27 April 2026

Saphnelo approved in the US for subcutaneous self-administration as a new autoinjector for the treatment of systemic lupus erythematosus

First-in-class Saphnelo Pen now offers greater flexibility and convenience, reaching a wider group of patients

AstraZeneca's *Saphnelo* (anifrolumab) has been approved in the US for self-administration as a once-weekly autoinjector, the *Saphnelo Pen,* for the treatment of adult patients with systemic lupus erythematosus (SLE) on top of standard therapy.

The approval by the US Food and Drug Administration (FDA) was based on results from the Phase III TULIP-SC trial, which showed that 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 SLE while receiving standard therapy.[1,2] Full results from the TULIP-SC trial were published in *Arthritis & Rheumatology* in January 2026.

The safety profile observed was consistent with the known clinical profile of *Saphnelo* administered as an intravenous (IV) infusion.[3-5]

Susan Manzi, MD, MPH, chair of the Allegheny Health Network (AHN) Medicine Institute, director of the Lupus Center of Excellence at the AHN Autoimmunity Institute and principal investigator of the TULIP-SC trial, said: "The approval of anifrolumab as a self-administered autoinjector is exciting news as it makes this important medicine more convenient and accessible for many more patients. With its proven ability to significantly reduce disease activity and the risk of organ damage, anifrolumab has been a much-needed innovation in lupus, which is a serious and often debilitating autoimmune condition impacting millions worldwide."

Louise Vetter, President and Chief Executive Officer, Lupus Foundation of America, said: "The FDA approval of a subcutaneous administration option for anifrolumab is an exciting milestone for the lupus community because it offers people with systemic lupus erythematosus more convenience and choice of where and how they want to receive treatment."

Ruud Dobber, Executive Vice President, BioPharmaceuticals Business Unit, AstraZeneca, said: "Since its launch, *Saphnelo* IV infusion has helped tens of thousands of people with systemic lupus erythematosus achieve lower disease activity with fewer steroids and has been shown to help many achieve remission. The approval of the *Saphnelo Pen* represents a significant step forward in expanding *Saphnelo's* clinical benefits to more people living with systemic lupus erythematosus."

SLE is amongst the leading causes of death in young women in the US and is more common amongst Asian, Black or Hispanic populations.[6,7] While oral corticosteroids 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.[8-10] Recent updates to clinical guidelines elevate the importance of treating to target remission or low disease activity and minimising the use of oral corticosteroids.[11,12]

Subcutaneous administration of *Saphnelo* is approved in the EU and Japan and under regulatory review in several other countries around the world. *Saphnelo* IV infusion is approved for the treatment of moderate to severe SLE in more than 70 countries worldwide, including the US and EU. To date, more than 40,000 patients globally have been treated with *Saphnelo*.[13] *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.[14,15]

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, updated in 2025, AstraZeneca will pay BMS a mid-teens royalty for sales in the US.

Notes

Systemic lupus erythematosus
SLE is an autoimmune disease in which the immune system attacks healthy tissue in the body.[16] It is a chronic and complex disease with a variety of clinical manifestations that can impact many organs and can cause a range of symptoms, including pain, rashes, fatigue, swelling in joints and fevers.[11,12,16,17]

Over 3.4 million people globally are affected by SLE.[18] Living with SLE can be painful, debilitating, have a profound impact on patients' mental and financial wellbeing.[17,19-23] 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.[9,23] Even a small reduction in daily steroid use (for example 1mg/day) can lower the risk of organ damage.[24]

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 SLE while receiving standard therapy (oral corticosteroids, antimalarial, and/or immunosuppressants).[25]

The primary endpoint was the reduction of disease activity measured using the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA) at week 52.[25] The BICLA requires improvement in all organs with disease activity at baseline with no new flares.[25]

In the TULIP-SC trial, *Saphnelo* demonstrated clinically meaningful effects across a range of outcome measures: reduction in SLE disease activity while tapering to low dose of OCS (≤7.5 mg/day), more patients achieving a BICLA response sooner, and numerically delayed time to first flare.[25,26] In pre-specified secondary and exploratory endpoints, 29.0% of patients taking *Saphnelo* achieved DORIS remission and 40.1% attained low-level disease activity, as measured by the Low-Level Disease Activity Score (LLDAS).[25,26]

Participants (367) were randomised 1:1 to receive 120mg subcutaneous dose of anifrolumab or placebo administered via a pre-filled, single-use syringe.[25] A planned interim analysis was conducted when the first 220 participants reached week 52 or withdrew from the study.[25] The trial also includes an open-label extension period of 52 weeks for participants who completed the 52-week treatment period.[25]

The *Saphnelo Pen*
Saphnelo will be available for subcutaneous self-administration via a once-weekly 120mg autoinjector (the *Saphnelo Pen*) or a pre-filled syringe.

