

New clinical and health-related quality of life data in multiple myeloma and rare blood disorders to be presented at ASH 2020

- * **Oncology:** Results from an interim analysis of Sarclisa® (isatuximab-irfc) in patients with relapsed multiple myeloma, including an evaluation of depth of response, will be shared in an oral presentation
- * **Rare Blood Disorders:** Presentations across three FDA-approved therapies and three investigational candidates show the breadth and depth of Sanofi's commitment to people living with rare blood disorders

November 5, 2020

New clinical and health-related quality of life data in Sanofi's oncology and rare blood disorders portfolios and pipelines, representing seven oral and 27 poster presentations, will be featured during the American Society of Hematology (ASH) Annual Meeting from December 5-8.

New data advances understanding of Sarclisa to treat multiple myeloma

Sarclisa is approved in several geographies to treat adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor. Data to be presented at ASH from the ICARIA trial reinforces its use in patients with this difficult-to-treat disease (abstracts #1411, 2289).

Additional data is emerging regarding the potential use of Sarclisa in combination with carfilzomib and dexamethasone after one to three prior therapies based on interim results from the IKEMA clinical study. In an oral presentation (abstract #414), results from an interim analysis will be presented, including an evaluation of the depth of response seen in patients with relapsed myeloma treated with Sarclisa plus carfilzomib and dexamethasone (compared to carfilzomib and dexamethasone alone). Poster presentations with results from an interim analysis of the IKEMA trial (abstract #2316), as well as a subgroup analysis in patients with renal impairment (abstract #3241) will also be presented. The use of Sarclisa in combination with carfilzomib and dexamethasone in relapsed MM is investigational; regulatory submissions were recently completed, but its safety and efficacy in this combination have not been fully evaluated by regulatory authorities.

Breaking barriers with ground-breaking science aiming to help people with rare blood disorders

Cold Agglutinin Disease (CAD): Two presentations (abstracts #2484, 1631) provide an overview of the experience of living with CAD, including patient-reported disease burden and medically attended anxiety or depression in newly diagnosed people with CAD. Currently, there are no approved therapies for CAD.

A new analysis (abstract #1674) from the Phase 3 pivotal study CARDINAL for sutimlimab, an investigational C1s inhibitor, in CAD evaluated complement-mediated inflammation contribution to fatigue in people living with CAD, and report new interim results from the CARDINAL Study Long-term Follow-up. Finally, additional oral presentations (abstracts #151, 426) describe the potential impact of sutimlimab on healthcare resource utilization.

Immune Thrombocytopenic Purpura (ITP): An oral presentation on sutimlimab, an investigational therapy, reports on long-term safety and efficacy data in people living with ITP (abstract #23).

Sutimlimab is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

Hemophilia: Several presentations (including abstracts #2693, 877) will be shared on fitusiran, a novel siRNA therapy in development for hemophilia A and B with or without inhibitors, including interim results from a Phase 2 study (abstract #511).

An overview of the ongoing BIVV001 Phase 3 trial design (the XTEND-1 study) will be shared in a poster presentation (abstract #856). BIVV001 is an investigational once-weekly factor therapy for people with hemophilia A and represents a potential new class of factor VIII therapy that has the potential to provide high sustained factor activity levels. BIVV001 is being developed in collaboration with Sobi.

Fitusiran and BIVV001 are currently under clinical investigation and their safety and efficacy have not been evaluated by any regulatory authority.

Acquired Thrombotic Thrombocytopenic Purpura (aTTP): An oral presentation (abstract #428) on the serious burden of illness for people living with aTTP will be presented. Additionally, two posters (abstracts #843, 1754) share outcomes for patients with worsening aTTP despite receiving daily plasma exchange therapy in the Phase 3 HERCULES trial, and the impact of caplacizumab on platelet response, respectively.

Oncology Abstracts:

- Depth of Response and Response Kinetics of Isatuximab plus Carfilzomib and Dexamethasone in Relapsed Multiple Myeloma: IKEMA Interim Analysis (Dr. Thomas Martin; Oral Presentation; Number 414)

