SANOFI

Media Update

New data in blood cancers, hemophilia, and other hematological disorders to be presented at ASH 2021

November 4, 2021

Six oral and 14 poster presentations will be featured during the American Society of Hematology (ASH) Annual Meeting from December 11-14.

> *"These upcoming data presentations demonstrate our ongoing commitment to delivering meaningful innovations for patients with significant unmet needs in oncology and hematology,"* said Dietmar Berger, Global Head of Clinical Development and Chief Medical Officer, Sanofi. *"In our efforts to support the transformation of therapeutic landscapes, we look forward to presenting our Phase 3 results on fitusiran's ability to provide protection from bleeds for people with hemophilia A or B with inhibitors. We're also pleased to work with GMMG as they present investigational data evaluating Sarclisa in patients with newly diagnosed multiple myeloma, the first Phase 3 trial adding an anti-CD38 monoclonal antibody in combination with bortezomib, lenalidomide and dexamethasone."*

Understanding the potential for Sarclisa® (isatuximab-irfc) in earlier lines of therapy for multiple myeloma and other blood cancers

New data are from the Phase 3 German-Speaking Myeloma Multicenter Group (GMMG) HD7 study evaluating the effect of isatuximab in combination with bortezomib, lenalidomide and dexamethasone (VRd) on the rate of achieving minimal residual disease (MRD) negativity in transplant-eligible patients with newly diagnosed multiple myeloma (MM) after induction therapy, before transplant. These are the first results from a Phase 3 trial adding an anti-CD38 monoclonal antibody to VRd, a recommended first regimen in transplant-eligible newly diagnosed MM. GMMG-HD7 is also the first trial to evaluate MRD negativity at the end of induction as a co-primary endpoint, along with progression free survival, in transplant-eligible patients with newly diagnosed MM. The results of the study were selected as an oral presentation (abstract #463) and as part of the press program. Sanofi provided financial support to GMMG for this study.

Additionally, data from the Phase 2 ISAKIDS trial evaluating isatuximab in combination with standard salvage chemotherapies in children with relapsed or refractory leukemia in first or second relapse will be shared as an oral presentation (abstract #516).

The uses of Sarclisa in adult patients with newly diagnosed multiple myeloma and children with leukemia are currently under clinical investigation and their safety and efficacy in these settings have not been fully evaluated by any regulatory authority.

Sarclisa is approved in several geographies, in combination with pomalidomide and dexamethasone, for the treatment of certain adult patients with relapsed refractory MM who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor. This anti-CD38 monoclonal antibody medicine is also approved in several geographies in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed or refractory MM who have received one to three prior lines of therapy.

Advancing our innovative approaches to find treatments for people with rare blood disorders

Hemophilia: The results of the ATLAS-003 Phase 3 study evaluating fitusiran prophylaxis in patients with hemophilia A or B with inhibitors dosed with the 80 mg monthly treatment will be presented in the plenary scientific session (abstract #150273).

Additionally, the Phase 1/2 study results for long-term health-related quality of life in patients with hemophilia A, with or without inhibitors, treated with fitusiran prophylaxis will be shared in a poster presentation (abstract #3197).

Fitusiran is a novel, subcutaneous small interference (si)RNA therapy in development for people with hemophilia A or B, with or without inhibitors.

A post hoc analysis from the Phase 1/2 studies looking at the half-life and clearance of efanesoctocog alfa – previously known as BIVV001 – will be shared in a poster presentation (abstract #1035).

Efanesoctocog alfa is an investigational once-weekly factor therapy for people with hemophilia A that may provide high sustained factor activity and near-normal factor levels for the majority of the week. It represents a potential new class of factor VIII therapy. Efanesoctocog alfa is being developed in collaboration with Sobi.

