



## Sanofi Provides an Update on its Research & Development Pipeline

**Paris, France – January 8, 2013** – Sanofi (EURONEXT: SAN and NYSE: SNY) today will provide an update on its Research & Development (R&D) pipeline with Dr. Elias Zerhouni, President, Global Research and Development, presenting at the JP Morgan Healthcare Conference in San Francisco, California.

Highlights of the presentation will include key products in late stage development in several disease areas with significant development and regulatory milestones in the next six months. Executing a successful strategy to reposition Sanofi R&D has fueled a pipeline with 65 NME (New Molecular Entity) projects and vaccine candidates in clinical development of which 17 are in Phase III or have been submitted to the health authorities for approval.

*“Sanofi has made significant progress in the transformation of its R&D over the last couple of years, including advances in late stage projects and early stage pipeline as well as talent recruitment. We feel we have the ingredients to ensure R&D contributes to Sanofi’s goal of sustainable growth in the coming years while rigorously managing R&D costs,”* said Dr. Elias Zerhouni.

Regarding regulatory milestones, Sanofi received two positive opinions from the Committee for Medicinal Products for Human Use (CHMP) since the last R&D update on October 25, 2012, with decisions from the European Commission targeted in Q1 2013: Lyxumia® (lixisenatide) in type 2 diabetes and Zaltrap® (afibercept) in metastatic second-line colorectal cancer.

### Portfolio update

- **SAR236553** (collaboration with Regeneron), a subcutaneously administered, fully-human antibody, is being evaluated for its impact on lowering low-density lipoprotein cholesterol (LDL-C) by targeting PCSK9. In November, Sanofi and Regeneron announced that the ODYSSEY OUTCOMES trial, a Phase III cardiovascular outcomes trial with SAR236553 started to recruit patients. This study will enroll approximately 18,000 patients, who recently suffered an acute coronary syndrome. With the start of this study, eleven Phase III trials are now recruiting hypercholesterolemic patients not at goal for LDL-C and mainly at high cardiovascular risk, a population estimated at 21 million people globally.
- **Clostridium Difficile Toxoid Vaccine**, for the prevention of primary symptomatic *Clostridium Difficile* infections (CDI), is expected to enter Phase III in Q3 2013 in patients at high risk of CDI. In the U.S., a Fast Track Development Program designation was granted by CBER (Center for Biologics Evaluation and Research). CDI is the most common cause of health-care related infections in the developed world and is increasingly reported globally.
- **SAR231893** (collaboration with Regeneron), an anti IL-4R $\alpha$  monoclonal antibody with dual IL-4/IL-13 cytokine antagonism, will enter Phase IIb in mid-2013 in asthma and atopic dermatitis following positive proof of concept data for both indications. These data will be submitted for presentation at medical conferences in 2013.
- **SAR302503**: In December, Sanofi announced that the Phase II trial evaluating its JAK2 inhibitor in myelofibrosis met its primary endpoint. The data was presented during the 2012 Annual Meeting of the American Society of Hematology. Recruitment of the Phase III JAKARTA study is completed.


- **Aubagio**<sup>®</sup> (teriflunomide): Sanofi has discontinued the TERACLES study. This decision is based on recruitment challenges and an assessment of changing market dynamics which suggests that combining oral and injectable immunomodulatory platform multiple sclerosis therapies may not be a preferred treatment option. This decision is not related to any safety concern.
- **Ombrabulin**: Results of the Phase III study in sarcoma did not demonstrate sufficient clinical benefit to support regulatory submissions despite reaching its primary endpoint of progression free survival and the phase II study in ovarian cancer was terminated early based on an interim analysis. There were no substantial safety concerns in these studies. We have informed our partner Ajinomoto of our decision to discontinue this project.
- **SAR245408** (XL 147, partnership with Exelixis): The Phase II trial in endometrial cancer has been discontinued. The study did not demonstrate sufficient clinical benefit to pursue late-stage trials in this indication. SAR245408 is being examined in an ongoing Phase II trial in combination with letrozole in breast cancer and in combination with SAR256212 in a Phase I trial.

### Key development milestones expected in the next six months

- **Eliglustat**: Phase III results of the ENCORE study evaluating the oral therapy eliglustat vs. Cerezyme<sup>®</sup> in patients with Gaucher disease are expected in Q1 2013.
- **Otamixaban**: Phase III results of the TAO study evaluating otamixaban, the first intravenous direct and selective factor Xa inhibitor with quick onset/offset, are expected in Q2 2013.
- **SAR302503**: Headline results from the Phase III JAKARTA study in myelofibrosis are expected in Q2 2013.
- **New glargine formulation**: The first Phase III headline results in diabetes are expected in Q2 2013.
- **Iniparib**: Headline results from the Phase III in first-line squamous non-small-cell lung cancer are expected in Q2 2013.

### Key regulatory milestones expected in the next six months

- **Zaltrap**<sup>®</sup> (afibercept, collaboration with Regeneron): The European Commission decision in second-line metastatic colorectal cancer is targeted in Q1 2013.
- **Lyxumia**<sup>®</sup> (lixisenatide, licensed from Zealand Pharma): The European Commission decision in type 2 diabetes is targeted in Q1 2013. The FDA decision on file acceptance in type 2 diabetes in the U.S. is expected in Q1 2013.
- **Aubagio**<sup>®</sup> (teriflunomide): The CHMP opinion for the treatment of relapsing multiple sclerosis is expected in Q1 2013.
- **Lemtrada**<sup>™1</sup> (alemtuzumab): The CHMP opinion for the treatment of relapsing multiple sclerosis is expected in Q2 2013. The FDA decision on file acceptance is expected in Q1 2013.
- **Kynamro**<sup>™</sup> (mipomersen sodium, development partnership with Isis Pharmaceuticals): The FDA decision for the treatment of patients with Homozygous Familial Hypercholesterolemia is expected in Q1 2013. In December, the CHMP adopted a negative opinion for its marketing authorization application for the treatment of patients with Homozygous Familial Hypercholesterolaemia. Genzyme has requested a re-examination of the CHMP Opinion.

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- **Vaxigrip® QIV IM** (quadrivalent inactivated flu vaccine, intramuscular): The submission of regulatory file in the EU is expected in Q1 2013.
  - **Paediatric hexavalent vaccine** (DTP-Hep B-Polio-Hib): The CHMP opinion is expected in Q1 2013.
  - **Fluzone® QIV IM** (quadrivalent inactivated flu vaccine, intramuscular): The FDA decision is expected in Q2 2013.

<sup>1</sup> Lemtrada™ is being developed in multiple sclerosis in collaboration with Bayer Healthcare

## About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### Forward-Looking Statements

*This press release contains forward-looking statements. 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's 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, 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 product candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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### Contacts:

#### Media Relations

Jean-Marc Podvin  
+ (33) 1 53 77 46 46  
E-mail : [mr@sanofi.com](mailto:mr@sanofi.com)

#### Investor Relations

Sébastien Martel  
+ (33) 1 53 77 45 45  
E-mail : [ir@sanofi.com](mailto:ir@sanofi.com)