Teva and Alvotech Announce FDA Approval of Interchangeability for SELARSDI™ (ustekinumab-aekn) with Stelara® (ustekinumab)

May 5, 2025

- *The U.S. FDA has approved SELARSDI ™(ustekinumab-aekn) as interchangeable with the reference biologic Stelara® (ustekinumab) in all presentations matching the reference product, effective as of April 30, 2025*
- *SELARSDI is approved for all indications matching the reference product*
- *SELARSDI is indicated for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in adults and pediatric patients 6 years and older, and the treatment of adult patients with moderately to severely active Crohn's disease and ulcerative colitis*

PARSIPPANY, N.J. and REYKJAVIK, Iceland, May 05, 2025 (GLOBE NEWSWIRE) -- Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), and Alvotech (NASDAQ: ALVO) today announced that the U.S. Food and Drug Administration (FDA) has approved SELARSDI™ (ustekinumab-aekn) injection as interchangeable with the reference biologic Stelara® (ustekinumab). As of April 30, 2025, SELARSDI is available and interchangeable in all presentations matching the reference product, including the treatment of adults and pediatric psoriatic arthritis and plaque psoriasis, as well as Crohn's disease, and ulcerative colitis.

"The FDA's confirmation of full interchangeability for SELARSDI is an important development for patients and providers seeking to expand access to this important treatment," said Thomas Rainey, Senior Vice President, U.S. Biosimilars at Teva. "Teva's recent launch of two biosimilars – SELARSDI and EPYSQLI – coupled with a rich pipeline of assets expected to launch over the next few years, position Teva to establish a strong leadership position in the growing landscape of biosimilars and to drive growth for the company as it embarks on the next phase of its strategy."

"Interchangeability of SELARSDI with Stelara will further enable increased access for U.S. patients to more affordable treatment options and contribute to lowering healthcare costs, which is an important part of our mission as a leading developer and manufacturer of biosimilars globally," said Anil Okay, Chief Commercial Officer for Alvotech. "With two important biosimilars on the U.S. market and Biologics License Applications for three new biosimilar candidates under FDA review, Alvotech continues to rapidly expand its portfolio of high-quality biologics based on a fully integrated approach to development and manufacturing, coupled with a unique focus on biosimilars."

Approved presentations of SELARSDI are 45 mg/0.5 mL and 90 mg/mL in a single-dose prefilled syringe for subcutaneous injection, 45 mg/0.5 mL in a single-dose vial for subcutaneous injection and 130 mg/26 mL in a single-dose vial for intravenous infusion.

Ustekinumab is a human monoclonal antibody (mAb) that selectively targets the p40 protein, a component common to both interleukin (IL)-12 and IL-23 cytokines, which play crucial roles in treating immune-mediated diseases like psoriasis and psoriatic arthritis, and inflammatory diseases like Crohn's disease and ulcerative colitis[1]. Alvotech developed and produces SELARSDI using Sp2/0 cells and a continuous perfusion process, which are the same type of host cell line and process used in the production of Stelara®.

In August 2020, Teva and Alvotech entered into a strategic partnership for the exclusive commercialization of five Alvotech biosimilar product candidates, and in July 2023, the partnership was extended to include two additional biosimilars and new presentations of two previously partnered products. Alvotech manages development and manufacturing, while Teva is responsible for the exclusive commercialization in the U.S., leveraging its experience and extensive sales and marketing infrastructure.

Two biosimilars developed under the Teva - Alvotech partnership have been granted FDA approval with interchangeability, including SELARSDI. In February 2024, the FDA approved SIMLANDI® (adalimumab-ryvk), the first high-concentration, citrate-free interchangeable biosimilar to Humira® (adaliumumab), which was launched in the U.S. in May 2024.

Biologics License Applications (BLAs) for three additional biosimilar candidates developed by Alvotech in partnership with Teva have been accepted for review by the FDA: AVT05, a proposed biosimilar for Simponi® (golimumab) and Simponi Aria® (golimumab), and AVT06, a proposed biosimilar for Eylea® (aflibercept). Biosimilar User Fee Act (BsUFA) goal dates for approval for these BLAs are in Q4 2025.

About SELARSDI™ (ustekinumab-aekn)

SELARSDI is a monoclonal antibody and a biosimilar to Stelara® (ustekinumab). The biosimilar has been launched in Canada as JAMTEKI™, in Europe as UZPRUVO® and in Japan as USTEKINUMAB BS (F). It has been approved in the U.S. as SELARSDI. Applications are also under review in multiple countries globally.

About SIMLANDI™ (adalimumab-rvyk)

SIMLANDI is a monoclonal antibody and a biosimilar to Humira® (adalimumab). It has been approved as a biosimilar to Humira® in over 50 countries globally, including the U.S. It is currently marketed in the U.S. as SIMLANDI and under private label (adalimumab-ryvk), in Europe as HUKYNDRA, in Canada as SIMLANDI and in Australia as ADALICIP. Applications are also under review in multiple countries globally.

