Novartis and collaborators discover novel antimalarial drug candidate

- New antimalarial drug candidate with novel mechanism of action has the potential to rapidly clear a Plasmodium infection upon administration of a single oral dose, as published in Science.

- Novartis led collaboration includes The Scripps Research Institute, the Swiss Tropical and Public Health Institute, with major support from the Wellcome Trust, Medicines for Malaria Venture, the Agency for Science, Technology and Research (A*STAR), Singapore, as well as the U.S. government.

- In 2008, there were 247 million cases of malaria and nearly one million deaths – mostly among children living in Africa.

**Singapore, September 3, 2010** — Novartis announced today that scientists at the Novartis Institute for Tropical Diseases (NITD), in collaboration with researchers from the Genomics Institute of the Novartis Research Foundation (GNF), the Swiss Tropical and Public Health Institute and The Scripps Research Institute have discovered a novel compound that shows promise as a next generation treatment for drug resistant malaria. Major support for the project was provided by the Wellcome Trust, the Medicines for Malaria Venture (MMV), A*STAR, Singapore and the US government.

Published this week in Science, the findings demonstrate that the antimalarial candidate, spiroindolone NITD609, is effective against both strains of the malaria parasite, *Plasmodium* (*P.*) *falciparum* and *P. vivax*. Through a novel mechanism, NITD609 rapidly clears plasmodium in a malaria mouse model and shows pharmacological properties compatible with a once-daily dosing regimen.

According to the World Health Organization (WHO), in 2008 there were approximately 247 million cases of malaria, causing nearly one million deaths, mostly among young children in Africa. Although malaria is preventable and curable, it is estimated that in Africa, a child dies every 45 seconds from the disease.¹

“Malaria remains a scourge,” said Mark Fishman, president, Novartis Institutes for BioMedical Research. “The parasite has demonstrated a frustrating ability to outwit new medicines, from quinine to today’s unsettling increased tolerance to artemisinin derivatives. We are delighted that our scientists could provide this potential new malaria therapy, based on an unprecedented chemical structure and directed to a novel target.”

Further regulatory pharmacological and safety evaluation is currently ongoing and, provided the outcome of these studies is favorable, the compound could progress to Phase I human trials.

**A novel mechanism of action**
Despite significant advances in *Plasmodium* genome biology, the identification and validation of new drug targets has proven challenging. In the *Science* paper the research team outlines how they identified a potential target by identifying mutations that decreased the parasite’s sensitivity to this novel compound class.

“Using a novel *Plasmodium* whole-cell assay we were able to tap into the Novartis archive of 12,000 pure natural products and synthetic compounds to identify 275 compounds highly active against *P. falciparum*, the most prevalent and deadly form of malaria,” said Novartis Institute for Tropical Disease’s Bryan Yeung, project team head. “From this set all but 17 compounds were discarded for failing to meet pharmacological and efficacy standards. Of the remaining compound class, spirotetrahydro-beta-carbolines or spiroindolones have favorable physical and chemical properties for drug development as well as a mechanism of action distinct from the currently used therapies based on aminoquinolines and artemisinin derivatives.”

**Combating malaria- a sustainable commitment**

As of June 2010, Novartis has delivered over 340 million of its antimalarial treatments without profit, to more than 60 malaria-endemic countries for public sector use, making Novartis the leading pharmaceutical partner in the fight against malaria. But Novartis does more than providing effective treatment. Since the beginning of its Malaria Initiatives program Novartis has pioneered access to medicines in the developing world through an innovative not-for-profit distribution concept, coordination of best practice sharing workshops, development of new formulations and capacity building. The program proves that increasing access is not just a matter of buying drugs and distributing them, it is about incorporating training, logistics management and other types of technical expertise to ensure long-term health impacts.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “promise,” “could,” or similar expressions, or by express or implied discussions regarding potential regulatory submissions or approvals for NITD609 or regarding potential future revenues from NITD609. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with NITD609 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that NITD609 will be submitted or approved for use in any market. Nor can there be any guarantee that NITD609 will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding NITD609 could be affected by, among other things, unexpected research results, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US 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 anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.
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