Phase III PHOENYCS-GO trial: Dapirolizumab pegol in SLE (NCT04294667)

N = 321

Primary endpoint: BICLA response at Week 48
Eligibility: Aged ≥16 years with moderate-to-severe, active SLE despite stable SoC medication

STUDY DESIGN

n = 213 — Randomized 2:1* — n = 108

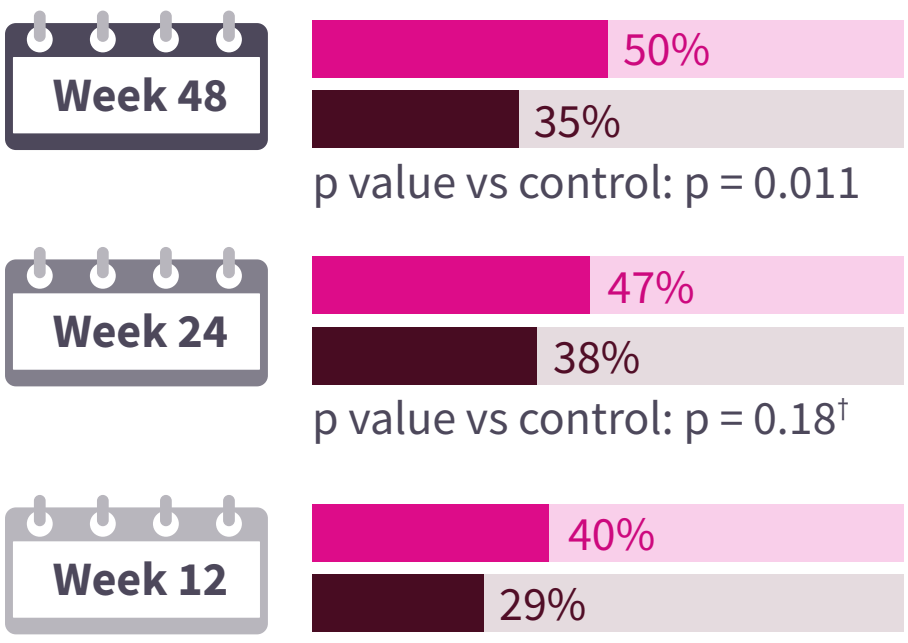
Dapirolizumab pegol | 24 mg/kg
2-hour infusion Q4W, then 1-hour infusion Q4W to Week 48 (last dose at Week 44)
+ SoC

