

## Sanofi’s virtual R&D Day event to highlight capabilities, platforms, and expertise in disease pathways to deliver potentially transformative treatments to patients

- \* R&D strategy driving pipeline momentum, productivity and innovation
- \* Significant progress made since December 2019 on priority pipeline programs that have the potential to transform patient care
- \* First multiple sclerosis patient has been enrolled in the Phase 3 program for brain penetrant BTK inhibitor ‘168
- \* Positive THOR-707 “not-alpha” IL-2 first-in-human biomarker data
- \* Accelerated development timeline for COVID-19 recombinant protein-based vaccine with potential approval in H1 2021
- \* Virtual R&D Day investor event today from 3:00-5:30 pm CET / 9:00-11:30 am ET

**PARIS – June 23, 2020** – Sanofi Chief Executive Officer Paul Hudson, Global Head of R&D John Reed, M.D., Ph.D., and members of the R&D and commercial leadership teams will provide an update on Sanofi’s approach to deliver potentially transformative medicines to patients.

This event is the fourth of a five-part series highlighting how Sanofi is leading with innovation. The previous three events focused on the Phase 2 results of Sanofi’s brain penetrant BTK inhibitor (‘168), Sanofi’s oncology pipeline progress, and future growth opportunities for Dupixent® (dupilumab)<sup>1</sup>.

*“Since last December, we have been making tremendous progress on our ability to grow a pipeline of potentially transformative treatments through a unique, adaptive strategy that best positions Sanofi to deliver on our goal of bringing practice-changing medicines and vaccines to patients,”* said Paul Hudson, Chief Executive Officer, Sanofi. *“While we have greatly accelerated our efforts across six priority development programs, the momentum we are seeing can be found across our entire pipeline. This is largely driven by how we are leveraging our innovative technology platforms and the deep insights we have gained into patients’ needs and disease pathways.”*

### Sanofi transforms R&D to drive productivity

Sanofi is transforming its R&D organization based on the pillars of the Company’s strategy announced at Capital Markets Day last December.

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<sup>1</sup> Partnered with Regeneron

- **Focus on priorities** by allocating R&D resources towards potential first-in-class or best-in-class medicines. Today, 75% of Sanofi's assets in development have the potential to be either first- or best-in-class treatments
- **Lead with innovation** Sanofi's unique range of internal technologies such as multi-specific antibody, Nanobody<sup>®</sup>, and Synthorin platforms are delivering novel, cutting-edge drug discovery capabilities. Approximately 65% of Sanofi's drug candidates in development are internally driven, including Sanofi's investigational oral selective estrogen receptor degrader (SERD '859) and its investigational anti-CEACAM5 ('701) antibody drug conjugate
- **Accelerate efficiency** by relentlessly improving clinical operations and embedding digital and real-world data capabilities, so Sanofi can move at greater speed. An example of this is Sanofi's investigational brain penetrant BTK inhibitor '168 Phase 1 and 2 trials that were conducted one year faster than the industry average. Sanofi today shared that the first patient has been enrolled in the Phase 3 program despite the complexities of the current COVID-19 environment
- **Reinvent the way R&D performs** by substantially simplifying the organization's ways of working. This includes an integrated development organization, streamlined governance and greater team empowerment which has resulted in rapid initiation of clinical trials such as the studies evaluating Kevzara<sup>®</sup> (sarilumab)<sup>2</sup> as a potential COVID-19 therapeutic

*“Today we are highlighting the unique attributes of Sanofi R&D and the extremely encouraging progress our dedicated scientists and physicians have delivered these last six months, despite a very challenging context,”* said John Reed, M.D. Ph.D., Global Head of Research & Development. *“We have built industry-leading capabilities, including a broad toolbox of drug discovery platforms, that allow us to design molecules that give us new and potentially better ways to fight disease, while also focusing on enhancing our pace of delivery by creating a more agile organization.”*

## Synthorin platform adds to Sanofi's diverse tools

The Synthorin platform, based on novel synthetic biology, is a unique platform that expands the genetic alphabet through the creation of a new DNA base pair. Addition of this new base pair to the two naturally occurring base pairs allows coding for a greater number of amino acids (up to 176 compared to 20 naturally occurring amino acids) resulting in substantially increased diversity of proteins, and gives scientists the potential to build a new generation of precision medicines for oncology and autoimmune disease.

One of the lead investigational product candidates, THOR-707, a “not-alpha” variant of interleukin-2, is in clinical development in multiple solid tumor types as both a single agent and in combination with immune checkpoint inhibitors. Early biomarker data from a Phase 1 study of THOR-707 showed that the molecule increased tumor-fighting CD8+ T and

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<sup>2</sup> Partnered with Regeneron

Natural Killer cells without significantly increasing regulatory T cells and eosinophils. Sanofi expects full Phase 1 results and the recommended Phase 2 dose by 2021. Additional precision interleukins will be entering the clinic between 2021-2023.

