Sanofi and Teva announce exclusive collaboration to deliver inflammatory bowel disease treatment

PUBLISHED OCT 3, 2023
BY SANOFI

Sanofi and Teva announce exclusive collaboration to deliver inflammatory bowel disease treatment

- TEV’574, a novel anti-TL1A therapy, is being developed to treat ulcerative colitis and Crohn’s disease

- Collaboration supports Sanofi’s immunology strategy of exploring novel mechanisms of action for chronic inflammatory diseases

- Collaboration leverages the innovative R&D and commercial expertise of both companies

Paris, France and Parsippany, New Jersey, October 4, 2023. Sanofi (EURONEXT: SAN and NASDAQ: SNY) and Teva Pharmaceuticals, a U.S. subsidiary of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) announce today a collaboration to co-develop and co-commercialize asset TEV’574, currently in Phase 2b clinical trials for the treatment of Ulcerative Colitis and Crohn's Disease, two types of inflammatory bowel disease.

Chief Executive Officer, Sanofi

> Anti-TL1As are a promising class of therapies, and we believe that TEV’574 could emerge as a best-in-class option for people living with serious gastrointestinal diseases. This collaboration strengthens our commitment to advancing innovative treatment options for inflammatory conditions with a high unmet need and bolsters our goal to be an industry leader in immunology.

President and Chief Executive Officer, Teva

> This is a new era for Teva, and our robust, innovative pipeline is key to our Pivot to Growth strategy. This collaboration further validates the great science that Teva has to offer with our internally developed anti-TL1A. We are honored to partner with Sanofi to bring their proven capabilities, leadership, and success in the immunology and gastroenterology space together with our capabilities to optimize development and global launches.

Under the terms of the new collaboration agreement, Teva will receive an upfront payment of €469 million ($500 million) and up to €940 million ($1 billion) in development and launch milestones. Each company will equally share the development costs globally and net profits and losses in major markets, with other markets subject to a royalty arrangement and Sanofi will lead the development of the Phase 3 program. Teva will lead commercialization of the product in Europe, Israel and specified other countries, and Sanofi will lead commercialization in North America, Japan, other parts of Asia and the rest of the world. The transaction will become effective after customary closing conditions are met. Initial program results are expected to be available in 2024.

Inflammatory bowel disease (IBD) is the term for two conditions -- Crohn's disease and ulcerative colitis – characterized by chronic inflammation of the gastrointestinal (GI) tract. Prolonged inflammation results in damage to the GI tract. The common symptoms for both conditions are persistent diarrhea, rectal bleeding, abdominal pain, fatigue, and weight loss. An estimated ~10 million people worldwide live with IBD.

Teva will hold an investor call and live webcast today (Wednesday, October 4, 2023) at 8:00 a.m. ET to discuss this collaboration. To participate, please register in advance here to obtain a local or toll-free phone number and your personal pin. A live webcast of the call will be available on Teva's website at: https://ir.tevapharm.com/Events-and-Presentations.

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

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic and innovative medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of innovative and biopharmaceutical products. Learn more at www.tevapharm.com.

Sally Bain | + 1 617 834 6026 |sally.bain@sanofi.com

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com

Victor Rouault | + 33 6 70 93 71 40 |victor.rouault@sanofi.com

Eva Schaefer-Jansen | + 33 7 86 80 56 39 |eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 6 73 69 36 93 |arnaud.delepine@sanofi.com

Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com

Felix Lauscher | + 1 908 612 7239 |felix.lauscher@sanofi.com

Tarik Elgoutni| + 1 617 710 3587 |tarik.elgoutni@sanofi.com

Nathalie Pham | + 33 7 85 93 30 17 |nathalie.pham@sanofi.com

Yael Ashman | +972 (3) 914 8262

Sanjeev Sharma | (973) 524-1908

Kelley Dougherty | (973) 658-0237

Eden Klein | +972 (3) 906 2645

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

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.

Teva Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management’s current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as “should,” “expect,” “anticipate,” “estimate,” “target,” “may,” “project,” “guidance,” “intend,” “plan,” “believe” and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include: risks relating to our exclusive collaboration with Sanofi, including uncertainties around the effective date of the collaboration and our ability to satisfy the closing conditions related thereto; risks related to the timing of and our ability to achieve expected results for TEV-48574 (anti-TL1A), including our ability to commercialize TEV-48574 (anti-TL1A); the extent to which we will realize the anticipated financial and other benefits of the Sanofi collaboration; our ability to satisfy the conditions to receiving milestone cash payments under the Sanofi collaboration agreement; the risk that we will incur significant costs in connection with the development of TEV-48574 (anti-TL1A), which may exceed any revenue generated by TEV-48574 (anti-TL1A); risks that regulatory approvals and other requirements may delay the development and commercialization of TEV-48574 (anti-TL1A); our ability to successfully compete in the marketplace, including our ability to develop and commercialize biopharmaceutical products, competition for our innovative medicines, including AUSTEDO®, AJOVY® and

COPAXONE®, our ability to achieve expected results from investments in our product pipeline, our ability to develop and commercialize additional pharmaceutical products, and the effectiveness of our patents and other measures to protect our intellectual property rights; our ability to successfully launch and execute our new Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generics medicines; our substantial indebtedness which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us; our business and operations in general, including, the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto, and costs and delays resulting from the extensive pharmaceutical regulation to which we are subject; compliance, regulatory and litigation matters, including failure to comply with complex legal and regulatory environments; other financial and economic risks; and other factors discussed in our Quarterly Report on Form 10-Q for the second quarter of 2023 and in our Annual Report on Form 10-K for the year ended December 31, 2022, including in the section captioned “Risk Factors.” Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

Press release distributed by Wire Association on behalf of Sanofi, on Oct 3, 2023. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/sanofi/releases/en/sanofi-and-teva-announce-exclusive-collaboration-to-deliver-inflammatory-bowel-disease-treatment-1446

Sanofi

Newsroom: https://wireassociation.eu/newsroom/sanofi
Website: https://www.sanofi.com/
Primary Email: uk-mr@sanofi.com

Social Media

Twitter - https://twitter.com/sanofi
Youtube - https://www.youtube.com/user/sanofiaventisTVen
Linkedin - https://www.linkedin.com/company/sanofi
Instagram - https://www.instagram.com/sanofi/
