



Media Statement

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Janssen Enters into Agreement with Sanofi to Advance Potential First-In-Class Vaccine Program

Vaccine candidate is being evaluated in Phase 3 study for the prevention of invasive E. coli disease (IED) which affects nearly 10 million adults annually¹

TITUSVILLE, N.J., October 3, 2023 – Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson Company, today announced a development and commercialization agreement with Sanofi for Janssen’s extraintestinal pathogenic *Escherichia coli* (ExPEC) investigational vaccine program. The lead vaccine candidate is currently being evaluated in the [Phase 3 E.mbrace study](#) for the prevention of invasive *E. coli* disease (IED) in adults aged 60 years and older.

IED occurs when bacteria that normally reside in the intestines leave the intestinal tract and infect other parts of the body. This can result in a range of infections that can be serious and life-threatening for adults over 60, including bacteremia (blood infections) and sepsis. ExPEC is a leading bacterial cause of sepsis.²

“We’re committed to addressing the unmet need for a vaccine to protect against IED, which affects nearly 10 million adults each year, has only limited therapeutic options available and can cause life-threatening infections,” said Penny Heaton, M.D., Global Therapeutic Area Head, Infectious Diseases & Vaccines, Janssen Research & Development, LLC. “This agreement will enable us to accelerate the development and potential commercialization of this important preventive option.”

The strategic agreement, which is subject to certain customary closing conditions, combines the research and development strength of Janssen with the global commercial vaccine expertise of Sanofi to advance the ExPEC vaccine development program. Under the terms of the agreement, both parties will co-fund current and future research and development costs. Sanofi will pay USD \$175 million 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. Payments are subject to customary clearances.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we are creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at [@JNJInnovMed](https://twitter.com/JNJInnovMed) and [@JanssenUS](https://twitter.com/JanssenUS). Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and efforts to develop a vaccine for the prevention of invasive Escherichia coli disease. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research and Development, LLC, Janssen Pharmaceuticals, Inc., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research and Development, LLC, Janssen Pharmaceuticals, Inc., nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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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 and Infection*. 2003 April;5(5):449–456. <https://www.sciencedirect.com/science/article/pii/S1286457903000492> Last accessed September 2023.

***NOTE:** The statistics around infections and deaths caused by ExPEC are based on figures in the U.S. which have been multiplied by a factor of 22, extrapolating the U.S. figure to a global population figure.

² Murray, CJL, et al. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *The Lancet*. 2022 February;399(10325): 629-655. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0). Last accessed September 2023.

