Press Release

Rilzabrutinib LUNA 3 phase 3 study met primary endpoint in immune thrombocytopenia

- Pivotal data from the first phase 3 study of a BTKi in immune thrombocytopenia (ITP) underscore the potential of rilzabrutinib to provide a clinically meaningful benefit to patients living with ITP
- Regulatory submissions in the US and EU anticipated by year-end
- Rilzabrutinib is one of 12 potential medicines and vaccines in Sanofi's robust immunology pipeline and a testament to Sanofi's ability to successfully accelerate and build a portfolio of next-generation transformative treatments for immune diseases
- In addition to ITP, rilzabrutinib is being studied across a variety of immune-mediated diseases including asthma, chronic spontaneous urticaria, prurigo nodularis, IgG4-related disease and warm autoimmune hemolytic anemia

Paris, April 23, 2024. Positive results from the LUNA 3 phase 3 study demonstrated that rilzabrutinib 400 mg twice daily orally achieved the primary endpoint of durable platelet response in adult patients with persistent or chronic immune thrombocytopenia (ITP). The safety profile of rilzabrutinib was consistent with that reported in previous studies.

LUNA 3 study met its primary endpoint demonstrating a significantly higher proportion of patients receiving rilzabrutinib achieved the primary endpoint of durable platelet response versus placebo. This clinically and statistically significant result was achieved in a population of patients with primary ITP that had been refractory to prior therapy. Overall, study participants had a median of four prior ITP therapies and a median baseline platelet count of 15,000/µL (normal platelet count levels typically range from 150,000-450,000/µL). Positive results on key secondary endpoints also underscore the potential for rilzabrutinib to deliver clinically meaningful benefits for patients living with persistent and chronic ITP.

Rilzabrutinib was granted Fast Track Designation by the US Food and Drug Administration (FDA) for the treatment of ITP in November 2020 and was previously granted Orphan Drug Designation.

> ***Houman Ashrafian***
> Executive Vice President, Head of Research and Development, Sanofi
> *"The results of this study reinforce rilzabrutinib's potential to be a first-in-class oral, reversible BTK inhibitor that can provide clinically meaningful improvements for people living with severe immune-mediated diseases like ITP. These pivotal results are a testament to our commitment and expertise in rare blood diseases and ability to build a portfolio of next-generation small-molecule inhibitors that are both more selective and optimized to deliver robust efficacy and safety outcomes as compared to existing therapies."*

ITP is a serious, acquired autoimmune blood disorder characterized by autoantibody-mediated platelet destruction and impaired platelet production, leading to thrombocytopenia (low platelet counts of less than 100,000/µL) and an increased risk of life-threatening bleeding episodes (like intracranial hemorrhage). In addition, patients with ITP often experience significant quality-of-life impairments such as fatigue and cognitive dysfunction. With its dual mechanisms of action that reduce production of pathogenic autoantibodies and decrease macrophage mediated platelet destruction, rilzabrutinib could address the underlying mechanisms responsible for a wide range of ITP complications.

About LUNA 3

LUNA 3 (NCT04562766) is a randomized, multicenter, phase 3 study evaluating the efficacy and safety of rilzabrutinib vs placebo in adult and adolescent patients with persistent or chronic ITP. Patients received either oral rilzabrutinib 400 mg twice a day or placebo through a 12- to 24-week double-blind treatment period, followed by a 28-week open-label treatment, and then a 4-week safety follow-up or long-term extension period. The adolescent part of the study is ongoing and still recruiting.

The primary endpoint is durable platelet response defined as the proportion of participants able to achieve platelet counts at or above 50,000/µL for for at least 8 out of the last 12 weeks of the 24-week blinded treatment period in the absence of rescue therapy. Secondary endpoints include the number of weeks with and time to platelet responses, rescue therapy use, and physical fatigue and bleeding score.

Detailed results of the LUNA 3 phase 3 study will be presented at a medical congress later this year.

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

About Rilzabrutinib

Rilzabrutinib is an oral, reversible, covalent BTK inhibitor that has the potential to be a first- or best-in-class treatment of several immune-mediated diseases. BTK, expressed in B cells, mast cells and other cells from the innate immune system, plays a critical role in inflammatory pathways and multiple immune-mediated disease processes. With the application of Sanofi's TAILORED COVALENCY® technology, rilzabrutinib can selectively inhibit the BTK target.

Rilzabrutinib is being studied across a variety of immune-mediated diseases, including immune thrombocytopenia (regulatory submission in H2 2024), asthma (phase 2), chronic spontaneous urticaria (phase 3 start in 2024), prurigo nodularis (phase 3 start in 2024), IgG4-related disease (phase 2b results in H2 2024), and warm autoimmune hemolytic anemia (phase 2b results in H2 2024).

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com
Victor Rouault | + 33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | + 1 516 521 2929 | timothy.gilbert@sanofi.com

Investor Relations

Thomas Kudsk Larsen |+ 44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | + 33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Tarik Elgoutni| + 1 617 710 3587 | tarik.elgoutni@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com

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