

Pfizer and Sigma-Tau Announce an Agreement to Market a Potential New Treatment for Malaria in Africa

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[\(BUSINESS WIRE\)](#)--Pfizer Inc (Pfizer) and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A (Sigma-Tau), a privately owned Italian pharmaceutical company, announced today that they have entered into a license and supply agreement under which, following applicable regulatory submissions and approvals, the companies will market Eurartesim®, a novel fixed dose artemisinin-based combination therapy (ACT), in Africa.

Eurartesim® (dihydroartemisinin + piperazine), a Phase III product candidate, aims to treat uncomplicated *Plasmodium falciparum* malaria in adults and children, while reducing the potential for re-infection. The product candidate, developed jointly by Medicines for Malaria Venture (MMV) and Sigma-Tau, is expected to be filed for registration with the European Medicines Agency and the U.S. Food and Drug Administration in 2009. Eurartesim® has already been granted orphan drug status by both the European and U.S. regulatory authorities.

The World Health Organization (WHO) recommends that all uncomplicated malaria be treated with ACTs. This policy is designed to reduce drug resistance which has rendered the most widely used monotherapies, such as chloroquine, useless in many parts of the world.

Malaria continues to be an endemic disease in sub-Saharan Africa and is one of the leading causes of infant mortality. The WHO estimates 881,000 deaths worldwide due to malaria in 2006, of which more than 90 percent occurred in Africa.

“Pfizer is excited about our collaboration with Sigma-Tau,” said Jean-Michel Halfon, president and general manager, Emerging Markets, Pfizer Inc. “The effective treatment of malaria, a preventable and treatable disease, is an essential need for patients in many countries in Africa and around the world. This agreement to make Eurartesim® available supports Pfizer’s vision to serve the needs of patients in developing countries and to improve global access to essential medicines.”

Under the agreement, Pfizer and Sigma-Tau will ensure access to this novel medicine in Africa in collaboration with the various local stakeholders. Following applicable regulatory submissions and approvals, Pfizer will market the drug in the public and private sectors locally in Africa, and Sigma-Tau will be responsible for the institutional sector. Further details of the financial terms were not disclosed.

“Sigma-Tau is delighted to announce this alliance with Pfizer. By combining our respective resources and expertise, we are confident we will powerfully tackle one of the greatest public health threats of all time,” said Ugo Di Francesco, Vice President and Chief Executive Officer at Sigma-Tau. “Sigma-Tau is firmly committed to providing its contribution to the eradication of malaria. Throughout the past century and until 1964, when the last case of malaria was reported in Italy, our country fought, and finally won, the tough battle against malaria (“malaria” is, after all, an Italian word). Through the development of new, effective treatments such as Eurartesim®, we like to think that the same results can be achieved in countries, especially in Africa, where

malaria continues to be an endemic disease.”

"Currently, quality ACTs are practically non-existent in the private market in Africa, where many people get their anti-malarials" said Chris Hentschel, CEO and president of Medicines for Malaria Venture. "The Pfizer and Sigma-Tau alliance has the potential to make a huge impact in getting this life-saving medicine to those in need. As the co-developer of this medicine, we are delighted by this alliance because, ultimately, the measure of our success will be how many lives we can save."

About Pfizer

Pfizer discovers and develops innovative medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality healthcare and health system support.

About Pfizer's Philanthropic Programs in Malaria

Mobilize Against Malaria is Pfizer's latest initiative to help close critical gaps in malaria treatment and education in Senegal, Ghana and Kenya. At the 2006 Clinton Global Initiative, Pfizer announced a five-year (2007-2012) program to prevent infection and spread of malaria by improving malaria symptom recognition, treatment and referral through local grassroots training, education and awareness. Partners in this initiative include Family Health International and the Ghana Social Marketing Foundation in Ghana, Population Services International in Kenya and IntraHealth in Senegal. The London School of Hygiene and Tropical Medicine serves as the lead global evaluator, collaborating with local evaluation organizations on the ground.

To learn more about Pfizer's philanthropic programs, please visit <http://www.pfizer.com/responsibility/>.

About Sigma-Tau

Sigma-Tau is a leading, all Italian capital, international pharmaceutical group that invests in the research, development and marketing of innovative and effective treatments to improve patient well-being and quality of life. Sigma-Tau Group has headquarters in Pomezia (Rome, Italy), and subsidiaries in France, Switzerland, The Netherlands, Portugal, Germany, the UK and the USA, as well as in Spain and Sudan where the Group operates two production facilities. It has over 2500 employees and an extensive network of licensees worldwide.

Sigma-Tau was founded in Italy in 1957 and achieved a global turnover of € 665 million (\$ 920 million) in 2007.

Sigma-Tau SpA consistently invests 16% of its annual turnover in R&D. Sigma-Tau's 400 R&D staff are currently running 43 R&D projects. A total of 14 NCEs and 12 known molecular entities in 30 different indications are at various stages of development.

Therapeutic areas in which the company's research and development are focused include metabolism, neurology, cardiovascular, oncology and immunology.

To learn more about Sigma-Tau, please visit: www.Sigma-Tau.it

Sigma-Tau's Malaria Programs

For several years now Sigma-Tau has focused in such area with a major social and health-care impact, namely the research and development of drugs for the treatment of rare diseases and malaria. In the case of malaria, the company's commitment has been made concrete by partnering with Medicines for Malaria Venture.

About Medicines for Malaria Venture (MMV)

Medicines for Malaria Venture (MMV) is a non-profit organization created to discover, develop and deliver effective and affordable anti-malarial drugs through public-private partnerships. Their vision is a world in which innovative medicines will cure and protect the millions at risk of malaria and help to ultimately eradicate this terrible disease.

MMV is currently managing the largest-ever portfolio of over 50 antimalarial projects in collaboration with over 100 pharmaceutical, academic, and endemic-country partners in 38 countries. The portfolio includes 19 completely new classes of compounds. New and improved treatment solutions are urgently needed for the 2.4 billion people at risk from malaria. MMV is working to ensure that its products will have the greatest possible public health impact and, most importantly, save lives.

For more information, please visit <http://www.mmv.org>

PFIZER DISCLOSURE NOTICE: *The information contained in this release is as of December 9, 2008. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.*

This release contains forward-looking information about an agreement to market a product candidate, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as -
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well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in its reports on Form 10-Q and Form 8-K.

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