

excluding only the serologic laboratory parameters from cSLE-DAI-2K. Including both clinical laboratory parameters and manifestations provides a more complete understanding of patients' status.

Methods Patients with moderate to severe SLE despite standard therapy could consent after the 52-week TULIP-1/2 trials to participate in the randomized, double-blind, 3-year LTE (NCT02794285). We analyzed patients randomized to intravenous anifrolumab 300 mg or placebo for the 4-year TULIP-LTE. In this new analysis, DORIS attainment was defined as total cSLEDAI-2K score (sum of all SLEDAI-2K items except increased DNA binding and low complement) =0, physician global assessment <0.5, prednisone/equivalent dosage ≤5 mg/day, stable maintenance immunosuppressant doses, no restricted medication use (TULIP-1/2 only), and no premature investigational product discontinuation. DORIS attainment was calculated using a stratified Cochran-Mantel-Haenszel approach.

Results We analyzed 369 patients (anifrolumab, n=257; placebo, n=112) who continued treatment in the LTE. Using the new analysis described above, 19.7% of anifrolumab-treated patients attained DORIS at the first LTE visit (Week 64) compared with 9.9% of the placebo group (treatment difference, Δ [95% CI]=9.8% [0.6–19.1], nominal $P=0.037$); DORIS attainment rates increased from baseline throughout the trial (figure 1). Trends favoring anifrolumab versus placebo were observed up to Week 208 (30.3% vs 18.3%; $\Delta=12.0\%$ [–0.6–24.6], nominal $P=0.062$).

Conclusion Remission is an important SLE treatment goal that protects from flares and organ damage. Anifrolumab treatment was associated with higher DORIS remission rates compared with placebo during the 4-year trial.

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REFERENCE

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LBO2 LONG-TERM RENAL AND CARDIOVASCULAR RISKS OF TACROLIMUS IN LUPUS NEPHRITIS PATIENTS

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Objective Systemic lupus erythematosus is associated with an increased risk of cardiovascular disease. Tacrolimus is a calcineurin inhibitor that finds its origin in solid organ transplantation, but is also effectively used in lupus nephritis. In a transplant setting, tacrolimus is associated with an increased cardiovascular risk, including nephrotoxicity, hypertension, dyslipidemia and hyperglycemia. In lupus nephritis the use of tacrolimus is off-label, and since head-to-head comparisons and long-term evaluations are lacking, its safety profile is less well-defined. Our objective was to investigate the long-term

effects of tacrolimus on cardiovascular and renal outcomes in lupus nephritis patients.

Methods In a retrospective, single-center cohort study, all adult lupus nephritis patients treated in the Leiden University Medical Center between 2004 and 2023 were investigated and dichotomized based on the prescription of systemic tacrolimus. We evaluated the Framingham risk score and the occurrence of cardiovascular events, diabetes, dyslipidemia, and change in kidney function.

Results Of 223 patients that were enrolled in the study, 45 (20.2%) were ever prescribed tacrolimus. The remaining 178 patients had never been prescribed calcineurin inhibitors and were assigned to the control group. There was an equally low incidence of cardiovascular events in both groups. The 10-year risk of coronary heart disease was significantly lower in the tacrolimus group, although this could largely be contributed to the age difference between the groups. Tacrolimus use was an independent predictor of eGFR decline, but did not result in larger incidence of end-stage kidney disease during the follow-up period. There was no difference in the occurrence of diabetes or dyslipidemia between the groups, although there was a significant increase in HbA1c in the tacrolimus group.

Conclusions Tacrolimus may have nephrotoxic and modest diabetogenic effects in lupus nephritis patients. Caution when prescribing tacrolimus and vigilance towards these possible side effects when continuing tacrolimus treatment as maintenance treatment is advised. However, further prospective studies in larger cohorts are necessary to confirm these findings and further assess the side-effects of tacrolimus in lupus nephritis patients.

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LBP1

INTERIM RESULTS OF AN OPEN-LABEL, MULTICENTRE, PHASE 1/2 STUDY TO ASSESS YTB323 (RAPCABTAGENE AUTOLEUCEL), A CAR T-CELL THERAPY, FOR SEVERE REFRACTORY SYSTEMIC LUPUS ERYTHEMATOSUS

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Objective Patients with severe refractory systemic lupus erythematosus (srSLE) exhibit failure to respond to treatments, progressive organ damage, and high mortality. Traditionally manufactured CD19-directed CAR T-cell therapies have potential to promote full clinical remission in srSLE. YTB323 (rapcabbage autoleucel) is a novel, rapidly manufactured,