RNS Number : 6545L
AstraZeneca PLC
16 December 2025

16 December 2025

Saphnelo approved in the EU for subcutaneous self-administration as a new pre-filled pen for systemic lupus erythematosus

Convenient subcutaneous option has potential to reach more patients with same clinical benefits as Saphnelo IV infusion

AstraZeneca's *Saphnelo* (anifrolumab) has been approved in the European Union (EU) for subcutaneous self-administration as a pre-filled pen for adult patients with systemic lupus erythematosus (SLE) on top of standard therapy.

The approval by the European Commission follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) and was based on the positive results from the Phase III TULIP-SC trial.[1] In the trial, subcutaneous (SC) administration of *Saphnelo* led to a statistically significant and clinically meaningful reduction in disease activity compared to placebo in participants with moderate to severe, active, autoantibody-positive SLE while receiving standard therapy.[1,2]

SLE is a debilitating autoimmune condition impacting over 3.4 million people globally.[3] It primarily affects women and can cause pain, rashes, fatigue, swelling in joints and fevers.[4-8] In Europe, people with SLE have a two to three times increased risk of death compared to the overall population.[9] While oral corticosteroids (OCS) are often used to provide relief from SLE symptoms, they are associated with adverse events and do not target the underlying drivers of the disease.[10-12]

Professor Thomas Dörner, Rheumatologist and Professor of Rheumatology and Hemostaseology at Charité University Hospital, Berlin, Germany and investigator of the TULIP-SC trial, said: "EU approval of anifrolumab in a self-administered pre-filled pen is fantastic news for people living with systemic lupus erythematosus as clinicians now have the potential to reach a wider group of patients with this important medicine, which has been shown to significantly reduce disease activity and the risk of organ damage. Lupus has historically been overlooked, but with treatment recommendations now aiming for disease remission with earlier use of biologics and less reliance on oral corticosteroids, we're beginning to see real momentum in delivering higher standards of care."

Jeanette Andersen, Chair of Lupus Europe, said: "Lupus is a devastating disease that primarily impacts young women and is associated with painful symptoms and a substantial impact on daily life. Anifrolumab has been a much-needed innovation in systemic lupus erythematosus and at home administration now offers patients a more flexible and convenient option."

Ruud Dobber, Executive Vice President, BioPharmaceuticals Business Unit, AstraZeneca, said: "We are committed to improving lupus care and since launch, *Saphnelo* IV infusion has transformed outcomes for tens of thousands of people living with systemic lupus erythematosus. With approximately 70% of SLE patients on biologics in Europe using a subcutaneous self-administration option, today's approval means we can now offer the clinically meaningful benefits of *Saphnelo* while expanding patient choice in how and where they receive treatment."

The safety profile of *Saphnelo* observed in the interim analysis of the TULIP-SC trial was consistent with the known clinical profile of the medicine administered as an intravenous (IV) infusion.[13-15] The TULIP-SC interim results were presented during the American College of Rheumatology (ACR) Convergence 2025 annual meeting and will be published in a forthcoming medical journal.

Subcutaneous administration of *Saphnelo* is under regulatory review in several other countries around the world including the US and Japan. *Saphnelo* IV infusion is approved for the treatment of moderate to severe SLE in more than 70 countries worldwide including the US, EU and Japan, with regulatory reviews ongoing in other countries. To date, more than 40,000 patients globally have been treated with *Saphnelo.*[16]

Notes

Financial considerations
AstraZeneca acquired global rights to *Saphnelo* through an exclusive license and collaboration agreement with Medarex, Inc. in 2004. The option for Medarex to co-promote the product expired on its acquisition by Bristol-Myers Squibb (BMS) in 2009. Under the agreement AstraZeneca will pay BMS a low to mid-teens royalty for sales dependent on geography.

Systemic lupus erythematosus
SLE is a chronic and complex autoimmune disease in which the immune system attacks healthy tissue in the body.[4] An estimated 50% of people with SLE have irreversible organ damage within five years of diagnosis due to long-term corticosteroid use and disease activity.[11,17] Even a small reduction in daily oral corticosteroid use (for example 1 mg/day) can lower the risk of organ damage.[18] Recent updates to clinical guidelines elevate the importance of treating to target remission or low disease activity and minimising the use of oral corticosteroids.[6,7]

TULIP-SC
TULIP-SC was a Phase III, multicentre, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of a subcutaneous administration of anifrolumab versus placebo in participants aged 18 to 70 years with moderate to severe, active, autoantibody-positive SLE while receiving standard therapy (oral corticosteroids, antimalarial, and/or immunosuppressants).[19]

The reduction of disease activity was measured using the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA) at week 52.[19] The BICLA requires improvement in all organs with disease activity at baseline with no new flares.[19]

baseline with no new flares.

