

Rilzabrutinib granted FDA Fast Track Designation for treatment of immune thrombocytopenia

- * Phase 3 trial initiated to evaluate rilzabrutinib, the potential first BTK inhibitor (Bruton's tyrosine kinase inhibitor) for the treatment of immune thrombocytopenia
- * Rilzabrutinib previously granted FDA orphan drug designation

PARIS – November 18, 2020 – The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to the oral investigational Bruton's tyrosine kinase (BTK) inhibitor, rilzabrutinib, which has the potential to be the first BTK inhibitor for the treatment of immune thrombocytopenia (ITP). In addition, following positive Phase 1/2 study results, a Phase 3 study evaluating rilzabrutinib for ITP has been initiated. Rilzabrutinib received orphan drug designation from the FDA for the treatment of ITP in October 2018.

"By awarding Fast Track Designation to rilzabrutinib, an investigational candidate for the treatment of ITP, the FDA has recognized rilzabrutinib's potential to meaningfully improve outcomes for patients with this debilitating disease. This is an excellent acknowledgement as we initiate our Phase 3 study," said Dolca Thomas, Chief Medical Officer of Principia, a Sanofi company. *"FTD is designed to facilitate the development and expedite the review of investigational treatments that demonstrate the potential to address unmet medical needs in serious or life-threatening conditions,"*

About Fast Track Designation

FTD is an FDA process designed to facilitate the development, and expedite the review of, medicines to treat serious conditions and fill unmet medical need. The FDA created this process to help deliver important new drugs to patients earlier, and it covers a broad range of serious illnesses. Fast Track designation can lead to an Accelerated Approval and Priority Review if certain criteria are met.

About Immune thrombocytopenia

ITP is characterized by immune-mediated platelet destruction and impairment of platelet production, which leads to downstream thrombocytopenia, a predisposition to bleeding, and adverse impact on patient quality of life. There remains an unmet medical need in ITP to achieve rapid and durable remission rates for patients who have relapsed or are refractory to corticosteroids.

About Rilzabrutinib

Rilzabrutinib is an oral, reversible covalent, Bruton's tyrosine kinase (BTK) inhibitor being investigated for the treatment of immune mediated diseases. BTK is involved in innate and adaptive immune responses and is a signalling molecule in immune mediated diseases. Rilzabrutinib data demonstrate an ability to block inflammatory immune cells, eliminate autoantibody destructive signalling, and prevent new autoantibody production without depleting B cells. Rilzabrutinib has the potential to target the underlying disease pathogenesis and has not been shown to alter platelet aggregation. The clinical significance of these mechanisms is currently under investigation and its safety and efficacy have not been reviewed by any regulatory authority.

Editor's Note: Rilzabrutinib is being investigated in a Phase 3 trial for pemphigus, an immune mediated disease characterized by blisters in mucous membranes and skin. Additionally, a Phase 2 study in the autoimmune condition IgG4 Disease has also been initiated.

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

Media Relations Contact

Sally Bain
Tel.: +1 781 264 1091
sally.bain@sanofi.com

Investor Relations Contacts Paris

Eva Schaefer-Jansen
Arnaud Delepine
Yvonne Naughton

Investor Relations Contacts North America

Felix Lauscher
Fara Berkowitz
Suzanne Greco

IR main line:
Tel.: +33 (0)1 53 77 45 45
investor.relations@sanofi.com

<https://www.sanofi.com/en/investors/contact>

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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.