

# Sanofi to acquire Principia Biopharma

- Further strengthens core R&D areas of autoimmune and allergic diseases
- Provides full control of brain-penetrant BTK inhibitor SAR442168 in multiple sclerosis (MS), making commercialization more efficient and eliminating future royalty payments
- Allows expansion of SAR442168 development program into other central nervous system diseases and therapeutic areas
- Adds clinically advanced oral BTK inhibitor rilzabrutinib with potential across a range of immunology and inflammation indications, complementing Sanofi's existing R&D pipeline

PARIS and SOUTH SAN FRANCISCO, Calif. – August 17, 2020 – Sanofi and Principia Biopharma Inc. (NASDAQ: PRNB), a late-stage biopharmaceutical company focused on developing treatments for immune-mediated diseases, entered into a definitive agreement under which Sanofi will acquire all of the outstanding shares of Principia for \$100 per share in cash, which represents an aggregate equity value of approximately \$3.68 billion (on a fully diluted basis). The Sanofi and Principia Boards of Directors unanimously approved the transaction.

"This acquisition advances our ongoing R&D transformation to accelerate development of the most promising medicines that will address significant patient needs," said Paul Hudson, Sanofi Chief Executive Officer. "The addition of multiple BTK inhibitors to our pipeline demonstrates our commitment to strategic product acquisitions in our priority therapeutic areas. Full ownership of our brain-penetrant BTK inhibitor '168 removes complexities for this priority development program and simplifies future commercialization."

"The Phase 2b data in relapsing multiple sclerosis showed the strong potential of '168 to address disability and disease progression, and triggered the start of Phase 3 studies across the full spectrum of MS. Through this acquisition, we will be able to expand and accelerate development of BTK inhibitors across multiple indications. Both '168 and rilzabrutinib, have 'pipeline in a product' potential, and we look forward to unlocking their full treatment benefits across an array of diseases," said John Reed, M.D., Ph.D., Global Head of Research & Development at Sanofi.

"Principia's successful design and development of a whole portfolio of BTK inhibitors for immunology is aimed to transform the treatment for patients with

immune-mediated diseases. By combining with Sanofi, we will bring significant resources to expand and accelerate the potential benefits of these therapies. The benefit of developing several BTK inhibitors will allow us to target specific organ systems for optimal patient benefit. The merger will provide global resources to get these novel therapies to patients faster," said Martin Babler, President and CEO at Principia Biopharma.

Principia's Bruton tyrosine kinase (BTK) inhibitors add to Sanofi's efforts to accelerate and build a portfolio of the next generation of transformative treatments for autoimmune diseases. BTK is present in the signaling pathways of key innate and adaptive cell types of the immune system. Being able to block or disrupt these signaling processes can help in stopping inflammation and tissue destruction related to autoimmune diseases and target some of the underlying pathophysiology.

- BTK inhibitor '168: In a Phase 2b study in patients with multiple sclerosis, '168 reduced Gd-enhancing T1 hyperintense lesions by 85% compared to placebo. In June, Sanofi announced the first multiple sclerosis patient was enrolled in the Phase 3 program for the BTK inhibitor, comprising four pivotal clinical trials across the disease spectrum. The Principia acquisition will provide an opportunity to expand the development program to evaluate indications beyond central nervous system diseases.
- Rilzabrutinib: This oral BTK inhibitor is currently being evaluated in a Phase 3 program for patients with moderate to severe pemphigus, a rare, debilitating autoimmune disease that causes blistering of the skin and mucous membranes. A Phase 3 program for immune thrombocytopenia, a disease that causes high risk for bleeding events, is expected to be initiated by the end of 2020, assuming no COVID-19 related impact. The company also has an ongoing Phase 2 program for IgG4-related diseases, which is driven by chronic inflammation, immune cell infiltration, and fibrosis within organs that can lead to severe morbidity.
- **PRN473 Topical**: This BTK inhibitor is a topical agent currently in Phase 1 trials and is being developed for immune-mediated diseases that could benefit from localized application to the skin.

The Principia BTK inhibitor franchise is based on its proprietary Tailored Covalency® platform that has generated potential best-in-class clinical candidates. The platform allows the design of both reversible covalent and irreversible covalent small molecule inhibitors that are more selective with less off-target effects. The optimized target residence time has potential to deliver a desired efficacy with a stronger safety profile.

In 2017, Sanofi formed a collaboration with Principia under which Principia granted Sanofi an exclusive, worldwide license to develop and commercialize BTK inhibitor '168 in multiple sclerosis and other central nervous system diseases.

#### **Transaction Terms**

Under the terms of the merger agreement, Sanofi will commence a cash tender offer to acquire all outstanding shares of Principia common stock for \$100 per share in cash for a total enterprise value of approximately \$3.36 billion.

The consummation of the tender offer is subject to customary closing conditions, including the tender of at least a majority of the outstanding shares of Principia common stock, the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and other customary conditions. Following the successful completion of the tender offer, a wholly owned subsidiary of Sanofi will merge with Principia and the outstanding Principia shares not tendered in the tender offer will be converted into the right to receive the same \$100 per share in cash paid in the tender offer. The tender offer is expected to commence later this month. Sanofi plans to finance the transaction with cash on hand. Subject to the satisfaction or waiver of customary closing conditions, Sanofi expects to complete the acquisition in the fourth quarter of 2020.

Evercore is acting as financial advisor to Sanofi and Weil, Gotshal & Manges LLP is acting as its legal counsel. Centerview Partners LLC and BofA Securities are acting as financial advisors to Principia and Cooley LLP is acting as its legal counsel.

