Sanofi Genzyme Announces Start of Phase III Study of Isatuximab for Relapsed and Refractory Multiple Myeloma

Sanofi Genzyme, the specialty care global business unit of Sanofi, today announced the initiation of the ICARIA-MM Phase III trial of isatuximab, an investigational anti-CD38 monoclonal antibody being studied for the treatment of patients with relapsed and refractory multiple myeloma. The trial will compare isatuximab in combination with pomalidomide and dexamethasone against pomalidomide and dexamethasone.

The primary endpoint of the study is progression-free survival. Key secondary endpoints include overall response rate and overall survival. The randomized, open label study will enroll 300 patients at trial sites around the world. Isatuximab has been granted orphan designation in the U.S. and European Union.

“The start of this trial is an important step in our effort to develop a new option for patients with multiple myeloma,” said Joanne Lager, Head of Oncology Development, Sanofi. “The development of isatuximab is a priority for us. “We are committed to advancing this study as quickly as possible and investigating the expanded use of isatuximab in multiple myeloma and additional malignancies.”

The initiation of Phase III development for isatuximab is supported by encouraging Phase I and II clinical trial results. Anti-CD38 mAbs are recognized by myeloma experts as an important class of therapies for the treatment of multiple myeloma.

Findings from studies of isatuximab were presented during a poster session on Saturday, December 3rd at this year’s American Society of Hematology meeting underway in San Diego, including the following abstracts.

**Abstract:** 2123  
**Title:** Preliminary Results From a Phase Ib Study of Isatuximab in Combination with Pomalidomide and Dexamethasone in Relapsed and Refractory Multiple Myeloma  
**Presenter:** Dr. Paul Richardson

**Abstract:** 2111  
**Title:** Phase Ib Study of Isatuximab and Carfilzomib in Relapsed and Refractory Multiple Myeloma  
**Presenter:** Dr. Thomas Martin

**Abstract:** 2105  
**Title:** Critical Analysis of the Mechanism of Action (MoA) of Isatuximab in Multiple Myeloma  
**Presenter:** Dr. Bruno Paiva

**About Multiple Myeloma**

The second most common cancer of the blood, multiple myeloma is a cancer that starts in plasma cells, a type of white blood cell. In time, myeloma cells collect in the bone marrow. They may damage the solid part of the bone, and eventually harm other tissues and organs, such as the kidneys. Worldwide, nearly 230,000 people are living with multiple myeloma, and each year, approximately 114,000 new cases are diagnosed.

**About Sanofi**

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial.

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often
difficult to diagnose and treat, providing hope to patients and their families.

Sanofi 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’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, Sanofi’s ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives 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, 2015. 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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