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

Cold Agglutinin Disease (CAD): An oral presentation (abstract #349) shares new data from the CADENZA study, looking at the safety and efficacy of sutimlimab to inhibit C1-activated hemolysis in people with CAD. Additionally, two poster presentations (abstracts #4057 and #2002) provide an overview of the burden of living with CAD, including patient-reported outcome symptom measures. Also, a new analysis from the Phase 3 CARDINAL and CADENZA studies which evaluated sutimlimab in CAD, will report on physical and mental component summary scores and contribution to fatigue in people living with the disease.

Sutimlimab, a first-in-class investigational C1s inhibitor, has the potential to be the first approved treatment for hemolysis in adults with CAD, a serious and chronic autoimmune

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

Immune Thrombocytopenic Purpura (ITP): An oral presentation on rilzabrutinib, an investigational oral Bruton tyrosine kinase inhibitor (BTKi), reports on updated Phase 1/2 safety and efficacy results for the treatment of ITP (abstract #14) and a poster presentation (abstract #1010) on the design of the Phase 3 LUNA3 study. Rilzabrutinib is a potential first-in-class, oral BTKi in development for immune-mediated diseases. It is also being investigated for the autoimmune condition IgG4-related disease, asthma, atopic dermatitis, chronic spontaneous urticaria and warm autoimmune hemolytic anemia.

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

Acquired Thrombotic Thrombocytopenic Purpura (aTTP): Two poster presentations will share safety and efficacy results for Cablivi® (caplacizumab-yhdp) in aTTP: abstract #2080 will share long-term safety and efficacy from the post-HERCULES study in aTTP; additionally, abstract #1009 will show results from a Phase 2/3 study in Japanese patients with immune-mediated TTP.

Cablivi® (caplacizumab-yhdp) is approved in several geographies in combination with plasma exchange and immunosuppression for the treatment of aTTP in adults.

Sickle Cell Disease: Preliminary data from the ongoing Phase 1/2 PRECIZN-1 study evaluating the safety and efficacy of SAR445136, formerly known as BIVV003, for the treatment of patients with severe sickle cell disease will be shared in a poster presentation (abstract #2930). SAR445136, an investigational zinc finger nuclease ex vivo gene-edited cell therapy in development with Sangamo, has the potential to be a one-time treatment for sickle cell disease.

SAR445136 is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

Oncology Abstracts:

- Abstract #463: Addition of Isatuximab to Lenalidomide, Bortezomib and Dexamethasone as Induction Therapy for Newly-Diagnosed, Transplant-Eligible Multiple Myeloma: The Phase III GMMG-HD7 Trial. Oral presentation by GMMG. Sanofi provided financial support for this study.
- Abstract #516: Isatuximab in Combination with Chemotherapy in Pediatric Patients with Relapsed/Refractory Acute Lymphoblastic Leukemia or Acute Myeloid Leukemia (ISAKIDS): Interim Analysis. Oral presentation.
- Abstract #4114: Real-World Multiple Myeloma Treatment Patterns by Patient Characteristics and Outcomes in the United States. Poster.
- Abstract #2744: A Multi-Center, Phase 1b Study to Assess the Safety, Pharmacokinetics and Efficacy of Subcutaneous Isatuximab Plus Pomalidomide

and Dexamethasone, in Patients with Relapsed/Refractory Multiple Myeloma. Poster.

- Abstract #1962: A Matching-Adjusted Indirect Comparison of Isatuximab Plus Carfilzomib and Dexamethasone Versus Daratumumab Plus Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma. Poster.
- Abstract #1671: Isatuximab Rescue for Inadequate Response to Lenalidomide and Dexamethasone in Transplant Ineligible Patients with Newly Diagnosed Multiple Myeloma: Interim Analysis of the Phase II IRIL Study of the Australian Myeloma Research Consortium (AMaRC 18-02). Poster.
- Abstract #4362: A Phase 1/2, Open-Label, Multicenter Study of Isatuximab in Combination with Cemiplimab in Patients with Lymphoma. Abstract online only.
- Abstract #4769: ITHACA, a Randomized Multicenter Phase 3 Study of Isatuximab in Combination with Lenalidomide and Dexamethasone in High-Risk Smoldering Multiple Myeloma: Safety Run-In Preliminary Results. Abstract online only.
- Abstract #4767: Trial in Progress: A Phase 2 Multi-Center, Open Label Study of Isatuximab Added to Standard CyBorD Induction and Lenalidomide Maintenance Treatments in Newly Diagnosed, Transplant Eligible Multiple Myeloma. Abstract online only.

