# Rifapentine is granted Orphan Drug Status by European Commission for Treatment of Tuberculosis

- Shorter treatment duration with rifapentine expected to bring significant benefits to patients -

**Paris, France – July 1, 2010 –** Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the European Commission has granted Orphan Drug status for rifapentine for the treatment of tuberculosis (TB). Rifapentine is an antibiotic member of the rifamycin class, with a higher inhibitory activity against *Mycobacterium tuberculosis* and a longer half-life than rifampin, the cornerstone of current TB treatment regimen. These combined are expected to improve the drug exposure of patients to the drug and potentially lead to better efficacy.

European Orphan Drug designation is granted to medicines intended for treatment of life-threatening or chronically debilitating pathologies that affect no more than 5 in 10,000 people in the European Community. The European Commission's decision follows the positive opinion released by the *Committee for Orphan Medicinal Products (COMP)* of the European Medicines Agency (EMA) that a rifapentine-based combination regimen may be of significant clinical benefit for drug-susceptible TB patients by shortening their tuberculosis treatment.

"Rifapentine is currently one of the most promising drugs for the improvement of patient compliance, which is key to the success of tuberculosis treatment," said Robert Sebbag, Vice President, Access to Medicines, sanofi-aventis. "To avoid as much as possible the emergence of resistant strains, it is of utmost importance to simplify the treatment of non-resistant TB."

Sanofi-aventis is revisiting the development of rifapentine to be given daily, in combination with standard daily companion drugs, with the objective of significantly shortening the duration of drug-susceptible TB treatment. This should lead to less premature cessations of treatment, and thus to a reduction of treatment failures, a lesser risk of development of drug-resistance, as well as a reduction of costs, all of which are expected to bring significant benefits to patients and public health systems.

Rifapentine is currently marketed in the United States for the treatment of pulmonary and drugsusceptible TB within a standard 6-month course combination regimen.

Rifapentine is now listed in the Community Register of Orphan Medicinal Products for Human use under the code **EU/3/10/750**.



## **About Orphan Drug designation in the EU**

European Orphan Drug designation is granted to therapeutics intended for treatment of life-threatening or chronically debilitating pathologies that affect no more than 5 in 10,000 people in the European Community. For these diseases, no other methods of treatment must exist in the European Community, or the orphan medicinal product must be expected to bring significant benefits over existing drugs. The Orphan Drug designation confers several benefits to drug development, including protocol assistance provided by the EMA throughout the drug development process, direct access to the European centralized procedure to register the medicinal product in Europe, reduced fees for filing drug approval and marketing exclusivity in the approved orphan indication for a period of 10 years in the European market.

## **About rifapentine**

Rifapentine is a member of the rifamycin class of antibiotics. Rifampin (rifampicin), the lead rifamycin antibiotic, is the cornerstone of the current 6-month combination treatment regimen for drug-susceptible TB as recommended by the World Health Organization (WHO). Rifapentine is a rifamycin derivative with a higher inhibitory activity against *M. tuberculosis* and a longer half-life than rifampin. These properties are expected to improve drug exposure and potentially lead to a better efficacy. In an experimental model of TB, replacing rifampin by rifapentine in the standard combination of drugs, reduces from 6 months to 10-12 weeks the treatment duration required to achieve stable cure (Rosenthal *et al. Am J Respir Crit Care Med.* 2008: 178: 969).

Rifapentine is currently approved in the United States under the trademark Priftin<sup>®</sup> for the treatment of pulmonary drug-susceptible TB in combination with other anti-TB drugs. It should be administered twice-a-week in the Intensive Phase (2 months) and once-a-week in the Continuation Phase (4 months), in combination with daily companion drugs within a standard, 6-month treatment duration.

Sanofi-aventis is revisiting the development of rifapentine to be given daily, in combination with standard daily companion drugs, with the objective of significantly shortening the duration of drug-susceptible TB treatment. Sanofi-aventis is a producer of rifapentine. Sanofi-aventis was also the very first company to manufacture rifampicin and remains one of the main producers of this fundamental ingredient in all antituberculosis treatments.

## About tuberculosis, its treatment and unmet medical needs

Tuberculosis describes a broad range of clinical illnesses caused by the bacteria *Mycobacterium tuberculosis*. One-third of the world's population is infected with *M. tuberculosis*, and approximately 9.8 million people develop active disease annually. Of these, 1.7 million die each year. Treatment of drugsusceptible TB is long and complex, involving frequent intake of multiple drugs for at least 6 months. When correctly followed, standard 6-month regimen is very efficacious, achieving more than 95% cure in previously untreated patients. In practice, however, this success rate is rarely achieved as a consequence of premature cessation of treatment and irregularity in taking drugs. Patient noncompliance significantly contributes to the rise of drug resistance. Treatment of drug-resistance is a great challenge, requiring 24-30 months of therapy. The control of drug-resistance TB starts with successful treatment of drug-susceptible TB. Shortening of TB treatment should bring significant benefit to current patient care and public health concerns.

#### **About Access to Medicines**

The sanofi-aventis "Access to Medicines" department brings together the Group's areas of expertise to address the challenge of access to healthcare in developing and emerging countries for specific diseases. Sanofi-aventis has a long-standing presence in the TB field: it was the first, and remains a leading producer of rifampin, a mainstay of TB treatment. Sanofi-aventis produces a complete range of anti-tuberculosis medicines distributed in many countries. In addition, sanofi-aventis has set up a Research and Development program for new TB drugs with a specific focus on multi-drug resistant TB.

### **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, please visit: <a href="https://www.sanofi-aventis.com">www.sanofi-aventis.com</a>

## Forward Looking Statements

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 projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential 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 sanofiaventis, 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 EMA, 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, the Group's ability to benefit from external growth opportunities 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, 2009. 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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