Press Release

Update on extraintestinal pathogenic E. coli vaccine phase 3 clinical study

- Independent interim analysis of the E.mbrace phase 3 study finds that the vaccine candidate didn't demonstrate sufficient efficacy in preventing invasive *E. coli* disease
- No safety signals related to the vaccine candidate were identified

Paris, February 13, 2025. A scheduled review of the E.mbrace phase 3 study (clinical trial identifier: NCT04899336) conducted by an independent data monitoring committee (IDMC) determined that Sanofi and Johnson & Johnson's vaccine candidate for extraintestinal pathogenic *E. coli* was not sufficiently effective at preventing invasive *E. coli* disease (IED) compared to placebo. No safety signals related to the vaccine candidate were identified and, throughout the study, investigators ensured that participants who developed IED received prompt treatment and care. As a result of the IDMC's determination, the E.mbrace study is being discontinued.

> ***Jean-François Toussaint***
> Global Head of Research and Development Vaccines, Sanofi
> *"E. coli sepsis is a devastating disease and there are no preventative measures available to date. Driven by our ambition to transform the practice of medicine, we entered this ambitious although challenging field. We are disappointed to see that the vaccine was not associated with sufficient efficacy to support the trial continuation, and we will work tirelessly to understand the factors behind the IDMC's finding and to share further analysis once available. We are grateful to the participants, families and healthcare professionals involved in this development program. While disappointed by this outcome, we remain steadfast in our commitment to drive innovation in R&D by developing first and best-in-class vaccines in areas of high unmet need."*

In October 2023, Sanofi entered into an agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company to develop and commercialize the vaccine candidate. Under the terms of the agreement, both parties agreed to co-fund current and future research and development costs. Sanofi paid $250 million in upfront and development milestones to be followed by commercial milestones.

The E.mbrace study is a randomized, double-blind, placebo-controlled, multicenter, interventional phase 3 study evaluating the efficacy, safety, and immunogenicity of a single dose of the vaccine candidate compared to a placebo in the prevention of IED, which includes sepsis and bacteremia (blood infections).

The study was initiated in June 2021 enrolling adults aged 60 years or older in stable health with a history of urinary tract infection in the past two years. The study was conducted at over 250 sites across five continents. Janssen Research & Development, LLC, is the trial sponsor and responsible party and will continue appropriate safety follow up for the currently enrolled participants.

Financial considerations

As a result of the discontinuation, Sanofi has recorded an impairment charge before tax of $250 million in the Q4 2024 IFRS results. This adjustment impacts negatively the full-year

IFRS EPS reported in the Q4 2024 results press release on January 30, 2025, by €0.15 from €4.59 previously to €4.44 now. This adjustment will be included in Sanofi's Form 20-F for 2024 to be filed with the US Securities and Exchange Commission. However, there is no impact to the business net income / business EPS remaining unchanged respectively at €8,912 million / €7.12 (non-IFRS). There is no change to the financial guidance for 2025.

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 the world, 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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