Rare Blood Disorders Abstracts:

Hemophilia

- Abstract #150273: Efficacy and Safety of Fitusiran Prophylaxis, an siRNA Therapeutic, in a Multicenter Phase 3 Study (ATLAS-INH) in People with Hemophilia A or B, with Inhibitors (PwHI). Plenary scientific session.
- Abstract #498: Prophylaxis with rFIXFc Reduces the Frequency and Delays Time to First Spontaneous Bleed Event in Previously Untreated Patients with Hemophilia B: A Post Hoc Analysis of the PUPs B-LONG Trial. Oral presentation joint with Sobi.
- Abstract #3197: Sustained Improvement in Health-Related Quality of Life in Patients with Hemophilia A with or without Inhibitors Treated with Fitusiran Prophylaxis. Poster.
- Abstract #1035: Efanesoctocog Alfa Half-life and Clearance Are Independent of von Willebrand Factor in Severe Hemophilia A: A Post Hoc Analysis from Phase 1/2a Studies. Poster joint with Sobi.
- Abstract #3031: A Retrospective Observational Descriptive Study on the Effectiveness and Usage of Emicizumab and Antihemophilic Factor (recombinant), Fc Fusion Protein in Patients with Hemophilia A in the U.S. Poster.

Cold Agglutinin Disease

- Abstract #349: Inhibition of Complement C1s by Sutimlimab in Patients with Cold Agglutinin Disease (CAD): Efficacy and Safety Results from the Randomized, Placebo-Controlled Phase 3 CADENZA Study. Oral presentation.
- Abstract #4057: Development of a Cold Agglutinin Disease-Specific Patient-Reported Outcome Symptom Measure. Poster.

- Abstract #2002: Clinically Important Change in SF-12v2 Physical (PCS) and Mental (MCS) Component Summary Scores for Patients with Cold Agglutinin Disease: An Analysis Using the Phase 3 CARDINAL and CADENZA Studies. Poster.

Immune Thrombocytopenic Purpura

- Abstract #14: Updated Phase I/II Safety and Efficacy Results for Oral Bruton Tyrosine Kinase Inhibitor Rilzabrutinib in Patients with Relapsed/Refractory Immune Thrombocytopenia. Oral presentation.
- Abstract #1010: LUNA3 Phase III Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of the Oral BTK Inhibitor Rilzabrutinib in Adults and Adolescents with Persistent or Chronic Immune Thrombocytopenia. Poster.

Acquired Thrombotic Thrombocytopenic Purpura

- Abstract #2080: Long-Term Safety and Efficacy of Caplacizumab for Acquired Thrombotic Thrombocytopenic Purpura (aTTP): The Post-HERCULES Study. Poster.
- Abstract #1009: The Efficacy and Safety of Caplacizumab in Japanese Patients with Immune-Mediated Thrombotic Thrombocytopenic Purpura (iTTP): An Open-Label, Phase 2/3 Study. Poster.

Sickle Cell Disease

- Abstract #2930: Preliminary Safety and Efficacy Results from PRECIZN-1: An Ongoing Phase 1/2 Study on Zinc Finger Nuclease-Modified Autologous CD34+ HSPCs for Sickle Cell Disease (SCD). Poster.
- Abstract #1860: Quantitative Systems Pharmacology Model of Sickle Cell Disease and Response to Gene Editing Therapy to Support Clinical Development of SAR445136 (BIVV003). Poster.

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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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 fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions 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 and market conditions, cost containment 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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.