



Alvotech and Teva Announce U.S. Approval of SIMLANDI® (adalimumab-ryvk) injection, the first interchangeable high-concentration, citrate-free biosimilar to Humira®

February 23, 2024

- SIMLANDI is the first citrate-free, high-concentration biosimilar to be designated interchangeable to Humira in the U.S.
- SIMLANDI is the first biosimilar approval under the strategic partnership between Alvotech and Teva in the U.S. market
- SIMLANDI will qualify for interchangeable exclusivity in the U.S. for some concentration strengths

REYKJAVIK, Iceland and PARSIPPANY, N.J., Feb. 24, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO) and Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), today announced that the U.S. Food and Drug Administration (FDA) has approved SIMLANDI (adalimumab-ryvk) injection, as an 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. In 2023, Humira was one of the highest-grossing pharmaceutical products in the world, with sales in the U.S. of nearly \$12.2 billion^[1]. Teva is Alvotech's strategic partner for the exclusive commercialization of SIMLANDI in the United States.

SIMLANDI is the first high-concentration, citrate-free biosimilar to Humira that has been granted an interchangeability status by the FDA, and will qualify for interchangeable exclusivity for the 40mg/0.4ml injection. While both low-concentration and high-concentration strength biosimilars of Humira are marketed in the U.S. today, nearly 88 percent of U.S. prescriptions for adalimumab are for the high-concentration presentation^[2].

An interchangeable biosimilar may be substituted at the pharmacy without consulting the prescriber, much like generic drugs are routinely substituted for brand name drugs. As the only interchangeable adalimumab biosimilar with the high-concentration formulation, SIMLANDI can be substituted for Humira at the pharmacy level, subject to state pharmacy laws.

"The approval of SIMLANDI marks the first high-concentration, citrate-free biosimilar to Humira with IC status," said Dr. Eric Hughes, Executive Vice President Global R&D and Chief Medical Officer at Teva. "Biosimilars create opportunities for cost savings across the healthcare system and introduce additional treatment options for patients. This approval marks an important milestone for Teva and Alvotech's partnership to collaborate on seven biosimilars and expand the availability, access, and uptake of biosimilars in the U.S."

Robert Wessman, Chairman and CEO of Alvotech, added, "This approval is an important milestone in Alvotech's journey to offer broader access worldwide to more affordable biologics, following approvals of our biosimilars in other global markets. We strongly believe that biosimilars are important in addressing inflationary pressures in the healthcare system across all markets, especially in the U.S. where biologics represent well over 40 percent of all pharmaceutical spending. An interchangeable citrate-free, high-concentration biosimilar adalimumab has the potential to change the market dynamics in a rapidly evolving environment for biosimilars in the U.S."

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. SIMLANDI is the first interchangeable, high-concentration, citrate-free biosimilar approved under the strategic partnership. Both Alvotech and Teva expect to launch SIMLANDI in the U.S. imminently with interchangeability designation.

The FDA approval of SIMLANDI was based on a totality of evidence, including analytical, non-clinical, and clinical data. The clinical development program, included data from (i) [AVT02-GL-101](#), a Phase I, multicenter, randomized, double blind, 3-arm study, to demonstrate pharmacokinetic (PK) similarity and compare safety and tolerability of SIMLANDI to Humira in healthy adult volunteers; (ii) [AVT02-GL-301](#), Phase III, multicenter, double-blind, randomized, parallel-group active control study to demonstrate similar efficacy, and compare safety and immunogenicity of AVT02 versus Humira in patients with moderate-to-severe chronic plaque psoriasis and (iii) [AVT02-GL-302](#), a Phase III, multicenter, randomized, double-blind, parallel-group study in moderate to severe chronic plaque psoriasis patients to demonstrate similar PK, and comparable efficacy, safety, and immunogenicity between patients receiving Humira and patients undergoing repeated switches between Humira and SIMLANDI.

Sources

[1] (AbbVie Full-Year and Fourth Quarter 2023 Financial Results): <https://investors.abbvie.com/static-files/831c0d3d-8813-4942-b7af-a3dade33bea5>

[2] Based on sales data from Symphony

Use of Trademarks

Humira® is a registered trademark of AbbVie Biotechnology Ltd.

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 www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

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 www.tevapharm.com.

INDICATIONS FOR SIMLANDI (adalimumab-ryvk) injection

SIMLANDI is a tumor necrosis factor (TNF) blocker indicated for:

- **Rheumatoid Arthritis (RA):** Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. SIMLANDI can be used alone or in combination with methotrexate or other nonbiologic disease-modifying anti-rheumatic drugs (DMARDs).
- **Juvenile Idiopathic Arthritis (JIA):** Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. SIMLANDI can be used alone or in combination with methotrexate.
- **Psoriatic Arthritis (PsA):** Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. SIMLANDI can be used alone or in combination with non-biologic DMARDs.
- **Ankylosing Spondylitis (AS):** Reducing signs and symptoms in adult patients with active AS.
- **Crohn's Disease (CD):** Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis (UC):** Treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis (Ps):** Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- **Hidradenitis Suppurativa (HS):** Treatment of moderate to severe hidradenitis suppurativa in adult patients (1.8)
- **Uveitis (UV):** Treatment of non-infectious intermediate, posterior, and panuveitis in adult patients (1.9)

