New data for isatuximab in multiple myeloma to be presented at ASH 2019

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Analyses from the ICARIA-MM trial for isatuximab, an investigational anti-CD38 monoclonal antibody, will highlight outcomes in an elderly patient population, depth of response and associated long-term outcomes, and health-related quality of life. These results are among data for isatuximab, being investigated for the treatment of multiple myeloma, that will be presented at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition from December 7-10 in Orlando, FL.

“We look forward to presenting further insights into isatuximab, including efficacy and safety data in patients 75 years of age and older, who generally experience poorer outcomes than those who are younger. In addition, we are detailing new results on depth of response, which is associated with long-term progression-free and overall survival,” said Dietmar Berger, Head of Global Development at Sanofi. “These data advance our understanding of multiple myeloma, a difficult-to-treat disease with significant patient need.”

The ICARIA-MM clinical trial serves as the basis of a Biologic License Application for isatuximab, which is currently under review by the U.S. Food and Drug Administration (FDA) with a target action date for a decision of April 30, 2020. The clinical trial is among a number of ongoing pivotal studies to evaluate the potential role of isatuximab in multiple standard-of-care treatment regimens for multiple myeloma. A Marketing Authorization Application for isatuximab was also accepted for review by the European Medicines Agency (EMA) in the second quarter of 2019.

Key Sanofi data being presented at ASH include:

- **Efficacy of Isatuximab with Pomalidomide and Dexamethasone in Elderly Patients with Relapsed/Refractory Multiple Myeloma: ICARIA-MM Subgroup Analysis** (Dr. Fredrik Schjesvold; Saturday, December 7, 2019: Poster Presentation, 5:30-7:30 p.m. ET)
- **Depth of Response and Response Kinetics in the ICARIA-MM Study of Isatuximab/Pomalidomide/Dexamethasone in Relapsed/Refractory Multiple Myeloma** (Dr. Cyrille Hulin; Sunday, December 8, 2019: Poster Presentation, 6:00-8:00 p.m. ET)
- **Health-Related Quality of Life in Patients with Relapsed/Refractory Multiple Myeloma Treated with Isatuximab plus Pomalidomide and Dexamethasone: ICARIA-MM Study** (Katherine Houghton; Saturday, December 7, 2019: Poster Presentation, 5:30-7:30 p.m. ET)
- **Evaluating Isatuximab Interference with Monoclonal Protein Detection By Immuno-Capture and Liquid Chromatography Coupled to High Resolution Mass Spectrometry in the Pivotal Phase 3 Multiple Myeloma Trial, ICARIA-MM** (Dr. Greg Finn; Sunday, December 8, 2019: Poster Presentation, 6:00-8:00 p.m. ET)
- **The Relationship Between Baseline Biomarkers and Efficacy of Isatuximab in Combination with Pomalidomide and Dexamethasone in RRMM: Insights from Phase 1 and Phase 3 studies** (Dr. Paul Richardson; Sunday, December 8, 2019: Poster Presentation, 6:00-8:00 p.m. ET)
- **Exposure-response Analyses and Disease Modeling for Selection and Confirmation of Optimal Dosing Regimen of Isatuximab in Combination Treatment in Patients with Multiple Myeloma** (Dr. Fatiha Rachedi; Saturday, December 7, 2019: Poster Presentation, 5:30-7:30 p.m. ET)

In addition, new Phase 2 results in smoldering multiple myeloma will be presented (Investigator-Sponsored Study):

- **A Multicenter Phase II Single Arm Trial of Isatuximab in Patients with High Risk Smoldering Multiple Myeloma** (Dr. Elisabet E. Manasanch; Sunday, December 8, 2019: Poster Presentation, 6:00-8:00 p.m. ET)

About ICARIA-MM and isatuximab

ICARIA-MM is a pivotal Phase 3 randomized, open-label, multi-center trial evaluating isatuximab in combination with pomalidomide and dexamethasone (pom-dex) versus pom-dex alone in patients with relapsed/refractory multiple myeloma (RRMM). The study enrolled 307 patients with RRMM across 96 centers spanning 24 countries. Overall, patients had received a median of three prior lines of anti-myeloma therapy, 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 pom-dex for the duration of treatment.

Isatuximab targets a specific epitope on the CD38 receptor and is designed to trigger multiple, distinct mechanisms of action that are believed to directly promote programmed tumor cell death (apoptosis) and immunomodulatory activity. CD38 is highly and uniformly expressed on multiple myeloma cells and cell surface receptors, making it a potential target for antibody-based agents such as isatuximab. The clinical significance of these findings is under investigation.

Isatuximab is an investigational agent and its safety and efficacy have not been evaluated by the U.S. FDA, the EMA, or any other regulatory authority.

For more information on isatuximab clinical trials please visit www.clinicaltrials.gov.

About Sanofi

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

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