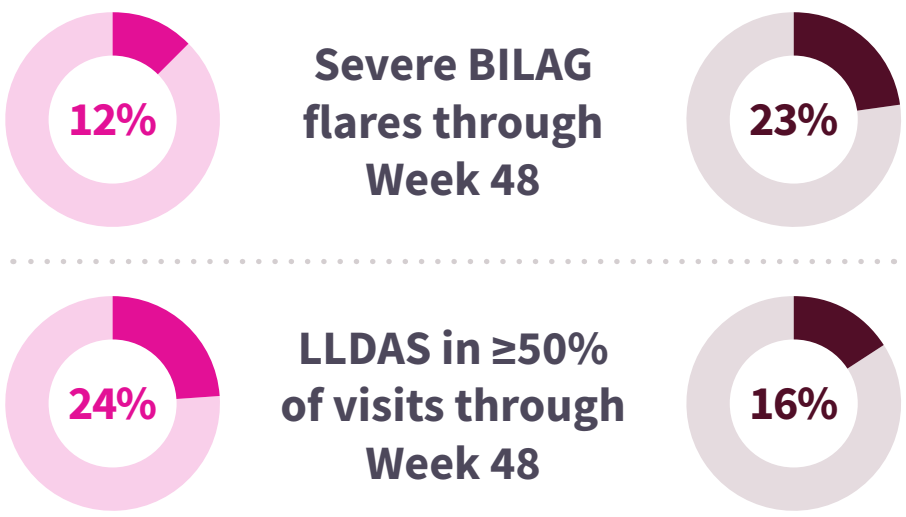
Placebo
2-hour infusion Q4W
+ SoC

EFFICACY

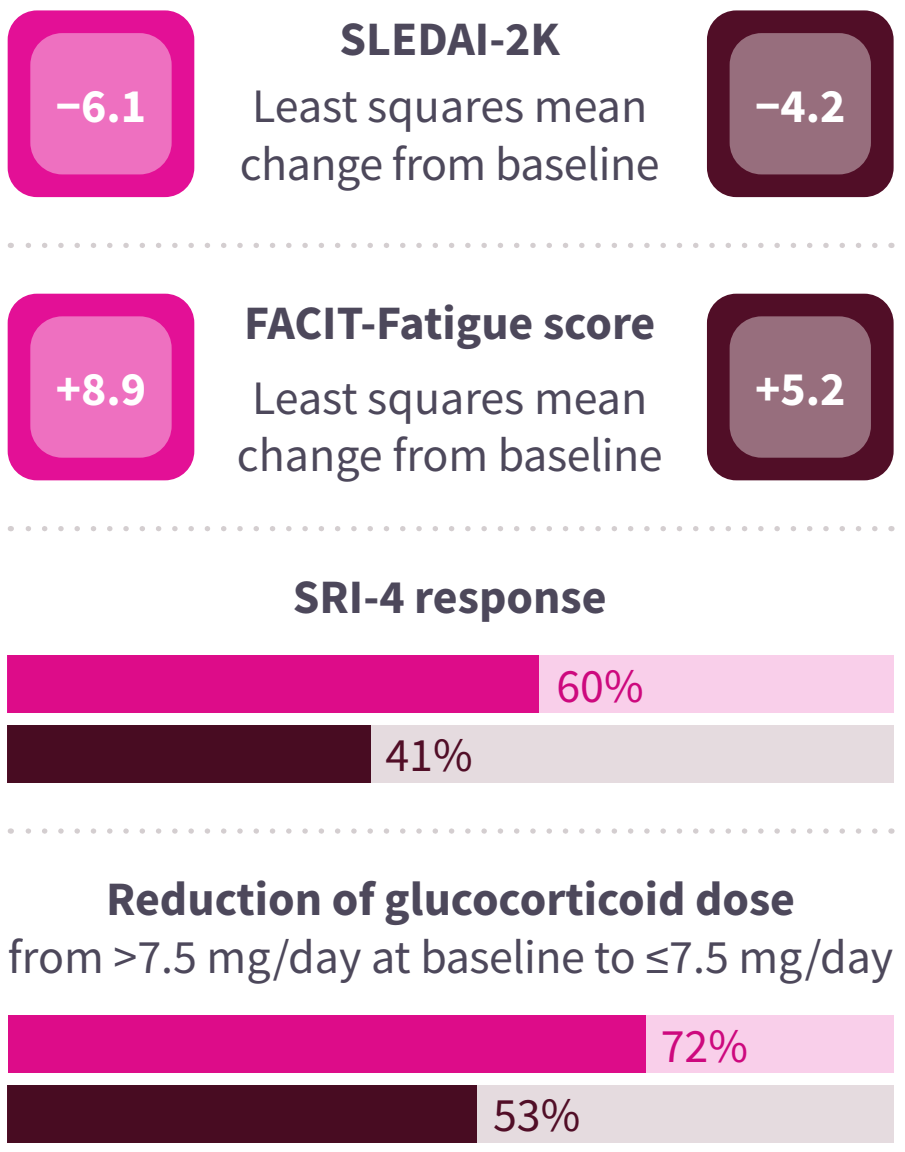
Treatment arm, n = 208 | **Control arm**, n = 107

