Sanofi and Innovent Biologics enter strategic collaboration to accelerate development of oncology medicines and expand presence in China

- Collaboration to accelerate the development and access of oncology medicines for cancer patients in China
- Clinical trial programs combining two of Sanofi’s prioritized oncology assets with sintilimab, the leading checkpoint inhibitor in China, to address some of the most prevalent solid tumors in China
- Sanofi to make an initial equity investment of €300 million in Innovent in addition to the strategic multi-product collaboration
- This strategic partnership demonstrates Sanofi and Innovent’s commitment to bringing high quality oncology medicines to patients in China

Paris, August 4, 2022. Sanofi and Innovent Biologics (HKEX: 1801.HK, “Innovent”) announced a collaboration to bring innovative medicines to patients in China with difficult-to-treat cancers. Innovent is a leading biopharmaceutical company with strong clinical development capabilities and a broad commercial footprint in China. Both companies are committed to accelerating the development and commercialization of two Sanofi key clinical stage oncology assets: Phase III SAR408701 (tusamitamab ravtansine; anti-CEACAM5 antibody-drug conjugate) and Phase II SAR444245 (non-alpha IL-2), combining with sintilimab, the leading checkpoint inhibitor in China.

In addition to the collaboration and license agreement, Sanofi will invest €300 million in Innovent through subscription of new common shares.

John Reed, M.D., Ph.D.
Global Head of Research and Development at Sanofi
“This strategic collaboration with Innovent will not only accelerate the development, market access and future commercialization of two of our key oncology medicines in selected combinations with sintilimab, but also bolster our overall presence in oncology in China. We look forward to a successful partnership with Innovent, one of the most innovative companies in China, and to leveraging their development capabilities and market leadership in the country.”

Michael Yu, Ph.D.
Founder, Chairman and CEO of Innovent
“This strategic collaboration with Sanofi, a leading global pharmaceutical company, opens the pathway to great synergy for accelerating the pace of innovation. This pioneering partnership will leverage the synergy between Sanofi and Innovent’s pipeline and R&D resources with the mutual aim to address major unmet medical needs for cancer patients. We hope this agreement will be a great start of the two parties’ long-term partnership, and we look forward to bringing more innovative therapies to patients.”
Clinical development and commercialization of tusamitamab ravtansine

SAR408701 (tusamitamab ravtansine) is a potential first-in-class antibody-drug conjugate (ADC) targeting CEACAM5 (carcinoembryonic antigen-related cell adhesion molecule 5), a cell-surface glycoprotein that is highly expressed in non-small cell lung cancer (NSCLC), gastric cancer and other cancers. SAR408701 is currently in a Phase 3 study for 2L NSCLC globally including China, and global Phase 2 studies in additional indications including 1L NSCLC, gastric cancers and other solid tumors.

According to the agreement, Innovent will be responsible for developing and exclusively commercializing tusamitamab in multiple oncology-based indications in China. Sanofi will be entitled to receive up to €80 million development milestone payment and royalties on the net sales of the product in China upon approval.

Clinical development and commercialization of SAR444245

SAR444245 is a potential first-in-class reprogrammed, site-directed, single PEGylated, recombinant human IL-2 (rIL-2) variant with extended half-life that specifically binds to the low-affinity IL-2 receptor but lacks binding affinity for the alpha chain of the high-affinity IL-2 receptor. SAR444245(IL-2) is currently under global Phase 2 studies for skin cancers, gastrointestinal cancer, NSCLC / mesothelioma, head and neck tumors, and lymphoma.

Innovent and Sanofi will jointly explore the development of SAR444245 in China in various cancer types, where Innovent will lead the clinical development. Sanofi remains the sole Marketing Authorization holder for both assets and will be fully responsible for SAR245 commercialization. Innovent will be entitled to receive up to €60 million development milestone payments and royalties on the net sales of the product in China upon approval.

Sanofi’s initial strategic equity investment in Innovent for €300 million

In addition to the strategic multi-product collaboration and license agreement, Sanofi, subject to conditions precedent including regulatory approval and customary closing conditions, will invest in new common shares issued by Innovent for €300 million, at a price of HK $42.42 per share, representing a 20% premium to the Innovent 30-trading-day average share price as of August 3, 2022, one day prior to the signing of the agreements.

