SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Isatuximab Phase 3 trial meets primary endpoint of prolonging progression free survival in patients with relapsed/refractory multiple myeloma

- Study evaluated the benefit of isatuximab in combination with standard of care in prolonging progression free survival as compared to standard of care in patients with relapsed/refractory multiple myeloma
- First randomized Phase 3 trial to evaluate the benefit of adding a monoclonal antibody to pomalidomide and dexamethasone for treatment of relapsed/refractory multiple myeloma
- Multiple ongoing Phase 3 studies with isatuximab, an investigational agent, in combination with standard of care therapies in newly diagnosed and relapsed/refractory multiple myeloma

PARIS – February 5, 2019 – The pivotal Phase 3 trial of isatuximab in patients with relapsed/refractory multiple myeloma met the primary endpoint of prolonging progression free survival in patients treated with isatuximab in combination with pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone alone (standard of care).

Results will be submitted to an upcoming medical meeting and are anticipated to form the basis of regulatory submissions planned for later this year.

> *"We are excited by these results, which represent significant progress in our ambition to extend the lives of multiple myeloma patients,"* said John Reed, Head of Research and Development at Sanofi. *"We look forward to engaging with regulatory authorities with the goal of bringing this potential new treatment to patients as quickly as possible."*

Multiple myeloma is the second most common hematologic malignancy[1], with more than 138,000[2] new cases worldwide each year. Multiple myeloma remains incurable in the vast majority of patients, resulting in significant disease burden.

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[1] Kazandjian. Multiple myeloma epidemiology and survival: A unique malignancy. Semin Oncol. 2016;43(6):676-681. doi:10.1053/j/seminoncol.2016.11.004

[2] Cowan AJ, Allen C, Barac A, et al. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018;4(9):1221–1227. doi:10.1001/jamaoncol.2018.2128

The randomized, multi-center, open label Phase 3 study, known as ICARIA-MM, enrolled 307 patients with relapsed/refractory multiple myeloma across 96 centers spanning 24 countries. All study participants received two or more prior anti-myeloma therapies, including at least two consecutive cycles of lenalidomide and a proteasome inhibitor given alone or in combination. During the trial, isatuximab was administered through an intravenous infusion at a dose of 10mg/kg once weekly for four weeks, then every other week for 28-day cycles in combination with standard doses of pomalidomide and dexamethasone for the duration of treatment. The safety profile was evaluated as a secondary endpoint.

About isatuximab clinical development program

Isatuximab targets a specific epitope of CD38 capable of triggering multiple, distinct mechanisms of action that are believed to promote programmed tumor cell death (apoptosis) and immunomodulatory activity. CD38 is highly and uniformly expressed on multiple myeloma cells and is a cell surface receptor target for antibody-based therapeutics in multiple myeloma and other malignancies. The clinical significance of these findings is under investigation.

ICARIA-MM is one of four ongoing Phase 3 clinical trials evaluating isatuximab in combination with currently available standard treatments for people with relapsed/refractory or newly-diagnosed multiple myeloma.

Isatuximab received orphan designation for relapsed/refractory multiple myeloma by the U.S. Food and Drug Administration and the European Medicines Agency. Isatuximab is an investigational agent and the safety and efficacy has not been evaluated by the U.S. Food and Drug Administration, the European Medicines Agency, or any other regulatory authority. Isatuximab is also under investigation for the treatment of other hematologic malignancies and solid tumors.

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.

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