EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends new malaria treatment for approval

Novel fixed dose artemisinin-based combination adds to the treatment options available to fight malaria

The European Medicines Agency has recommended the approval of Eurartesim, from Sigma-tau Industrie Farmaceutiche Riunite S.p.A., a fixed combination product consisting of dihydroartemisinin and piperaquine phosphate. Eurartesim is intended for the treatment of uncomplicated *Plasmodium falciparum* malaria in adults, children and infants aged 6 months or over and weighing 5 kg or more.

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected mosquitoes. The World Health Organization (WHO) estimates that in 2009, malaria caused nearly 800,000 deaths, mostly among African children. The disease is present in over 100 countries and threatens half of the world's population.

P. falciparum, the parasite causing the most lethal type of human malaria has become resistant to many conventional treatments in most parts of the world. Over the past decade, a new group of antimalarials – known as artemisinin-based combination therapies (ACTs) – has brought new hope in the fight against malaria and the WHO's 2010 Malaria treatment guidelines recommend ACTs as the most effective treatment for malaria.

Eurartesim, an ACT that has been studied in clinical trials in Africa and Asia, will give doctors a much needed alternative option to treat children and adult patients.

In the European Union, the medicine is recommended for approval as an orphan medicine due to the limited number of patients affected in this region. The framework for orphan medicines provides incentives to encourage the development of medicines for neglected diseases that would not be developed under normal market conditions. While malaria affects hundreds of millions of people worldwide, it is considered a rare disease in the European Union, affecting approximately 1 in 33,000 people. The orphan status will be reviewed at the next meeting of the Committee for Orphan Medicinal Products.

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Notes

1. This press release, together with all related documents, is available on the Agency's website
2. A summary of the opinion of the Agency's Committee for Medicinal Products (CHMP) is available on the Agency's website
3. The summary of opinion for the orphan designation for Eurartesim is available at Agency's website.
4. More information about the WHO's fight against Malaria is available here: http://www.who.int/malaria/en/
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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