About AVT05

AVT05 is a biosimilar candidate for Simponi® and Simponi Aria® (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha). Elevated TNF alpha levels have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis [2]. AVT05 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

About AVT06

AVT06/AVT29 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept) 2 mg dose, which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [3]. AVT06/AVT29 are investigational products and have not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

Use of Trademarks

Stelara®, Simponi® and Simponi Aria® are registered trademarks of Johnson & Johnson. Humira® is a registered trademark of AbbVie Biotechnology Ltd. Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc. JAMTEKI™ is a trademark of JAMP Pharma Group. UZPRUVO® and HUKYNDRA® are registered trademarks of STADA and Alvotech. ADALICIP is a registered trademark of Cipla Australia.

SELARSDI INDICATIONS AND SAFETY INFORMATION

INDICATIONS

SELARSDI™ (ustekinumab-aekn) Injection, is a human interleukin-12 and -23 antagonist indicated for:

- the treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- the treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis.
- the treatment of adult patients with moderately to severely active Crohn's disease.
- the treatment of adult patients with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

SELARSDI™ (ustekinumab-aekn) injection is contraindicated in patients with clinically significant hypersensitivity to ustekinumab products or to any of the excipients in SELARSDI.

Infections

Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients receiving ustekinumab products. Serious infections requiring hospitalization or otherwise clinically significant infections were reported. In patients with plaque psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn's disease, these included anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and Listeria meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

Treatment with SELARSDI should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of SELARSDI in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with SELARSDI and discontinue SELARSDI for serious or clinically significant infections until the infection resolves or is adequately treated.

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), *Salmonella* (including nontyphi strains), and Bacillus Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with ustekinumab products may be susceptible to these types of infections. Consider diagnostic testing, e.g., tissue culture, stool culture, as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with SELARSDI. Do not administer SELARSDI to patients with active TB infection. Initiate treatment of latent TB before administering SELARSDI. Consider anti-tuberculosis therapy prior to initiation of SELARSDI in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving SELARSDI for signs and symptoms of active TB during and after treatment.

Malignancies

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among patients who received ustekinumab in clinical trials. The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been post-marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving ustekinumab products who had pre-existing risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving SELARSDI, especially those greater than 60 years of age or those with a history of Psoralen plus ultraviolet A (PUVA) or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab products. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue SELARSDI.

Posterior Reversible Encephalopathy Syndrome (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis, and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab product initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab products.

Monitor all patients treated with SELARSDI for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue SELARSDI.

Immunizations

Prior to initiating therapy with SELARSDI, patients should receive all age-appropriate immunizations as recommended by current immunization

guidelines. Patients being treated with SELARSDI should not receive live vaccines. Avoid administering BCG vaccines during treatment with SELARSDI or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving SELARSDI because of the potential risk for shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of SELARSDI may not elicit an immune response sufficient to prevent disease.

Concomitant Therapies
The safety of ustekinumab products, in combination with other biologic immunosuppressive agents or phototherapy has not been evaluated in clinical trials of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant methotrexate use did not appear to influence the safety or efficacy of ustekinumab.

Noninfectious Pneumonia
Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab products. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and, in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue SELARSDI and institute appropriate treatment.

Allergen Immunotherapy
Ustekinumab products have not been evaluated in patients who have undergone allergy immunotherapy. Ustekinumab products may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

Most Common Adverse Reactions
The most common adverse reactions for plaque psoriasis (greater than or equal to 3%) were nasopharyngitis, upper respiratory tract infection, headache, and fatigue. The safety profile in pediatric patients with plaque psoriasis was similar to that of adults with plaque psoriasis. The most common adverse reaction for Crohn's disease induction (greater than or equal to 3%) was vomiting. The most common adverse reactions for Crohn's disease maintenance (greater than or equal to 3%) were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis. The most common adverse reaction for ulcerative colitis induction (greater than or equal to 3%) was nasopharyngitis. The most common adverse reactions for ulcerative colitis maintenance (greater than or equal to 3%) were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

Please click here for full Prescribing Information for SELARSDI.

About Teva
Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a different kind of global biopharmaceutical leader, one that operates across the full spectrum of innovation to reliably deliver medicines to patients worldwide. 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 57 markets to advance health by developing medicines for the future while championing the production of generics and biologics. We are dedicated to addressing patients' needs, now and in the future. Moving forward together with science that treats, inspired by the people we serve. To learn more about how Teva is all in for better health, visit www.tevapharm.com.

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. Two biosimilars to Humira® (adalimumab) and Stelara® (ustekinumab) are already approved and marketed in multiple global markets. The current development pipeline includes nine 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), Dr. Reddy's (EEA, UK and US), Biogaran (FR), 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 https://www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

For more information, please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram and YouTube.

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) Alvotech's ability to obtain regulatory approval or authorizations of its products, including the timing or likelihood of

expansion into additional markets or geographies; (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 maintain regulatory approval or authorizations of its products; (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 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 SELARSDI (ustekinumab-aekn) in the U.S; 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, including 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 generic medicines; and other factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2024, including in the section 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.

Sources

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