<ul style="list-style-type: none"> • Isatuximab Plus Carfilzomib and Dexamethasone Versus Carfilzomib and Dexamethasone in Relapsed Multiple Myeloma Patients with Renal Impairment: IKEMA Subgroup Analysis (Dr. Marcelo Capra; Poster Presentation; Number 3241)
<ul style="list-style-type: none"> • Isatuximab Plus Carfilzomib and Dexamethasone vs Carfilzomib and Dexamethasone in Relapsed/Refractory Multiple Myeloma (IKEMA): Interim Analysis of a Phase 3, Randomized, Open-label Study (Dr. Philippe Moreau; Poster Presentation; Number 2316)
<ul style="list-style-type: none"> • Isatuximab Plus Pomalidomide and Dexamethasone in Frail Patients with Relapsed/Refractory Multiple Myeloma: ICARIA-MM Subgroup Analysis (Dr. Fredrik Schjesvold; Poster Presentation; Number 1411)
<ul style="list-style-type: none"> • Isatuximab Plus Pomalidomide and Dexamethasone in Patients With Relapsed/Refractory Multiple Myeloma and Soft-tissue Plasmacytomas: ICARIA-MM Subgroup Analysis (Dr. Meral Beksac; Poster Presentation; Number 2289)
<ul style="list-style-type: none"> • Isatuximab Short-Duration Fixed-Volume Infusion Plus Bortezomib, Lenalidomide and Dexamethasone Combined Therapy for Newly Diagnosed Multiple Myeloma (NDMM): Results from a Phase 1b Feasibility/Safety Study (Dr. Enrique Ocio; Poster Presentation; Number 1413)
<ul style="list-style-type: none"> • Updates from a Phase Ib Study of Isatuximab, Bortezomib and Dexamethasone Plus Cyclophosphamide or Lenalidomide in Transplant Ineligible Newly Diagnosed Multiple Myeloma (Dr. Enrique Ocio; Poster Presentation; Number 2288)
<ul style="list-style-type: none"> • Isatuximab Short-duration Fixed-Volume Infusion Combination Therapy for Relapsed/Refractory Multiple Myeloma: Final Results of a Phase 1b Feasibility/Safety Study (Dr. Saad Usmani; Poster Presentation; Number 3207)
<ul style="list-style-type: none"> • Development of a Hydrasys 2/4 -Isatuximab Assay to Mitigate Interference with Monoclonal Protein Detection on Immunofixation Electrophoresis IVD Tests in Multiple Myeloma (Greg Finn; Poster Presentation; Number 1562)
<ul style="list-style-type: none"> • Health-Related Quality of Life in Heavily Pre-Treated and Renally Impaired Patients with Relapsed/Refractory Multiple Myeloma Receiving Isatuximab plus Pomalidomide and Dexamethasone: ICARIA-MM Study (Dr. Meletios Dimopoulos; Poster Presentation; Number 3438)
<ul style="list-style-type: none"> • Daratumumab Dose Analysis Among Patients with Multiple Myeloma in a US Community Oncology Setting: A Retrospective Observational Study in Integra Connect Network (Dr. Robert Smith; Poster Presentation; Number 3222)
<ul style="list-style-type: none"> • Model Based Approach to Evaluate Isatuximab Monthly Dosing Regimen in Relapsed/Refractory Multiple Myeloma Patients (Hoai-Thu Thai; Online Publication Only; Number 4165)
<ul style="list-style-type: none"> • Treatment Patterns and Healthcare Resource Utilization in Patients with Multiple Myeloma and Baseline Renal Impairment (Dr. Parameswaran Hari, Online Publication Only)
<ul style="list-style-type: none"> • Real-World Renal Function Among Patients with Multiple Myeloma in the United States (Dr. Joseph Mikhael; Online Publication Only)
<ul style="list-style-type: none"> • Examination of Real-World Outcomes and Health Care Resource Utilization in the Prevention and Treatment of Tumor Lysis Syndrome (Wynter Balcerski; Online Publication Only)

Rare Blood Disorders Abstracts:

Hemophilia

<ul style="list-style-type: none"> • Long-Term Durability, Safety and Efficacy of Fitusiran Prophylaxis in People with Hemophilia a or B, with or without Inhibitors – Results from the Phase II Study (Dr. Steven Pipe; Oral Presentation; Number 511)
<ul style="list-style-type: none"> • Final Results of PUPs A-LONG Study: Evaluating Safety and Efficacy of rFVIII Fc in Previously Untreated Patients with Haemophilia A (Dr. Christoph Königs; Oral Presentation; Number 509)
<ul style="list-style-type: none"> • Final Results of PUPs B-LONG Study: Evaluating Safety and Efficacy of rFIX Fc in Previously Untreated Patients with Haemophilia B (Dr. Beatrice Nolan; Poster Presentation; Number 856)
<ul style="list-style-type: none"> • Longitudinal Assessment of Thrombin Generation in Patients with Hemophilia Receiving Fitusiran Prophylaxis: Phase II Study Results (Prof. Claude Négrier; Poster Presentation; Number 2693)

