



NOTE FOR THE PRESS

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Note for the Press WHO/8
25 November 2002

TDR, MEDICINES FOR MALARIA VENTURE AND SHIN POONG PHARMACEUTICALS SIGN AGREEMENT FOR DEVELOPMENT OF PYRONARIDINE-ARTESUNATE FOR TREATMENT OF MALARIA

An agreement has been signed for the joint development of a new combination antimalarial medicine, pyronaridine-artesunate, by the Tropical Diseases Research Programme (TDR),¹ the Medicines for Malaria Venture (MMV),² and Shin Poong Pharmaceuticals³. It is hoped that pyronaridine-artesunate will be an affordable, well-tolerated and efficacious medicine in the fight to Roll Back Malaria.

New medicines for malaria are badly needed as the disease kills more than one million people every year, mostly children under the age of five in Africa. In recent years, medicines to treat the most deadly form of malaria, caused by *Plasmodium falciparum*, have increasingly become ineffective due to development of drug resistance by the parasite. While the problem of drug resistance is most acute on the Thai-Myanmar border in South-East Asia, it is also widespread in Africa.

Artemisinin derivative containing combination therapy is seen as a breakthrough in malaria treatment. When combinations of antimalarial medicines with different modes of action and different biochemical targets in the parasite are used, the effects of both medicines may be added together, resulting in improved clinical efficacy and delay in development of drug resistance. One of the advantages of the pyronaridine-artesunate combination is that there is no pre-existing resistance to either component. It is, therefore, expected that this combination will be able to be deployed in areas with both sensitive and multi-drug resistant malaria.

The medicines known as artemisinins, of which artesunate is an example, are particularly useful in combinations as they have a rapid effect and are generally well tolerated by the patient. The artemisinins are derived from a natural plant, *Artemisia annua* (also known as

qinghaosu or sweet wormwood), whose antimalarial activity was first discovered centuries ago by the Chinese.

The other component in the new combination, pyronaridine, is an antimalarial that belongs to the same class of medicines as chloroquine (a very effective antimalarial whose use has become increasingly limited due to development of drug resistance). Pyronaridine is a newer antimalarial first developed in China. Extensive experience has been gained in its use alone (not in combination) for malaria in Hunan and Yunan Provinces, China, where it has been found to be safe and effective.

The combination of pyronaridine and artesunate would offer an advantage over other combinations of antimalarial medicines already in use. The dose of the new combination would be a single tablet taken just once a day, which is easier for the patient to take than existing combinations, which have to be taken twice a day and/or are not co-formulated. Being easier to take should mean that more people fully comply with the course of treatment, which is important not only for attaining higher cure rates but also for delaying the development of drug resistance.

It is hoped the medicine will cure acute malaria in patients in all countries affected by *Plasmodium falciparum*, and that, although the final price is not yet known, the combination will be affordable to malaria-endemic countries.

The signing of the agreement to develop pyronaridine-artesunate marks the official beginning of the development of this medicine combination to fight the continuing scourge of malaria. Assuming phase I clinical studies begin in the second quarter of 2003, as currently planned, registration of the new combination (if shown to be safe and effective) could be achieved in early 2006.

¹The UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases was founded in 1975 with two interrelated objectives: to research and develop new tools to control tropical diseases, and to help train individuals and strengthen institutions in tropical diseases research so as to increase the research capacity of developing tropical countries. For more information, see www.who.int/tdr/

²MMV is a not-for-profit Swiss Foundation formed in 1999. MMV brings together public, private and philanthropic partners (including WHO and the International Federation for Pharmaceutical Associations) to fund and manage the discovery, development and registration of new medicines for the treatment and prevention of malaria in disease-endemic countries. For more information, see www.mmv.org

³Shin Poong Pharmaceuticals, Co. Ltd. was founded in 1962 and is headquartered in Seoul, Republic of Korea. Under the principle of the company, "For the health of the people by the wisdom and the dignity of a nation", Shin Poong founded a tropical diseases medicine centre in 2000 with a focus on therapeutics for malaria, schistosomiasis, soil transmitted helminths, filariasis and onchocerciasis. For more information see www.shinpoong.co.kr