Participants (367) were randomised 1:1 to receive 120mg subcutaneous dose of anifrolumab or placebo administered via a pre-filled, single-use syringe.[19] A planned interim analysis was conducted when the first 220 participants reached week 52.[19] The trial also included an open-label extension period of 52 weeks for participants who completed the 52-week treatment period.[19]

***Saphnelo* subcutaneous administration**
Saphnelo will be available for subcutaneous self-administration via a once-weekly 120mg pre-filled pen. Since 2021, *Saphnelo* has been available in an IV infusion administered by healthcare professionals in a hospital or clinic setting. Subcutaneous administration offers patients the choice to self-administer treatment outside of the clinic and or with support from an HCP or caregiver via a simple process.

Saphnelo
Saphnelo (anifrolumab) is a first-in-class, fully human monoclonal antibody that binds to subunit 1 of the type I interferon (IFN) receptor, blocking the activity of type I IFN.[15,20] Type I IFNs, such as IFN-alpha, IFN-beta and IFN-kappa, are cytokines involved in regulating the inflammatory pathways implicated in SLE.[21-26]

Saphnelo IV is the first biologic with remission data in SLE from a four-year placebo-controlled Phase III trial (TULIP-LTE) and was measured with the DORIS criteria for remission.[27,28] DORIS is measured as clinical SLEDAI-2K, or "Systemic Lupus Erythematosus Disease Activity Index 2000" score of 0, physician global assessment <0.5, prednisolone/ equivalent dose of OCS dose of ≤5 mg per day and stable maintenance doses of immunosuppressants, including biologics.[29]

Saphnelo continues to be evaluated in diseases where type I IFN plays a key role, including Phase III trials in cutaneous lupus erythematosus, myositis, systemic sclerosis and lupus nephritis.[30-33]

AstraZeneca in Respiratory & Immunology
Respiratory & Immunology, part of AstraZeneca BioPharmaceuticals, is a key disease area and growth driver to the Company.

AstraZeneca is an established leader in respiratory care with a 50-year heritage and a growing portfolio of medicines in immune-mediated diseases. The Company is committed to addressing the vast unmet needs of these chronic, often debilitating, diseases with a pipeline and portfolio of inhaled medicines, biologics and new modalities aimed at previously unreachable biologic targets. Our ambition is to deliver life-changing medicines that help eliminate COPD as a leading cause of death, eliminate asthma attacks and achieve clinical remission in immune-mediated diseases.

AstraZeneca
AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Social Media @AstraZeneca.

Contacts
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

References

1. AstraZeneca. Saphnelo self-administration TULIP-SC Phase III trial meets primary endpoint in patients with systemic lupus erythematosus based on an interim analysis. Available at: Saphnelo self-administration TULIP-SC Phase III trial meets primary endpoint in patients with systemic lupus erythematosus based on an interim analysis. [Last accessed: December 2025].
2. Furie R, et al. What does it mean to be a British Isles Lupus Assessment group-based composite lupus assessment responder? Post hoc analysis of two phase III trials. *Arthritis Rheumatol*. 2021;73:2059-2068.
3. Tian J, et al. Global epidemiology of systemic lupus erythematosus: a comprehensive systematic analysis and modelling study. *Ann Rheum Dis*. 2023;82(3):351-356.
4. Bruce IN, et al. Factors associated with damage accrual in patients with systemic lupus erythematosus: results from the systemic lupus international collaborating Clinics (SLICC) inception cohort. *Ann Rheum Dis*. 2015;74:1706-1713.
5. Guéry JC. Why is systemic lupus erythematosus more common in women? *Joint Bone Spine*. 2019;86(3):297-299.
6. American College of Rheumatology. 2025 American College of Rheumatology (ACR) guideline for the treatment of systemic lupus erythematosus (SLE). Available at: lupus-guideline-sle-2025.pdf. [Last accessed: December 2025].
7. Fanouriakis A, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis*. 2024;83:15-29.
8. Kaul A, et al. Systemic lupus erythematosus. *Nat Rev Dis Primers*. 2016;2:16039.
9. Barber MRW, et al. Global epidemiology of systemic lupus erythematosus. *Nat Rev Rheumatol*. 2021;17(9):515-532.
10. Apostolopoulos D and Morand EF. It hasn't gone away: the problem of glucocorticoid use in lupus remains. *Rheumatology (Oxford)*. 2017;56(Suppl 1):i114-22.
11. Ji L, et al. Low-dose glucocorticoids should be withdrawn or continued in systemic lupus erythematosus? A systematic review and meta-analysis on risk of flare and damage accrual. *Rheumatology*. 2021;60:5517-26.
12. Lateef A and Petri M. Unmet medical needs in systemic lupus erythematosus. *Arthritis Res Ther*. 2012;14(Suppl 4):S4.
13. Morand E, et al. Trial of anifrolumab in active systemic lupus erythematosus. *N Engl J Med*. 2020;382(3):211-221.
14. Furie R, et al. Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. *Lancet Rheumatol*. 2019;1(4):e208-e219.
15. Furie R, et al. Anifrolumab, an anti-interferon - α receptor monoclonal antibody, in moderate - to - severe systemic lupus erythematosus. *Arthritis Rheumatol*. 2017;69(2):376-386.
16. AstraZeneca data on file. 2025. REF-290598.
17. Murimi-Worstell IB, et al. Association between organ damage and mortality in systemic lupus erythematosus: a systematic review and meta-analysis. *BMJ Open*. 2020;10:e031850.
18. Katsumata Y et al. Risk of flare and damage accrual after tapering glucocorticoids in modified serologically active clinically quiescent patients with systemic lupus erythematosus: a multinational observational cohort study. *Ann Rheum Dis*. 2024;83:998-1005.
19. Clinicaltrials.gov Subcutaneous Anifrolumab in Adult Patients With Systemic Lupus Erythematosus (Tulip-SC). Available at: https://clinicaltrials.gov/study/NCT04877691. [Last accessed: December 2025].
20. Riggs JM, et al. Characterisation of anifrolumab, a fully human anti-interferon receptor antagonist antibody for the treatment of systemic lupus erythematosus. *Lupus Sci Med*. 2018;5(1):e000261.
21. Lauwerys BR, et al. Type I interferon blockade in systemic lupus erythematosus: where do we stand?