<ul style="list-style-type: none"> • Mechanistic Studies of Thrombin Generation Assay to Evaluate Procoagulant Potential of Fitusiran (Dr. Sravya Kattula; Poster Presentation; Number 857)
<ul style="list-style-type: none"> • Reducing antithrombin in plasma to levels observed in fitusiran-treated patients does not interfere with coagulation assays (Arjan van der Flier; Poster Presentation; Number 862)
<ul style="list-style-type: none"> • Fitusiran Treatment Impacts on Health-Related Quality of Life in Subjects With Hemophilia A and B with Inhibitors assessed with the Haemophilia Quality of Life Questionnaire for Adults (Haem-A-QoL) (Dr. Sylvia von Mackensen; Poster Presentation; Number 877)
<ul style="list-style-type: none"> • Evaluating BIVV001, a New Class of Factor VIII Replacement Therapy: A Phase 3 Study (XTEND-1) Design (Dr. Barbara Konkle; Poster Presentation; Number 856)

Cold Agglutinin Disease

<ul style="list-style-type: none"> • Long-term Safety and Efficacy of Sutimlimab in Patients with Chronic Immune Thrombocytopenia (Dr. Catherine Broome; Oral Presentation; Number 23)
<ul style="list-style-type: none"> • Longitudinal Analysis of Anemia Severity, Treatment and Healthcare Resource Utilization among Patients with Primary Cold Agglutinin Disease in a Large US Database (Dr. Huy P Pham; Oral Presentation; Number 151)
<ul style="list-style-type: none"> • Effect of Sutimlimab Treatment on Healthcare Resource Utilization in Patients with Cold Agglutinin Disease (Dr. Alexander Röth; Oral Presentation; Number 426)
<ul style="list-style-type: none"> • Inhibition of Complement C1s with Sutimlimab in Patients with Cold Agglutinin Disease (CAD): Interim Results of the Phase 3 Cardinal Study Long-term Follow-up (Dr. Alexander Röth; Poster Presentation; Number 1674)
<ul style="list-style-type: none"> • Inflammation and Fatigue in Patients with Cold Agglutinin Disease (CAD): Analysis from the Phase 3 Cardinal Study (Dr. Ilene Weitz; Poster Presentation; Number 759)
<ul style="list-style-type: none"> • Medically Attended Anxiety or Depression Is Increased Among Newly Diagnosed Patients With Cold Agglutinin Disease (CAD) (Parija Patel; Poster Presentation; Number 1631)
<ul style="list-style-type: none"> • Patient-Reported Disease Burden: In-depth Interviews of Patients with CAD (Jun Su; Poster Presentation; Number 2484)
<ul style="list-style-type: none"> • Sutimlimab, a Complement C1s Inhibitor, Improves Quality of Life in Patients With Cold Agglutinin Disease: Patient-Reported Outcomes Results of the Phase 3 Cardinal Study (Dr. Alexander Röth; Poster Presentation; Number 765)
<ul style="list-style-type: none"> • Cold Agglutinin Disease (CAD) Real World Evidence (CADENCE) Registry: Design of the First International, Prospective CAD Registry (Dr. Alexander Röth; Poster Presentation; Number 2537)

Immune Thrombocytopenic Purpura

<ul style="list-style-type: none"> • Treatment Patterns Among Patients with Immune Thrombocytopenia (ITP) in the United States: an Electronic Medical Record (EMR)–Based Analysis (Amanda Wilson; Poster Presentation; Number 2544)
<ul style="list-style-type: none"> • Understanding and measuring key symptoms and health-related quality of life in patients with chronic ITP (Prof. Florence Joly; Poster Presentation; Number 3461)

Acquired Thrombotic Thrombocytopenic Purpura

<ul style="list-style-type: none"> • Burden of Illness Among Medicare and Non-Medicare Populations With Acquired Thrombotic Thrombocytopenic Purpura, 2010-2018 (Dr. Huy P Pham; Oral Presentation; Number 428)
<ul style="list-style-type: none"> • Outcomes of patients with worsening acquired thrombotic thrombocytopenic purpura despite daily therapeutic plasma exchange in the Phase 3 HERCULES trial (Dr. Marie Scully; Poster Presentation; Number 843)
<ul style="list-style-type: none"> • Caplacizumab Induces Fast and Durable Platelet Count Responses With Improved Time to Complete Remission and Recurrence-Free Survival in Patients With Acquired Thrombotic Thrombocytopenic Purpura (Dr. Paul Coppo; Poster Presentation; Number 1754)

Rare Disease Abstract:

- Hematologic Malignancies and Monoclonal Gammopathy of Undetermined Significance (MGUS) in Gaucher Disease Type 1 Patients in the International Cooperative Gaucher Group Gaucher Registry (Dr. Barry E. Rosenbloom; Poster Presentation; Number 3164)

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, Empowering Life

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initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties 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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.