BICLA response

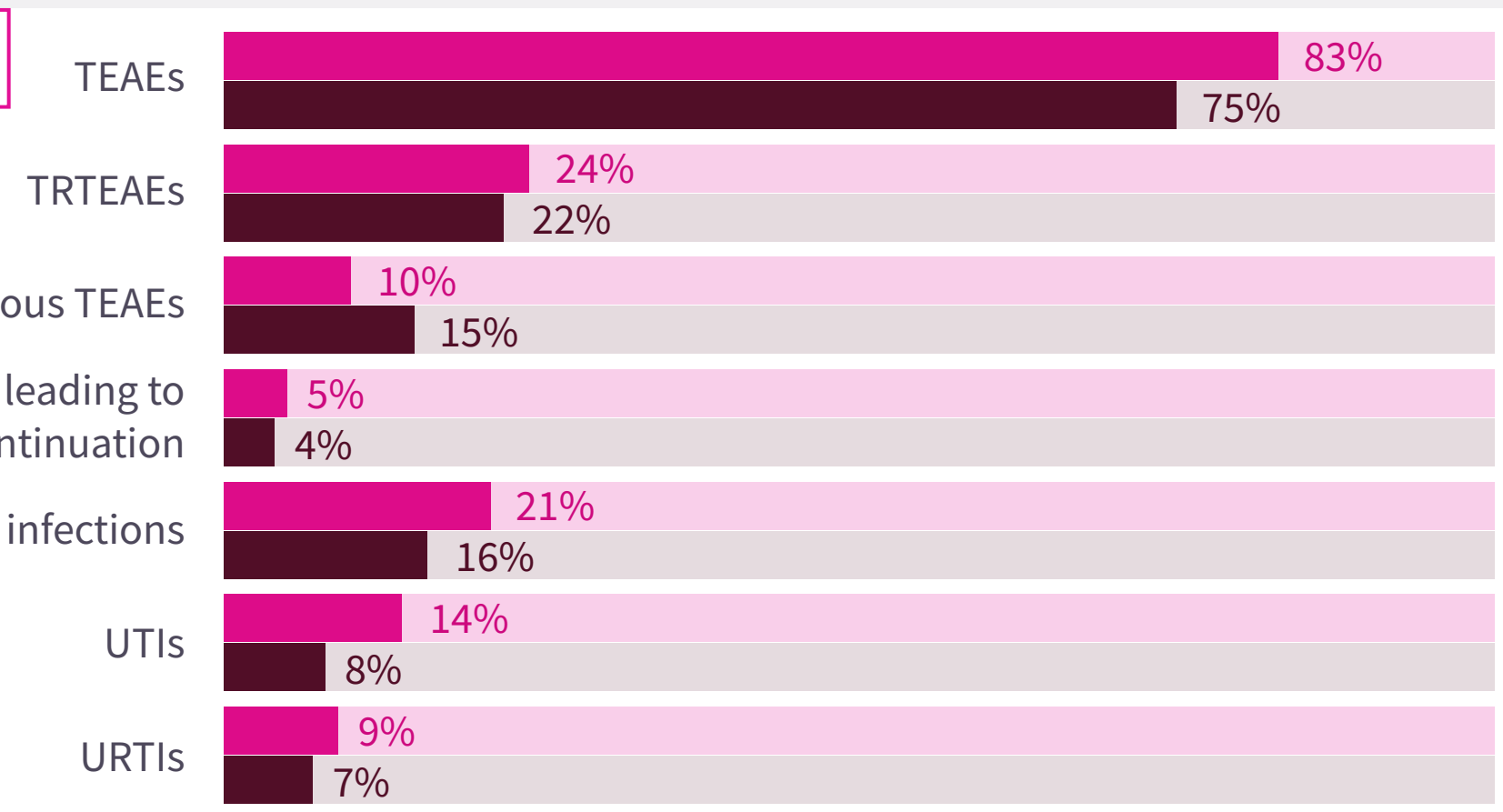




At Week 48



SAFETY



Dapirolizumab pegol + SoC significantly improved disease activity vs placebo + SoC at Week 48 in patients with moderate-to-severe, active SLE, supporting further evaluation in the PHOENYCS GLIDE OLE (NCT04976322) and the confirmatory phase III PHOENYCS FLY trial (NCT06617325).

*Investigators were required to initiate glucocorticoid tapering for patients on a dose exceeding 7.5 mg/day prednisone equivalent at baseline, aiming to reach no more than 7.5 mg/day by Week 24, with tapering starting no later than Week 8.

†The key secondary outcome was not met; therefore, subsequent key secondary outcomes were not controlled for multiplicity.

BICLA, BILAG-based Composite Lupus Assessment; BILAG, British Isles Lupus Assessment Group; FACIT, Functional Assessment of Chronic Illness Therapy; IV, intravenous; LLDAS, Lupus Low Disease Activity State; OLE, open-label extension; Q4W, once every 4 weeks; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; SoC, standard of care; SRI-4, SLE Responder Index 4; TEAE, treatment-emergent adverse event; TRTEAE, treatment-related TEAE; URTI, upper respiratory tract infection; UTI, urinary tract infection.

Clowse MEB, *et al. Lancet.* 2026;407(10545):2291-2304.

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