Subject to mutual agreement of both parties in the future, Sanofi will have the right to acquire additional Innovent new common shares for €300 million, at a subscription price that represents 20% premium to Innovent 30-trading-day average share price as the date of the separate agreement that may be entered into by both parties.

About SAR408701

SAR408701 (tusamitamab ravtansine) is a potential first-in-class antibody-drug conjugate (ADC) targeting CEACAM5 (carcinoembryonic antigen-related cell adhesion molecule 5), a cell-surface glycoprotein that is highly expressed in non-small cell lung cancer (NSCLC), gastric cancer and other cancers. Tusamitamab ravtansine is currently in a Phase 3 study for second-line NSCLC globally including China, and global Phase 2 studies in additional indications including first-line NSCLC, gastric cancers and other solid tumors.
About SAR444245
SAR444245 is a potential first-in-class recombinant human IL-2 (rIL-2) variant that includes a site-directed single PEG moiety/chain that prevents it from binding to the α chain of the IL-2 receptor while retaining near-native affinity for the beta/gamma subunits. SAR444245 is currently being investigated in global Phase 2 studies for the treatment of skin cancers, gastrointestinal cancer, NSCLC / mesothelioma, head and neck tumors, and lymphoma.

About Sintilimab (TYVYT®)
Sintilimab, marketed as TYVYT® (sintilimab injection) in China, is a PD-1 immunoglobulin G4 monoclonal antibody jointly developed by Innovent and Eli Lilly and Company. Innovent is currently conducting more than 20 clinical studies of sintilimab to evaluate its safety and efficacy in a wide variety of cancer indications, including more than 10 registrational or pivotal clinical trials. In China, sintilimab has been approved for six indications including relapsed or refractory classic Hodgkin’s lymphoma, first-line treatment of non-squamous NSCLC, first-line treatment of squamous NSCLC, first-line treatment of hepatocellular carcinoma, first-line treatment of esophageal squamous cell carcinoma, and first-line treatment of gastric or gastroesophageal junction adenocarcinoma, of which the first four indications have been included in the National Reimbursement Drug List (NRDL).

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 some 100 countries, 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

Note:
SAR408701 and SAR444245 are not approved products in China

About Innovent
Inspired by the spirit of “Start with Integrity, Succeed through Action,” Innovent’s mission is to develop, manufacture and commercialize high-quality biopharmaceutical products that are affordable to ordinary people. Established in 2011, Innovent has developed a fully integrated multi-functional platform which includes R&D, CMC (Chemistry, Manufacturing, and Controls), clinical development and commercialization capabilities. Leveraging the platform, the company has built a robust pipeline of 34 valuable assets in the fields of cancer, autoimmune, metabolic, ophthalmology and other major therapeutic areas. On October 31, 2018, Innovent was listed on the Main Board of the Stock Exchange of Hong Kong Limited with the stock code: 01801.HK.

For more information, please visit: www.innoventbio.com. and www.linkedin.com/company/innovent-biologics/.

Sanofi
Media Relations
Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com
Kate Conway | + 1 508 364 4931 | kate.conway@sanofi.com
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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

This news release may contain certain forward-looking statements that are, by their nature, subject to significant risks and uncertainties. The words “anticipate”, “believe”, “estimate”, “expect”, “intend” and similar expressions, as they relate to Innoven Biologics, Inc. ("Innovent" or "Company") , are intended to identify certain of such forward-looking statements. The Company does not intend to update these forward-looking statements regularly. These forward-looking statements are based on the existing beliefs, assumptions, expectations, estimates, projections and understandings of the management of the Company with respect to future events at the time these statements are made. These statements are not a guarantee of future developments and are subject to risks, uncertainties and other factors, some of which are beyond the Company’s control and are difficult to predict. Consequently, actual results may differ materially from information contained in the forward-looking statements as a result of future changes or developments in our business, the Company’s competitive environment and political, economic, legal and social conditions.

The Company, the Directors and the employees of the Company assume (a) no obligation to correct or update the forward-looking statements contained in this site; and (b) no liability in the event that any of the forward-looking statements does not materialise or turn out to be incorrect.