21. Lauwerys BR, et al. Type I interferon blockade in systemic lupus erythematosus: where do we stand? *Rheumatology*. 2014;53(8):1369-1376.
22. Sarkar MK, et al. Photosensitivity and type I IFN responses in cutaneous lupus are driven by epidermal-derived interferon kappa. *Ann Rheum Dis*. 2018;77(11):1653-1664.
23. Jefferies CA. Regulating IRFs in IFN driven disease. *Front Immunol*. 2019;10:325.
24. Mai L, et al. The baseline interferon signature predicts disease severity over the subsequent 5 years in systemic lupus erythematosus. *Arthritis Res Ther*. 2021;23(1):29.
25. López de Padilla CM, et al. The type I interferons: basic concepts and clinical relevance in immune-mediated inflammatory diseases. *Gene*. 2016;576(101):14-21.
26. Rönnblom L, et al. Interferon pathway in SLE: one key to unlocking the mystery of the disease. *Lupus Sci Med*. 2019;6(1):e000270.
27. Mosca M, et al. Attainment of LLDAS and DORIS remission during anifrolumab treatment: interim results from a multinational, observational, post-launch study of treatment effectiveness in the real world. *Ann Rheum Dis*. 2025. 84(1):168-169.
28. Morand EF, et al. LLDAS and remission attainment with anifrolumab treatment in patients with systemic lupus erythematosus: results from the TULIP and long-term extension randomised controlled trials. *Ann Rheum Dis*. 2025; 84(5): 777-778.
29. Vollenhoven R, et al. 2021 DORIS definition of remission in SLE: final recommendations from an international task force. *Lupus Science & Medicine*. 2021; 8: e000538. doi:10.1136/ lupus-2021-000538.
30. Clinicaltrials.gov. A 2-stage, Phase III Study to Investigate the Efficacy and Safety of Anifrolumab in Adults with Chronic and/ or Subacute Cutaneous Lupus Erythematosus (LAVENDER). Available at: https://clinicaltrials.gov/study/NCT06015737. [Last accessed: December 2025].
31. Clinicaltrials.gov. A Study to Investigate the Efficacy and Safety of Anifrolumab Administered as Subcutaneous Injection and Added to Standard of Care Compared with Placebo Added to Standard of Care in Adult Participants with Idiopathic Inflammatory Myopathies (Polymyositis and Dermatomyositis) (JASMINE). Available at: https://clinicaltrials.gov/study/NCT06455449. [Last accessed: December 2025].
32. Clinicaltrials.gov. Determine Effectiveness of Anifrolumab In SYstemic Sclerosis (DAISY). Available at: https://clinicaltrials.gov/study/NCT05925803. [Last accessed: December 2025].
33. ClinicalTrials.gov. Phase 3 Study of Anifrolumab in Adult Patients with Active Proliferative Lupus Nephritis (IRIS). Available at: https://www.clinicaltrials.gov/ct2/show/NCT05138133. [Last accessed: December 2025].

Matthew Bowden
Company Secretary
AstraZeneca PLC