# Sanofi-aventis and Medicines for Malaria Venture to launch the largest ever study of an antimalarial drug

## *- Ambitious drug-monitoring program started in Africa -*

**Paris, France and Geneva, Switzerland – November 19, 2009 –** Sanofi-aventis ( EURONEXT: SAN and NYSE: SNY) and Medicines for Malaria Venture (MMV) announced today that they have entered an agreement to launch the largest safety and efficacy study of an antimalarial drug. This field-monitoring program on ASAQ, a fixed-dose combination of artesunate and amodiaquine, started in Côte d'Ivoire in October 2009. MMV is a not-for-profit drug research and development organization dedicated to reducing the burden of malaria.

ASAQ is the only fixed-dose combination of artesunate and amodiaquine prequalified by WHO in the treatment of *Plasmodium falciparum* uncomplicated malaria. ASAQ is the result of a partnership between sanofi-aventis and Drugs for Neglected Diseases initiative (DNDi) and was launched in 2007.

*"We have designed an innovative field-monitoring program to assess the effectiveness and safety of ASAQ in real life conditions",* said Robert Sebbag, Vice President, Access to Medicines at sanofi-aventis. *"Thanks to MMV's support, we are now able to launch in Côte d'Ivoire this large study that completes the most ambitious drug monitoring program ever launched in Africa",* he added.

Under the terms of the agreement, MMV will provide $1.5 million towards the implementation of this large field-monitoring study developed by sanofi-aventis and the National Malaria Control Program of Côte d'Ivoire. Over a two-year period, approximately 15,000 patients afflicted by malaria are expected to be enrolled. All patients diagnosed with uncomplicated malaria at public health clinics in selected parts of the Agboville district (approximately 100km north of Abidjan) will receive a prescription of ASAQ. Within a week, patients will be visited at home by specially trained community health workers to assess treatment tolerability and compliance.

*"Data collected in clinical trials do not always provide the full picture of a new drug's efficacy and safety. This large Côte d'Ivoire study will use innovative methods to monitor antimalarial drugs' efficacy and safety and generate critical data,"* said Dr. Chris Hentschel, President and CEO of MMV. *"MMV is pleased to support this important study. The experience gained with ASAQ in the field will help us design pharmacovigilance programs for the new antimalarials in our own pipeline."*

Malaria is a fatal infectious disease that causes almost a million deaths a year of which over 90% are in Africa and 85% are children under the age of five. Most of these deaths are due to lack of access to effective antimalarials and erratic patient compliance.



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## About ASAQ

ASAQ, the first fixed-dose combination of artesunate (AS) and amodiaquine (AQ) was developed by sanofi-aventis and the FACT (Fixed-dose, Artemisinin-based Combination Therapy) partners, managed by DNDi. First registered in Morocco, where it is manufactured, in 2007, it was pre-qualified by the WHO in 2008. ASAQ is available under the name Artesunate-Amodiaquine Winthrop® (ASAQ) for public markets, and under the brand name Coarsucam® in private markets.

## About the ASAQ field-monitoring program

Drug development studies are conducted under very controlled circumstances that differ enormously from the situation on the ground. Once a new drug is widely distributed, it is important to monitor its rational use. Due to the wide distribution of antimalarials and the shortcomings of pharmacovigilance systems in many endemic countries, post registration studies to assess the safety and efficacy of the product are necessary. Following the launch of ASAQ in 2007, sanofi-aventis and DNDi decided to set-up a proactive monitoring plan of the drug's efficacy and safety in real life conditions: the "ASAQ field-monitoring program". The Côte d'Ivoire study is a key component, and the largest study, of this program.

The ASAQ field-monitoring program includes several studies throughout Africa. Each will provide specific sets of data on ASAQ safety and efficacy using a variety of study designs. These studies have been set up by sanofi-aventis, by DNDi, or by academic or government institutions, in close collaboration with each country's National Malaria Control Program. All the data collected will be aggregated into a single data base to enable detailed analyses. With over 20,000 malaria episodes to be treated with ASAQ, this is the most ambitious proactive drug monitoring program ever launched in Africa, for any drug. The WHO Department of Medicines Policy and Standards has expressed interest in seeing this program formalized as a Risk Management Plan (RMP) for ASAQ, the first program of this kind to be submitted to the WHO. The experience gained through this RMP will be useful for future antimalarials that will be launched in developing countries with relatively limited sets of safety and efficacy data.

## About Medicines for Malaria Venture

Medicines for Malaria Venture (MMV) was established in 1999 as a not-for-profit organization created to discover, develop and deliver safe, effective and affordable antimalarial drugs through effective public-private partnerships. MMV's vision is a world in which affordable and effective 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 130 pharmaceutical, academic, and endemic-country partners in 44 countries. With its partners, MMV has recently launched its first ever product – a sweet, paediatric formulation, Coartem® Dispersible. Another MMV-supported product, Eurartesim™, has been submitted to the EMEA for approval and a third, Pyramax® is being prepared for submission in 2010. Seven further potential medicines are in clinical development. The portfolio of discovery projects includes 19 completely new classes of compounds.

With over USD 470 million received and committed from government agencies, private foundations, international organizations, and corporate foundations; research carried out in the labs and clinical trial sites of its research partners; and industry partners contributing to the effort with staff, facilities, and technology, MMV is well set to deliver a range of new medicines. These will be the tip of the spear that, with an array of other tools and strategies, will finally be capable of eradicating malaria once and for all.

## About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, visit: www.sanofi-aventis.com

***Forward Looking Statements for sanofi-aventis***

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMEA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

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