

# U.S. Commercialization Agreement with Quallent to Drive Patient Savings with First High-Concentration Citrate-Free Interchangeable Biosimilar to Humira® (adalimumab)

April 30, 2024

- Alvotech will manufacture its high-concentration interchangeable biosimilar to Humira® (adalimumab) for Quallent Pharmaceuticals
- The strategic agreement is in alignment with Alvotech's U.S. commercialization agreement with Teva Pharmaceuticals
- The high-concentration interchangeable biosimilar to Humira® manufactured by Alvotech will be distributed under Quallent's private-label

REYKJAVIK, Iceland and PARSIPPANY, N.J. and TEL AVIV, Israel, April 30, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), disclosed today that under the recently announced U.S. strategic partnership agreement, Alvotech will manufacture its high-concentration interchangeable biosimilar to Humira<sup>®</sup> (adalimumab) for Quallent Pharmaceuticals, in alignment with its U.S. commercialization agreement with Teva. The interchangeable biosimilar will be distributed under Quallent's private label.

"We are pleased to be working with Alvotech to bring adalimumab-ryvk to more patients. Our intent is to offer a copay assistance program, which will provide eligible patients access," said John Caufield, President of Quallent Pharmaceuticals Health, LLC. "Quallent was established to help pharmacies give their patients safe and affordable medication, and this collaboration will help us deliver on this goal."

"Being able to obtain interchangeable exclusivity for the high-concentration formulation which dominates the adalimumab market, has generated significant payor interest for this unique product in the U.S. market. With our commercial partners for the U.S., we aim to increase healthcare access and ensure that affordable high-quality biologics are available to patients in need," said Robert Wessman, Chairman and CEO of Alvotech.

"At Teva we continue to be focused on creating cost savings across the healthcare system and providing affordable options, like the high-concentration interchangeable adalimumab, for patients who need them," said Thomas Rainey, Senior Vice President, U.S. Market Access at Teva. "The strategic partnership between Teva and Alvotech has already yielded two approved critical biosimilars, from a portfolio of nine partnered products. Two partnered biosimilar candidates are coming out of clinical development this year."

The U.S. Food and Drug Administration (FDA) approved Alvotech's biosimilar on February 24, 2024, as a high-concentration interchangeable biosimilar to Humira, for the treatment of adult rheumatoid arthritis, juvenile idiopathic arthritis, adult psoriatic arthritis, adult ankylosing spondylitis, Crohn's disease, adult ulcerative colitis, adult plaque psoriasis, adult hidradenitis suppurativa and adult uveitis. This is the first high-concentration, citrate-free biosimilar to Humira<sup>®</sup> granted an interchangeability status by the FDA and Alvotech will have interchangeable exclusivity for the 40mg/0.4mL strength. Nearly 88 percent of U.S. prescriptions for adalimumab are for the high-concentration presentations [1].

In August 2020, Alvotech and Teva entered into a strategic partnership for the exclusive commercialization of five of Alvotech's biosimilar product candidates, and in August 2023 the partners extended the partnership to include two additional biosimilars and two new presentations of previously partnered products. Alvotech handles development and manufacturing, and Teva is responsible for U.S. commercialization, which leverages Teva's extensive experience and sales and marketing infrastructure. Alvotech's high concentration interchangeable biosimilar to Humira <sup>®</sup> (adalimumab) was the first biosimilar approved under the strategic partnership, and Teva expects to launch it to patients in the U.S. imminently.

## **Use of Trademarks**

 $\label{eq:humira} \textit{Humira}^{\circledR} \ \text{is a registered trademark of AbbVie Biotechnology Ltd.}$ 

#### Sources

[1] Based on sales data from Symphony

### **About Teva**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a global pharmaceutical leader with a category-defying portfolio, harnessing our generics expertise and stepping up innovation to continue the momentum behind the discovery, delivery, and expanded development of modern medicine. For over 120 years, Teva's commitment to bettering health has never wavered. Today, the company's global network of capabilities enables its ~37,000 employees across 58 markets to push the boundaries of scientific innovation and deliver quality medicines to help improve health outcomes of millions of patients every day. To learn more about how Teva is all in for better health, visit <a href="https://www.tevapharm.com">www.tevapharm.com</a>.

#### **About Alvotech**

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline includes eight disclosed biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation

(Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit <a href="www.alvotech.com">www.alvotech.com</a>. None of the information on the Alvotech website shall be deemed part of this press release.

## **Alvotech Forward Looking Statements**

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial operating performance of Alvotech and may include, for example, Alvotech's expectations regarding competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential", "aim" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (2) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech's estimates of expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (13) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (14) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (16) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (17) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, on the Company's business, financial position, strategy and anticipated milestones; and (18) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forwardlooking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. 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# **TEVA Cautionary Note Regarding 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 strategic partnership with Alvotech; our ability to successfully commercialize SIMLANDI in the U.S.; our ability to commercialize the additional biosimilar product candidates under the strategic partnership with Alvotech, once U.S. regulatory approval is obtained; our ability to successfully compete in the marketplace; our ability to develop and commercialize additional pharmaceutical products; our ability to successfully execute our 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; and other factors discussed in this press release, and in our Annual Report on Form 10-K for the year ended December 31, 2023, including in the sections 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 caut

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