Subcutaneous administration of *Saphnelo* was approved in the EU and Japan. Since 2021, *Saphnelo* has been available in an IV infusion administered by healthcare professionals in a hospital or clinic setting. The *Saphnelo Pen* offers patients the choice to self-administer treatment outside of the clinic 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.[5,27] Type I IFNs, such as IFN-alpha, IFN-beta and IFN-kappa, are cytokines involved in regulating the inflammatory pathways implicated in SLE.[28-33]

Saphnelo IV is the first biologic with remission data in SLE from a four-year placebo-controlled Phase III trial (TULIP-LTE) measured with the DORIS criteria for remission.[14,15] 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.[34]

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.[35-38]

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/NYSE: 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: April 2026].
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(11):2059-2068.
3. Morand E, et al. Trial of anifrolumab in active systemic lupus erythematosus. *N Engl J Med*. 2020;382(3):211-221.
4. 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.
5. 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.
6. The Rheumatologist. SLE Is a leading cause of death among women. Available at: https://www.the-rheumatologist.org/article/sle-is-a-leading-cause-of-death-among-women. [Last accessed: April 2026].
7. Izmirly PM, et al. Prevalence of Systemic Lupus Erythematosus in the United States: Estimates From a Meta-Analysis of the Centers for Disease Control and Prevention National Lupus Registries. *Arthritis Rheumatol*. 2021;73(6):991-996.
8. 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-i122.
9. 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(12):5517-5526.
10. Lateef A and Petri M. Unmet medical needs in systemic lupus erythematosus. *Arthritis Res Ther*. 2012;14(Suppl 4):S4.
11. 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: April 2026].
12. Fanouriakis A, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis*. 2024;83(1):15-29.
13. AstraZeneca data on file. 2025. REF-290598.
14. 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.

15. 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.
16. 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(9):1706-1713.
17. Kaul A, et al. Systemic lupus erythematosus. *Nat Rev Dis Primers*. 2016;2:16039.
18. 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.
19. Elefante E, et al. Impact of disease activity patterns on health-related quality of life (HRQoL) in patients with systemic lupus erythematosus (SLE). *Lupus Sci Med*. 2024;11:e001202.
20. Primavera D, et al. Quality of Life in Systemic Lupus Erythematosus and Other Chronic Diseases: Highlighting the Amplified Impact of Depressive Episodes. *Healthcare*. 2024;12:233. 25.
21. Liu X, et al. Mental health conditions in patients with systemic lupus erythematosus: a systematic review and meta-analysis. *Rheumatology (Oxford).* 2024;63:3234-3242.
22. Leung J, et al. "…Not Having the Real Support That We Need": Patients' Experiences With Ambiguity of Systemic Lupus Erythematosus and Erosion of Social Support. *ACR Open Rheumatol*. 2019;1:135-144.
23. Murimi-Worstell IB, et al.: Healthcare utilization and costs of systemic lupus erythematosus by disease sever- ity in the United States. *J Rheumatol* 2021; 48: 385-93.
24. 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(8):998-1005.
25. Clinicaltrials.gov. Subcutaneous Anifrolumab in Adult Patients With Systemic Lupus Erythematosus (Tulip SC). Available at: https://clinicaltrials.gov/study/NCT04877691. [Last accessed: April 2026].
26. Manzi S, et al. Efficacy and Safety of Subcutaneous Anifrolumab in Systemic Lupus Erythematosus: the Randomized, Phase 3, TULIP-SC Study. Arthritis Rheumatol. 2025. doi: 10.1002/art.70041.
27. 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.
28. Lauwerys BR, et al. Type I interferon blockade in systemic lupus erythematosus: where do we stand? *Rheumatology*. 2014;53(8):1369-1376.
29. 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.
30. Jefferies CA. Regulating IRFs in IFN driven disease. *Front Immunol*. 2019;10:325.
31. Mai L, et al. The baseline interferon signature predicts disease severity over the subsequent years in systemic lupus erythematosus. *Arthritis Res Ther*. 2021;23(1):29.
32. 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.
33. Rönnblom L, et al. Interferon pathway in SLE: one key to unlocking the mystery of the disease. *Lupus Sci Med*. 2019;6(1):e000270.
34. 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.
35. 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: April 2026].
36. 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: April 2026].
37. Clinicaltrials.gov. Determine Effectiveness of Anifrolumab in Systemic Sclerosis (DAISY). Available at: https://clinicaltrials.gov/study/NCT05925803. [Last accessed: April 2026].
38. 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: April 2026].

Matthew Bowden

Company Secretary
AstraZeneca PLC