IMPORTANT SAFETY INFORMATION FOR SIMLANDI (adalimumab-ryvk) injection

INDICATIONS

SIMLANDI[®] (adalimumab-ryvk) injection, is a tumor necrosis factor (TNF)-blocker indicated for:

- **Rheumatoid Arthritis (RA):** Alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs), for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA.
- **Juvenile Idiopathic Arthritis (JIA):** Alone or in combination with methotrexate for reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
- **Psoriatic Arthritis (PsA):** Alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- **Ankylosing Spondylitis (AS):** Reducing signs and symptoms in adult patients with active AS.
- **Crohn's Disease (CD):** Treatment of moderately to severely active CD in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis (UC):** Treatment of moderately to severely active UC in adult patients.

Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.

- **Plaque Psoriasis (Ps):** The treatment of adult patients with moderate to severe chronic Ps who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. SIMLANDI should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa (HS):** The treatment of moderate to severe HS in adult patients.
- **Uveitis:** The treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

SERIOUS INFECTIONS

Patients treated with adalimumab products, including SIMLANDI, are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue SIMLANDI if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB.** Patients with TB have frequently presented with pulmonary or extrapulmonary disease. Evaluate patients for tuberculosis risk factors and test for latent TB before initiating SIMLANDI and periodically during therapy. Initiate treatment for latent TB prior to SIMLANDI use.
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis.** Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with SIMLANDI prior to initiating therapy in patients: 1. with chronic or recurrent infection, 2. who have been exposed to TB, 3. with a history of opportunistic infection, 4. who resided in or traveled in regions where mycoses are endemic, 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with SIMLANDI, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start SIMLANDI during an active infection, including localized infections
- Patients 65 years of age and older, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants, may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of SIMLANDI with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of TNF blocker-treatment, including SIMLANDI, prior to initiating therapy in patients with known malignancy.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy for the presence of NMSC prior to and during treatment with SIMLANDI.
- In the adalimumab clinical trials there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at a higher risk than the general population for the development of lymphoma, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia have been reported in association with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases represented a variety of different malignancies and included rare malignancies associated with immunosuppression and malignancies that are not usually observed in children and adolescents.

Hypersensitivity Reactions

Anaphylaxis or serious allergic reactions have been reported following administration of adalimumab products. If an anaphylactic or other serious hypersensitivity reaction occurs, immediately discontinue administration of SIMLANDI and institute appropriate therapy.

Hepatitis B Virus Reactivation

- Use of TNF blockers, including SIMLANDI, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases with HBV reactivation occurring in conjunction with TNF blocker therapy have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in patients identified as carriers of HBV and closely monitor during and after SIMLANDI treatment.
- In patients who develop HBV reactivation, stop SIMLANDI and initiate effective anti-viral therapy. Exercise caution when resuming SIMLANDI after HBV treatment.

Neurologic Reactions

- Use of TNF blocking agents, including adalimumab products, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating disease, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering SIMLANDI for patients with these disorders; discontinuation of SIMLANDI should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

Hematological Reactions

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blocking agents. Medically significant cytopenia has been infrequently reported with adalimumab products.
- Advise patients to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor).
- Consider stopping SIMLANDI if significant hematologic abnormalities occur.

Heart Failure

Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Cases of worsening CHF have also been observed with adalimumab products; exercise caution when using SIMLANDI in patients who have heart failure and monitor them carefully.

Autoimmunity

Treatment with adalimumab products may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

Immunizations

- Patients on SIMLANDI should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations prior to initiating SIMLANDI therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the *in utero* exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to adalimumab products *in utero* is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

The most common adverse reactions (greater than or equal to 10%): are infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information for SIMLANDI, including BOXED WARNINGS.

Please click here for full Prescribing Information for SIMLANDI, including BOXED WARNINGS.

Scroll for the full Prescribing Information for SIMLANDI, including BOXED WARNINGS.

Please click here for full [Prescribing Information](#) for SIMLANDI, including BOXED WARNINGS and Medication Guide.

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 outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech; (2) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing standards; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech’s estimates of expenses and profitability; (7) Alvotech’s ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (8) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (9) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech’s partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) 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; (14) the success of Alvotech’s current and future collaborations, joint ventures, partnerships or licensing arrangements; (15) Alvotech’s ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (16) Alvotech’s ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech’s products and product candidates; (18) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, on the Company’s business, financial position, strategy and anticipated milestones; and (19) 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 forward-looking 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. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed. The recipient agrees that it shall not seek to sue or otherwise hold Alvotech or any of its directors, officers, employees, affiliates, agents, advisors, or representatives liable in any respect for the provision of this communication, the information contained in this communication, or the omission of any information from this communication.

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 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 business and operations in general, including: the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto; our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments; compliance, regulatory and litigation matters; other financial and economic risks; 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” and “Forward Looking Statements.” 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.

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