Sanofi announces agreement for potential first-in-class vaccine against extraintestinal pathogenic E. coli

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- Extraintestinal pathogenic E. coli (ExPEC) is a leading bacterial cause of sepsis, causing approximately 10 million cases of invasive ExPEC disease (IED) annually, worldwide1,2

- Phase 3 clinical trial of vaccine candidate ongoing. Novel ExPEC vaccine expected to complement existing older adult vaccine portfolio

Paris, October 3, 2023. Sanofi announces today that it has entered into an agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company, to develop and commercialize the vaccine candidate for extraintestinal pathogenic E. coli (9-valent) developed by Janssen, currently in Phase 3. The agreement brings together Janssen's robust science behind this potential first-in-class product and Sanofi's worldwide manufacturing footprint and recognized world-class expertise in launching innovative vaccines.

Executive Vice President, Vaccines, Sanofi

> E. coli is a significant cause of sepsis, mortality, and antimicrobial resistance in older adults, and the number of cases is rising as the population ages. In line with our commitment to design and deliver first- or best-in-class medicines and vaccines, this agreement with Janssen aims to positively impact public health by reducing hospitalization costs and the burden on health systems associated with ExPEC and help older adults around the world to live longer, healthier lives.

Under the terms of the agreement, both parties will co-fund current and future research and development costs. Sanofi will pay USD 175M upfront to Janssen, followed by development and commercial milestones. There will be a profit-share arrangement in the U.S., EU4 (France, Germany, Italy, Spain), and the UK. In the rest of the world (ROW), Janssen will receive tiered royalties and sales milestones. Closing is subject to customary regulatory clearance.

Extraintestinal pathogenic E. coli is a leading cause of sepsis, particularly in older adults3. Sepsis is a life-threatening bloodstream infection accompanied by severe illness and widespread organ damage, generated by the body's self-destructive response to the infection. The main risk factors include age, especially 60+, and chronic illnesses (e.g., diabetes, cancer, or kidney disease). Antimicrobial resistant (AMR) E. coli strains are an ongoing healthcare concern, with extraintestinal pathogenic E. coli a major driver behind the global AMR crisis4.

The ongoing Phase 3 E.mbrace trial is designed to evaluate the efficacy of the 9-valent extraintestinal pathogenic E. coli vaccine (ExPEC9V) compared to placebo in the prevention of invasive E. coli disease (IED) caused by ExPEC9V O-serotypes. The study was started in 2021 by Janssen and continues to enroll patients.

Learn more: https://classic.clinicaltrials.gov/ct2/show/NCT04899336

1 Russo TA and Johnson JR. Medical and economic impact of extraintestinal infections due to Escherichia coli: focus on an increasingly important endemic problem. Microbes Infect. 2003;5:449–456.

2 Rudd KE, Johnson SC, Agesa KM, et al. Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet. 2020;395(10219):200-211. doi:10.1016/S0140-6736(19)32989-7

3 Rhee C, et al. Prevalence of Antibiotic-Resistant Pathogens in Culture-Proven Sepsis and Outcomes Associated with Inadequate and Broad-Spectrum Empiric Antibiotic Use. JAMA Netw Open. 2020;3(4): e202899.

4 O'Neill J. Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. Review on Antimicrobial Resistance. Available at: https://amr-review.org/sites/default/files/AMR%20Review%20Pa

per%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf. Last accessed: October 2022.

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

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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 pandemics or other global crises may 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. 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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