### **Venglustat builds on Sanofi's rare diseases heritage combined with a deep understanding of disease pathways**

**Venglustat** is an investigational oral glucosylceramide synthase inhibitor in development for several monogenetic diseases including rare diseases such as Gaucher disease type 3, Fabry disease, and GM-2 gangliosidoses, but also leveraging conserved glycosphingolipid disease biology in more monogenetic disorders, especially Autosomal dominant polycystic kidney disease and GBA-Parkinson's disease.

In rare diseases:

- A Phase 2/3 study in Gaucher disease type 3 is ongoing
- A Phase 3 trial in Tay-Sachs disease, a type of GM-2 gangliosidoses, was initiated at the beginning of this year
- A Phase 3 trial in Fabry disease is expected to initiate in 2021

Regulatory filings for all three indications could be made during 2023 dependent upon positive data.

Beyond rare diseases:

- Proof of concept data for GBA-Parkinson's disease is expected by the first half of 2021.
- Pivotal results for Autosomal dominant polycystic kidney disease are expected by Q4 2021, and if positive, regulatory filings could begin in early 2022.

### **Fitusiran & BIVV001 use new modalities and cutting-edge protein engineering to potentially deliver differentiated solutions for patients suffering from hemophilia**

**Fitusiran** is a potential best-in-class, investigational RNAi therapy for patients with hemophilia A and B (with or without inhibitors) aiming to rebalance the deficient coagulation cascade while significantly reducing the treatment burden with once-monthly subcutaneous dosing convenience. Fitusiran could potentially be the first ever product in hemophilia that does not require refrigeration. Positive data for fitusiran from interim analysis of the Phase 2 extension study in people with hemophilia A and B, with or without inhibitors were presented at the World Federation of Hemophilia Virtual Summit [earlier this month](#). Two of three Phase 3 studies are fully enrolled with a near completion of the third. The pediatric Phase 3 study is currently enrolling. If data are positive, regulatory submission for fitusiran in adults and adolescents is planned in the second half of 2021.

**BIVV001<sup>3</sup>** is a potential new class of factor VIII therapy for people with hemophilia A designed to extend protection from bleeds through high factor levels with once-weekly prophylactic dosing. Positive Phase 1 repeat dose study results were presented at the World Federation of Hemophilia Virtual Summit earlier this month. The Phase 3 study in previously treated hemophilia A patients started last year, and if data are positive, regulatory submissions could be made in the first half of 2022.

### On the front lines in the fight against COVID-19

Since the beginning of the pandemic, Sanofi has played a leading role in the fight against COVID-19. In collaboration with global health authorities and leading partners, Sanofi is one of the only companies in the world to work on the search for COVID-19 vaccine candidates by exploring two complementary technological platforms. This approach increases the overall probability of success and strengthens Sanofi's capabilities to prepare for potential future pandemics.

- **A recombinant protein-based vaccine approach (baculovirus)**, in collaboration with GSK. The recombinant protein vaccine candidate applies the same technology and established manufacturing capacity based on the baculovirus expression platform used for Sanofi's influenza vaccine Flublok® while GSK is contributing its adjuvant AS03.

Sanofi expects a Phase 1/2 study to start in September and at the earliest, full approval by the first half of 2021. Sanofi has capacity to manufacture up to 1 billion doses a year.

- **A messenger RNA (mRNA) candidate** in collaboration with Translate Bio. With several exploratory vaccine platforms currently investigated across the industry, mRNA is considered among the most promising.

Sanofi expects a Phase 1 study to start by the end of the year, and, if data is positive, an approval at the earliest in the second half of 2021. Translate Bio has established mRNA manufacturing capacity and Sanofi expects to be able to supply annual capacity of 90 to 360 million doses.

The R&D investor event will be held today from **3:00-5:30 pm CET / 9:00-11:30 am ET**. The virtual set up of Sanofi's R&D Day provides the opportunity to meet a wider group of the Company's incredible leadership and strong scientific bench. Sanofi speakers include:

- Paul Hudson, Chief Executive Officer
- John Reed, M.D. Ph.D., Global Head of Research & Development
- Yong-Jun Liu, Global Head of Research
- Marcos Milla, Chief Scientific Officer, Synthorx

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<sup>3</sup> BIVV001 is being developed in collaboration with Sobi.

- Karin Knobe, Therapeutic Head, Rare Diseases and Rare Blood Disorders Development
- Pablo Sardi, Therapeutic Head, Rare Diseases Research
- Vanessa Wolfeler, Global Head, Rare Blood Disorders Franchise
- Dietmar Berger, Global Head of Development and Chief Medical Officer
- John Shiver, Global Head of Sanofi Pasteur Research & Development

The Company plans to hold its fifth event at a later date focused on nirsevimab, a monoclonal antibody that could potentially offer a population-based solution to prevent respiratory syncytial virus (RSV) infection for all infants.

Additional information about today's session can be found at: <https://www.sanofi.com/en/investors/financial-results-and-events/investor-presentations/2020-rd-presentation>

### 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.*