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## **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.<sup>1,2</sup> 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.<sup>3-5</sup>

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.<sup>6,7</sup> 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.<sup>8-10</sup> Recent updates to clinical guidelines elevate the importance of treating to target remission or low disease activity and minimising the use of oral corticosteroids.<sup>11,12</sup>

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*.<sup>13</sup> *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.<sup>14,15</sup>

### **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.<sup>16</sup> 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.<sup>11,12,16,17</sup>

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

#### **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).<sup>25</sup>

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.<sup>25</sup> The BICLA requires improvement in all organs with disease activity at baseline with no new flares.<sup>25</sup>

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 ( $\leq 7.5$  mg/day), more patients achieving a BICLA response sooner, and numerically delayed time to first flare.<sup>25,26</sup> 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).<sup>25,26</sup>

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

#### **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.<sup>5,27</sup> Type I IFNs, such as IFN-alpha, IFN-beta and IFN-kappa, are cytokines involved in regulating the inflammatory pathways implicated in SLE.<sup>28-33</sup>

*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.<sup>14,15</sup> 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  $\leq 5$  mg per day and stable maintenance doses of immunosuppressants, including biologics.<sup>34</sup>

*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.<sup>35-38</sup>

#### **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](#)**

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