#### **Investor Relations Call**

Sanofi will host an audio webcast live and conference call at 3:00 pm CET / 9:00 am ET on Monday, August 17, 2020. The webcast, conference call details, and full presentation will be made available on Sanofi's Investor Relations webpage.

## **About Principia Biopharma**

Principia is a late-stage biopharmaceutical company dedicated to bringing transformative therapies to patients with significant unmet medical needs in immune-mediated diseases. Through Principia's proprietary Tailored Covalency® platform, our strategy is to build and advance a pipeline of best-in-class drug candidates with significant therapeutic benefits, limit unintended side effects, improve quality of life and over time modify the course of disease. This highly reproducible approach enables the company to pursue multiple programs efficiently, having discovered three drug candidates. Rilzabrutinib, a reversible covalent BTK inhibitor, is being evaluated in a global Phase 3 clinical trial in participants with pemphigus, a Phase 1/2 clinical trial in participants with immune thrombocytopenia (ITP), and the company plans to initiate a Phase 2 clinical trial in participants with IgG4-Related Diseases and a Phase 3 trial in ITP. PRN2246/SAR442168 is a covalent BTK inhibitor which crosses the blood-brain barrier and is licensed to Sanofi. Sanofi has announced that SAR442168 will be evaluated in four Phase 3 clinical trials in participants with relapsing and progressive forms of multiple sclerosis. PRN473 Topical, a topical reversible covalent BTK inhibitor designed for immune-mediated diseases that could benefit from localized application to the skin, is being evaluated in Phase 1 trials. For more information, please visit www.principiabio.com.

#### **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 and Principia Forward-Looking Statements

This communication contains forward-looking statements. Forward-looking statements are statements that are not historical facts and may 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", "will be" and similar expressions. Although Sanofi's and Principia 's management each believes that the expectations reflected in such forwardlooking 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 and Principia, 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, risks related to Sanofi's and Principia's ability to complete the acquisition on the proposed terms or on the proposed timeline. including the receipt of required regulatory approvals, the possibility that competing offers will be made, other risks associated with executing business combination transactions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, timeconsuming or costly than expected or that the expected benefits of the acquisition will not be realized, risks related to future opportunities and plans for the combined company, including uncertainty of the expected financial performance and results of the combined company following completion of the proposed acquisition, disruption from the proposed acquisition making it more difficult to conduct business as usual or to maintain relationships with customers, employees, manufacturers, suppliers or patient groups, and the possibility that, if the combined company does not achieve the perceived benefits of the proposed acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of Sanofi's shares could decline, as well as other risks related Sanofi's and Principia's respective businesses, including the ability to grow sales and revenues from existing products and to develop, commercialize or market new products, competition, including potential generic competition, the uncertainties inherent in research and development, including future clinical data and analysis, regulatory obligations and oversight by regulatory authorities, such as the FDA or the EMA, including decisions of such authorities regarding whether and when to approve any drug, device or biological application that may be filed for any product candidates as well as decisions regarding labelling and other matters that could affect the availability or commercial potential of any product candidates, the absence of a guarantee that any product candidates, if approved, will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and to complete related transactions and/or obtain regulatory clearances, risks associated with Sanofi's and Principia's 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 Sanofi and Principia and their respective customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on Sanofi's and Principia's employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact Sanofi and Principia. This situation is changing rapidly and additional impacts may arise of which Sanofi and Principia are not currently aware and may exacerbate other previously identified risks. While the list of factors presented here is representative, no list should be considered a statement of all potential risks, uncertainties or assumptions that could have a material adverse effect on companies' consolidated financial condition or results of operations. The foregoing factors should be read in conjunction with the risks and cautionary statements discussed or identified in the public filings with the U.S. Securities and Exchange Commission (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, and the current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K filed by Principia with the SEC. The forwardlooking statements speak only as of the date hereof and, other than as required by applicable law, Sanofi and Principia do not undertake any obligation to update or revise any forward-looking information or statements.

### **Additional Information for US shareholders**

The tender offer for the outstanding shares of Principia common stock referenced in this press release has not yet commenced. This press release is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell securities, nor is it a substitute for the tender offer materials that Sanofi and its acquisition subsidiary will file with the SEC, upon the commencement of the tender offer. At the time the tender offer is commenced, Sanofi and its acquisition subsidiary will file a tender offer statement on Schedule TO and thereafter Principia will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL OTHER **TENDER** OFFER DOCUMENTS) SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 WILL CONTAIN IMPORTANT INFORMATION. PRINCIPIASTOCKHOLDERS ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE (AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF PRINCIPIA SECURITIES SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SECURITIES. The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of Principia stock at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement will be made available for free at the SEC's website at www.sec.gov. Additional copies may be obtained for free by contacting Sanofi or Principia. Copies of the documents filed with the SEC by Principia will be available free of charge on Principia's internet website at https://ir.principiabio.com or by contacting Principia's Investor Relations Department at ir@principiabio.com. Copies of the documents filed with the SEC by Sanofi will be available free of charge on Sanofi's internet website at https://en.sanofi.com/investors or by contacting Sanofi's Investor Relations Department at ir@sanofi.com.

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Sanofi files annual and special reports and other information with the SEC and Principia files annual, quarterly and special reports and other information with the SEC. You may read and copy any reports or other information filed by Sanofi and Principia at the SEC public reference room at 100 F. Street, N.E., Washington D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Sanofi's and Principia's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at www.sec.gov