HIV from efficiently entering host cells, thus preventing infection.

A study published in this week’s *Nature* will report that entry inhibitor compounds developed by Merck (CMPD 167) and by Bristol-Myers Squibb (BMS-378806), when used as vaginal microbicides, protected some macaque monkeys from infection with a virus similar to HIV. The research team was led by Dr. John Moore of the Weill Medical College of Cornell University and Dr. Ronald Veazey of the Tulane National Primate Research Center, and the study was funded primarily by US National Institutes of Health and other groups. Merck and BMS are providing IPM with royalty-free licenses to these drugs or other closely related compounds.

These microbicides could be developed as products, such as gels or creams, that could be applied topically in the vagina or in a vaginal ring that releases the drug gradually over time, reducing transmission of HIV during vaginal intercourse. It is estimated that even a partially effective microbicide could prevent 2.5 million HIV infections over a period of three years.

“These historic agreements mark a turning point in the pharmaceutical industry’s commitment to developing a safe and effective microbicide to protect women from HIV,” said Dr. Zeda Rosenberg, Chief Executive Officer of IPM. “These entry inhibitors hold significant promise as potential microbicides. We are grateful to Merck and Bristol-Myers Squibb for their leadership and commitment in helping us develop new technologies to protect millions of women.” Dr. Rosenberg pledged that IPM’s scientific team would move quickly to develop and test these compounds as microbicides.

“Merck is proud to contribute the results of our research and development to this worldwide effort to protect women,” said Dr. Adel Mahmoud, Chief Medical Advisor for Vaccines and Infectious Diseases at Merck. “This agreement builds on Merck’s longstanding work in HIV/AIDS, both through our research and development of new anti-HIV drugs and candidate vaccines, and through public-private partnerships such as our program with the government of Botswana and the Bill & Melinda Gates Foundation.”

“We take our responsibility as a corporate citizen seriously,” said John L. McGoldrick, Executive Vice President of Bristol-Myers Squibb. “This agreement and other Bristol-Myers Squibb programs, such as our Secure the Future program that is dedicated to helping women and children impacted by AIDS in Africa, demonstrate our company’s commitment to help people in developing countries effectively respond to HIV/AIDS.”

Under the agreements, Bristol-Myers Squibb and Merck will provide royalty-free licenses to IPM to develop, manufacture and distribute the compounds as microbicides in developing countries. Three leading pharmaceutical companies have now entered partnerships with IPM. In March 2004, the group signed an agreement with Johnson & Johnson subsidiary Tibotec Pharmaceuticals Ltd. to develop the company’s TMC120 non-nucleoside reverse transcriptase inhibitor as a microbicide.

“These innovative agreements demonstrate how the public and private sectors can work together to move exciting new technologies forward to protect women from acquiring HIV,” said Dr. Helene Gayle of the Bill & Melinda Gates Foundation, which is a major supporter of IPM. “Bristol-Myers Squibb, Merck and J&J are leading by example in entering into partnerships to develop their most promising compounds as potential new HIV prevention technologies. We hope other companies with promising anti-HIV compounds will make similar commitments.”

“These companies could not have been more cooperative in providing their compounds for our research, and now in providing intellectual property rights to a non-profit group

like IPM to develop them as microbicides,” said Dr. Moore. “This is a very significant step forward.” Moore noted that his research was also funded by Bristol-Myers Squibb’s Freedom to Discover program, a no-strings-attached grant program funding biomedical research.

"The search for an effective microbicide is crucial to providing women with more options to protect themselves against HIV infection," said Dr. Peter Piot, Executive Director of UNAIDS. "The partnerships announced today by the International Partnership for Microbicides with the pharmaceutical companies Bristol Myers Squibb and Merck represent the kind of innovative collaboration needed with the private sector not only to making this technology a reality, but ensuring it reaches the millions of women around the world who could benefit from it."

About IPM

The International Partnership for Microbicides was established to accelerate the development and accessibility of vaginal microbicides to prevent the transmission of HIV. By screening compounds, designing optimal formulations, establishing manufacturing capacity, developing trial sites and conducting large scale efficacy trials, the organization works to improve the efficiency of all efforts to develop and deliver safe and effective microbicides as soon as possible. IPM receives funding from the governments of Canada, Denmark, Ireland, the Netherlands, Norway, Sweden, the United Kingdom and the United States, as well as the European Commission, the Rockefeller and Bill & Melinda Gates Foundations, and the World Bank. More information is available at www.ipm-microbicides.org.

About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in more than 20 therapeutic categories. The company devotes extensive efforts to increasing access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. These include the African Comprehensive HIV/AIDS Partnerships (ACHAP) that was created by Merck, the government of Botswana, and the Bill & Melinda Gates Foundation to support and enhance the response to the HIV epidemic in Africa, and the *Mectizan* Donation Program which has provided more than one billion tablets of *Mectizan* (ivermectin) free to people at risk for onchocerciasis (river blindness) and lymphatic filariasis. More information is available at www.merck.com.

About Bristol-Myers Squibb

Bristol-Myers Squibb Company is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life. Bristol-Myers

Squibb and its Foundation launched *SECURE THE FUTURE* in 1999 to help alleviate the HIV/AIDS crisis among women and children in sub-Saharan Africa. Over the years, the public-private initiative – the first and largest corporate commitment of its kind to fight HIV/AIDS in Africa – has grown in size and scope to encompass nearly 200 grants providing medical care and research, infrastructure- and capacity-building and community outreach and education in ten hard-hit countries in Africa. The \$150 million commitment includes funding to create a Pediatric AIDS Corps in partnership with Baylor College of Medicine and a network of children's clinics. In addition to its commitments in Africa, the Bristol-Myers Squibb Foundation funds programs through its Global HIV/AIDS Initiative in Thailand, Vietnam, Mexico, Russia, Ukraine and France. Visit Bristol-Myers Squibb on the World Wide Web at www.bms.com.