

Sanofi to evaluate the safety and efficacy of novel investigational candidate THOR-707 and KEYTRUDA® (pembrolizumab) in pursuit of establishing a new treatment option in oncology

- * THOR-707 (SAR444245) is a non-alpha IL-2 candidate with a best-in-class profile currently being evaluated in Phase 1 trials for the treatment of solid tumors

PARIS – October 29, 2020 – Sanofi has entered into an agreement with Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the U.S. and Canada) to conduct a Phase 2 clinical trial to evaluate the safety, pharmacokinetics, and preliminary efficacy of THOR-707, a highly differentiated non-alpha IL-2 candidate with a best-in-class profile, combined with or in sequenced administration with MSD's KEYTRUDA® (pembrolizumab) in patients with various cancers.

Under the agreement, Sanofi will sponsor the clinical trials while MSD will provide KEYTRUDA.

"We believe that THOR-707 has the potential to become a foundation of the next generation of immuno-oncology therapies," said Peter Adamson, Global Head, Oncology Development and Pediatric Innovation, Sanofi. *"This collaboration with MSD will enable us to explore whether THOR-707 can increase and expand the effectiveness of KEYTRUDA and improve the outcomes for patients with cancer."*

THOR-707 is currently being evaluated by Sanofi in an ongoing Phase 1 open-label, multi-center, dose escalation and expansion trial. This study is designed to evaluate the safety and tolerability of THOR-707, and to determine its recommended Phase 2 dose alone and in combination with anti-PD-1 and anti-EGFR antibodies.

In addition to testing THOR-707 in combination with KEYTRUDA, Sanofi is separately evaluating the activity of this novel biologic in combination with other anti-PD-1 antibodies, including Libtayo® (cemiplimab-rwlc) and with anti-EGFR and anti-CD38 antibodies for various types of cancer tumors.

THOR-707 demonstrated in preclinical studies the ability to induce the expansion of CD8+T-cells resulting in anti-tumor effects both as single agent as well as in combination with an anti-PD1 mAb.

It is the first molecule from the Synthorin platform, Sanofi's unique expanded genetic alphabet platform, which has the potential to create a new generation of precision medicines for oncology and autoimmune disease.

About THOR-707

THOR-707 has the potential to be a best-in-class IL-2 therapeutic for the treatment of many types of malignancies and may demonstrate improved pharmacology allowing for less frequent dosing. In pre-clinical experiments, THOR-707 shows striking synergy with anti-PD-1 therapeutics.

It is a precisely PEGylated engineered version of interleukin-2 (IL-2), where the PEG chain is attached at a location on IL-2 that prevents it from binding to immune receptors that cause drug toxicities (IL-2R-alpha, CD25) while preserving binding to immune receptors that selectively expand tumor-killing T effector and Natural Killer (NK) cells without the immunosuppressive effects of regulatory T cells or vascular leak syndrome (VLS) inducing eosinophils.

Editor's Note: As discussed at Sanofi's R&D Day in June, full Phase 1 results for THOR-707 and the recommended Phase 2 dose are expected by 2021.

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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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.