# Treat-to-Target Roadmap in SLE: Anifrolumab Subcutaneous Data

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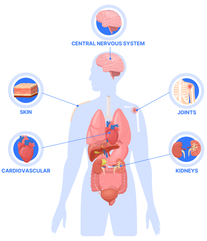
## Treatment Targets in Systemic Lupus Erythematosus

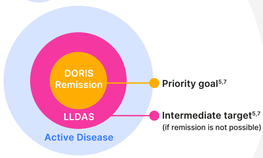
### Type I IFN activity impacts multiple organ systems in SLE.[1-3]




### ACR Guidelines and EULAR Recommendations are aligned on key treatment recommendations:[4,5]


### DORIS Remission is a clinically important goal in SLE associated with:[5,6]

- Organ damage accrual
- Hospitalizations
- Flares
- Health-related quality of life




### How is DORIS defined?[6]

**✓ No clinical disease activity**
- Clinical SLEDAI-2K=0
- PGA <0.5

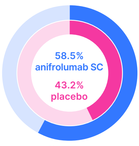
**✓ Minimal GC use**
- Prednisone or equivalent dose ≤5 mg/day

## TULIP-SC Study: Key Evidence Milestones

### SC administration route for anifrolumab[8]

- Anifrolumab SC received FDA approval in SLE based on the TULIP-SC study.[8,9]
- This Phase III RCT compared once-weekly anifrolumab SC (120 mg) (n=184) to placebo (n=183) (+ standard therapy) over 52 weeks in patients with moderate-to-severe SLE.[9]

**Figure 1: BICLA response at Week 52 interim analysis (n=220).[8]**

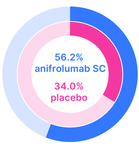



Difference: 15.3% [p=0.0231]

### Milestone 1

**Primary endpoint met (Figure 1):***

*Results consistent with Week 52 full analysis (n=367).[9]




### Milestone 2

**Disease activity and steroid burden[9]**

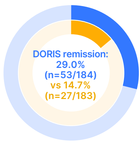
More patients attained a BICLA response while maintaining low or reduced oral GC use in week 40 to week 52 with anifrolumab SC (**56.2%**; n=103/184) versus placebo (**34.0%**; n=62/183), p<0.0001.[9]

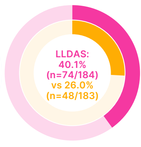
Percentages reflect the prespecified adjusted analysis (e.g., stratified CMH and, where applicable, multiple imputation) and are rounded for display; therefore, reported percentages may not equal simple n/N.

## TULIP-SC: Treat-to-Target Outcomes

### Milestone 3
### Focus on DORIS remission and LLDAS‡[,9]

Week 52 target attainment was evaluated in patients receiving anifrolumab and in those receiving placebo:[1,9]




‡Results are descriptive only.

### Safety snapshot[8,9]

The safety profile observed for anifrolumab administered SC was consistent with the known safety profile of anifrolumab administered IV.

| | Anifrolumab SC (n=185) | Placebo (n=182) |
|---|---|---|
| Serious AEs | 11.9% | 10.4% |
| AEs leading to discontinuation | 7.6% | 4.4% |
| Herpes zoster | 3.8% | 1.1% |
| Injection-site reactions | 15.7% | 15.4% |

The most common AEs (≥5%) were nasopharyngitis, URTI, COVID-19, bronchitis, UTI, and diarrhea.

Percentages reflect the prespecified adjusted analysis (e.g., stratified CMH and, where applicable, multiple imputation) and are rounded for display; therefore, reported percentages may not equal simple n/N.

## Clinical Practice Context

### Anifrolumab SC delivered improvement across key SLE treatment goals in the TULIP-SC study compared to standard therapy:[9]

- Significant reduction in overall disease activity.
- BICLA response alongside sustained low or reduced oral glucocorticoid use.

**In TULIP-SC, the efficacy and safety profile of anifrolumab SC proved consistent with IV anifrolumab.[9-11]**

**Anifrolumab SC once-weekly offers an additional treatment option for patients with SLE and their treating physicians.[9]**

### INDICATION

SAPHNELO® (anifrolumab-fnia) is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

**Limitations of Use:** The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use is not recommended in these situations.

### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATION**

Known history of anaphylaxis with SAPHNELO.

**WARNINGS AND PRECAUTIONS**

- **Serious Infections:** Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including SAPHNELO. SAPHNELO increases the risk of respiratory infections and herpes zoster. Use caution in patients with severe or chronic infections. Avoid initiating treatment during an active infection and consider interrupting therapy in patients who develop a new infection during treatment
- **Hypersensitivity Reaction Including Anaphylaxis:** Serious hypersensitivity reactions (including anaphylaxis) have been reported following SAPHNELO administration. Events of angioedema have also been reported. Other hypersensitivity reactions and infusion-related reactions have occurred following administration of SAPHNELO. SAPHNELO should be administered by healthcare providers prepared to manage hypersensitivity reactions, including anaphylaxis and infusion-related reactions, if they occur. Immediately interrupt administration and initiate appropriate therapy if a serious infusion-related or hypersensitivity reaction (eg, anaphylaxis) occurs
- **Malignancy:** There is an increased risk of malignancies with the use of immunosuppressants. The impact of SAPHNELO on the potential development of malignancies is not known
- **Immunization:** Avoid the use of live or live-attenuated vaccines in patients treated with SAPHNELO
- **Use With Biologic Therapies:** SAPHNELO is not recommended for use in combination with other biologic therapies, including B-cell targeted therapies

**ADVERSE REACTIONS**

The most common adverse reactions (incidence ≥5%) are nasopharyngitis, upper respiratory tract infections, bronchitis, infusion-related reactions, herpes zoster and cough.

In the controlled clinical trials, the incidence of infusion-related reactions was 9.4% in patients while on treatment with SAPHNELO and 7.1% in patients on placebo. Infusion-related reactions were mild to moderate in intensity; the most common symptoms were headache, nausea, vomiting, fatigue, and dizziness.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to SAPHNELO during pregnancy. For more information about the registry or to report a pregnancy while on SAPHNELO, contact AstraZeneca at 1-877-693-9268.

There are insufficient data on the use of SAPHNELO in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. Advise female patients to inform their healthcare provider if they intend to become pregnant during therapy, suspect they are pregnant or become pregnant while receiving SAPHNELO.

**Lactation:** No data are available regarding the presence of SAPHNELO in human milk, the effects on the breastfed child, or the effects on milk production.

**Pediatric Use:** The safety and efficacy of SAPHNELO in pediatric patients less than 18 years of age has not been established.

**Please see full Prescribing Information, including Patient Information.**

***You may report side effects related to AstraZeneca products.***

**References:**

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**Abbreviations:**

ACR: American College of Rheumatology; AE: adverse event; BICLA: British Isles Lupus Assessment Group–based Composite Lupus Assessment; CMH: Cochran–Mantel–Haenszel test; DORIS: Definition of Remission in SLE; EULAR: European Alliance of Associations for Rheumatology; GC: glucocorticoid; IFN: interferon; IV: intravenous; LLDAS: Low Lupus Disease Activity State; PGA: Physician Global Assessment of disease activity; SC: subcutaneous; SLE: systemic lupus erythematosus; SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000; URTI: upper respiratory tract infection; UTI: urinary tract infection; vs: versus.

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