Sanofi explores combination treatments for multiple myeloma in new late-stage trials

Release Date:
Thursday, December 7, 2017 8:00 am EST

Terms:
Dateline City:
CAMBRIDGE, Mass.

* Phase 3 trials will evaluate isatuximab, an anti-CD38 antibody, in combination with other cancer treatments

* Studies will focus on patients with relapsed and first-line multiple myeloma

* Separate isatuximab data will be presented at upcoming American Society of Hematology meeting

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sanofi has launched two new late-stage clinical studies to determine if an investigational biologic called isatuximab, when used in combination with other commonly used cancer treatments, might be an effective treatment option for certain people with multiple myeloma, a rare blood cancer related to lymphoma and leukemia. Isatuximab is an investigational anti-CD38 monoclonal antibody being studied for the treatment of patients with relapsed and previously untreated multiple myeloma.

“The start of two new Phase 3 trials will provide further clinical data as we continue to advance the development of isatuximab,” said Joanne Lager, M.D. Head of Oncology Development, Sanofi. “Our multi-study program across major multiple myeloma segments aims to demonstrate the value of isatuximab in combination with emerging standard treatment regimens. We are committed to developing a potential new treatment option for a continuum of patients with multiple myeloma, a population with high unmet need.”

Late-stage studies include approximately 750 patients with multiple myeloma

- IKEMA study is a 325-patient randomized, open-label, global multicenter Phase 3 trial that will compare isatuximab in combination with carfilzomib and dexamethasone against carfilzomib and dexamethasone in patients with relapsed and refractory multiple myeloma that have previously been treated with one-to-three lines of therapy.
- IMROZ study is a 425-patient randomized, open-label, global multicenter Phase 3 trial that will compare isatuximab in combination with bortezomib, lenalidomide and dexamethasone against bortezomib, lenalidomide and dexamethasone in newly diagnosed multiple myeloma patients not eligible for transplant.

Both studies will evaluate progression-free survival as the primary endpoint. Key secondary endpoints include overall survival, overall response rate, depth of response, safety and quality of life.

Isatuximab granted orphan designation
Isatuximab has been granted orphan designation in the U.S. and European Union. In December 2016, Sanofi started an additional Phase 3 study (ICARIA), comparing isatuximab in combination with pomalidomide and dexamethasone against pomalidomide and dexamethasone in patients with relapsed and refractory multiple myeloma. The development program for isatuximab will now total three Phase 3 studies.

Other isatuximab data being presented at upcoming American Society of Hematology meeting
Findings from additional ongoing studies of isatuximab will be presented during poster sessions at this year's American Society of Hematology meeting, December 8-12, in Atlanta, GA, including the following abstracts:

Saturday, December 9, 5:30 p.m.-7:30 p.m.:

- Updated Results from a Phase Ib Study of Isatuximab Plus Pomalidomide (Pom) and Dexamethasone (dex) in Relapsed/Refractory Multiple Myeloma (RRMM)
  Abstract: 1887
  Presenter: Dr. Paul Richardson

- “In Vivo Vaccination” Effect in Clinical Responders to Anti-Myeloma Monoclonal Antibody Isatuximab
  Abstract: 1830
Sunday, December 10, 6:00 p.m. - 8:00 p.m.:

- **A Phase Ib Study of Isatuximab in Combination with Bortezomib, Cyclophosphamide, and Dexamethasone (VCDI) in Patients with Newly Diagnosed Multiple Myeloma Non-Eligible for Transplantation**
  Presenter: Dr. Tim Luetkens

- **Pre-Clinical Efficacy of the Anti-CD38 Monoclonal Antibody (mAb) Isatuximab in Acute Myeloid Leukemia (AML)**
  Presenter: Tomas Jelinek

**About Sanofi**

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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. Learn more at [www.sanofigenzyme.com](http://www.sanofigenzyme.com).

**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, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.