

## Novartis Institute for Tropical Diseases and TB Alliance announce partnership to develop novel tuberculosis drugs

**Singapore / New York, October 27, 2004** – The Novartis Institute for Tropical Diseases (NITD) and the Global Alliance for TB Drug Development (TB Alliance), a public-private partnership developing affordable new TB drugs, today announced plans to pursue a joint research program into novel, promising anti-tuberculosis agents.

The research will focus on identifying more lead compounds in the nitroimidazopyran class for the treatment of tuberculosis (TB), which continues to be a major global health problem. TB now infects one-third of the world's population and causes close to nine million new cases of active TB and 2 million deaths each year.

The TB Alliance will collaborate with the NITD in Singapore to identify a next generation of nitroimidazopyran compounds related to PA-824 for further development to improve TB therapy. PA-824 is one of the lead compounds of the TB Alliance portfolio and is on track to enter Phase I trials in 2005. The successful preclinical development of PA-824 has demonstrated the potential of this class of compounds and prompted additional investigations into this family of drugs for tuberculosis.

“The partnership between Novartis and the TB Alliance opens up global, cross-disciplinary avenues to test the full potential of this exciting novel class of compounds,” said Maria C. Freire, President and CEO of the TB Alliance. “It combines the know-how of the pharmaceutical industry and the agility of the TB Alliance to accelerate the development of better and affordable treatments and bring them to registration.”

Since its launch in 2003, the NITD pledged to partner with the TB Alliance and committed that the Novartis Group intends to make the resulting treatments readily available to poor patients without profit in those developing countries where the disease is endemic. This commitment falls directly in line with the TB Alliance's principle of “affordability, adoption and access.”

“Novartis elected to contribute discovery science to the search for new, fast-acting and affordable TB drugs. This undertaking is tangible proof of our commitment and demonstrates the vision inherent to the NITD,” said Dr. Paul Herrling, Head of Corporate Research at Novartis and Chairman of the Novartis Institute for Tropical Diseases.

The agreement between the two organizations covers research and development roles for each party. The NITD will design, synthesize and optimize a series of nitroimidazopyran analogs for TB indication, tapping its broad medicinal chemistry expertise, know-how and biological evaluation capacity. The TB Alliance will contribute chemical intermediates, scientific expertise including structure design, and support for pharmacological studies.

As evidenced by PA-824 studies, nitroimidazopyrans have attractive features as potential drugs for TB. Their new mechanism of action is critical against multi-drug-resistant TB. Both *in vitro* and *in vivo* studies demonstrated excellent biological activity of this drug class. Other preclinical studies also indicated a favorable metabolic profile allowing combination with anti-retroviral therapy in joint TB-HIV treatment.

NITD's facility in Singapore is becoming central to the search for new TB therapies. Currently with 65 researchers, Novartis' investment in the field of tropical and infectious disease research is an exception in an industry that has traditionally neglected illnesses that are seen as endemic within the developing world. The program, which has already been initiated, will synthesize multiple compounds around the most promising areas for chemical modification of PA-824. Scientists at U.S. National Institutes of Allergy and Infectious Disease of the NIH in Bethesda, Maryland, will also be contributing to the project.

"Developing faster-acting TB drugs is a critical strategy in the global response to the TB epidemic. The pragmatic plan and vision of this partnership is the kind of approach necessary to reverse this devastating health threat. New therapies that reduce treatment times and combat multi-drug resistant strains of TB are indispensable in our expanding efforts," said Dr. Mario Raviglione, Director of Stop TB at the World Health Organization.

The TB Alliance is taking the lead of building the first, most comprehensive portfolio of TB drug candidates in decades, and is accelerating discovery, preclinical and clinical research of nitroimidazopyrans, quinolones, macrolides, carboxylates and other known or novel classes of antibiotics to shorten and simplify the treatment of tuberculosis. The last class of TB drugs was registered in 1970 and the lengthy treatment (6-9 months) imposed by old drugs is hindering the progress of TB control.

"After a thirty-year wait, TB patients everywhere gain new hope at each sign of affordable new drugs coming down the pipeline. We commend public-private partnerships, such as this one between Novartis and the TB Alliance, that embrace principles of affordability, access and adoption," said Winstone Zulu, a TB-HIV patient advocate from Zambia.

For more information on TB drug development, nitroimidazopyrans, PA-824 and the TB Alliance, please visit [www.tballiance.org](http://www.tballiance.org).

This release contains certain forward-looking statements which can be identified by the use of forward-looking terminology such as "plans to pursue", "promising", "will", "is on track", "potential", "intends to", "indicated", or similar expressions, or by express or implied discussions regarding the potential development and commercialization of new products or regarding potential future sales from any such products. Such statements reflect the current views of Novartis and/or TB Alliance with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantee that the aforementioned joint research program will lead to the development or commercialization of any new products in any market, or that any such products will reach any particular sales levels. Any such commercialization or sales can be affected by, among other things, uncertainties relating to product development and clinical trials; regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; the ability to gain funding for clinical development; competition in general; and government, industry and general public pricing pressures; as well as factors discussed in Novartis AG's current Form 20-F on file with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

### **About the Global Alliance for TB Drug Development**

The Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, public-private partnership accelerating the discovery and/or development of affordable, new anti-TB drugs that will shorten treatment, be effective against multi-drug resistant strains, and improve treatment of latent infection. In collaborations with public and private research laboratories worldwide, it is leading the development of the first, most comprehensive portfolio of TB drug candidates in three decades. It operates with the support of public and philanthropic funds from the Bill and Melinda Gates Foundation, the Rockefeller Foundation, the United States Agency for International Development, the Netherlands Ministry for Cooperation Development and the National Institutes of Health.

### **About Novartis Institute for Tropical Diseases**

The Novartis Institute for Tropical Diseases aims to discover novel treatments and prevention methods for major tropical diseases. Initially, Dengue fever and Tuberculosis will be addressed. In those developing countries where these diseases are endemic, the Novartis Group intends to make treatments readily available and without profit to poor patients. The Institute will recruit the best scientific specialists in the world, and as a major center of excellence, will offer exceptional teaching and training opportunities for post-doctoral fellows and graduate students.

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