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OUTRACE Sjögren's:
A Phase 1b Study of
CLN-978, a Bispecific
CD19 × CD3 T-Cell
Engager, in Patients
With Active
Sjögren's Disease

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INTRODUCTION

- Targeting CD19-expressing B cells has demonstrated clinical benefit across autoimmune diseases, including Sjögren's disease (SjD)¹⁻³
- CLN-978 is a subcutaneously administered CD19×CD3 T-cell engager with a high affinity to CD19 and an albumin-binding domain to extend half-life (**Figure 1**)
- In recent phase 1b clinical trials, a single target dose of CLN-978 induced robust B cell depletion in both peripheral blood and tissues, with promising clinical efficacy in patients with rheumatoid arthritis and systemic lupus erythematosus at the initial dose levels tested⁵
- These data support the evaluation of CLN-978 in patients with SjD

HOW CLN-978 WORKS

- CLN-978 binds CD3 on T cells and CD19 on B cells
- T cell activation induces release of cytotoxic proteins (granzymes and perforin), resulting in depletion of CD19+ B cells

ADVANTAGES OF T-CELL ENGAGERS

- No patient-specific manufacturing → off-the-shelf
- No preconditioning/lymphodepletion
- Subcutaneous dosing → ease of administration
- Dosing flexibility
- Potential for re-dosing to extend remissions
- Outpatient potential

Figure 1. T-cell engagers drive targeted depletion of autoreactive B cells⁴

HSA, human serum albumin; NKT, natural killer T cell; scFv, single-chain variable fragment; Treg, regulatory T cell; VHH, variable heavy domain.

METHODS

- OUTRACE Sjögren's (NCT07041099; EUCTR 2025-521462-96-00) is an ongoing, Phase 1b study designed to evaluate the safety, pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, and preliminary clinical activity of CLN-978 in patients with active SjD
- The study consists of 2 parts (**Figure 2**)
 - Part A dose escalation evaluates step-up dosing, beginning with a priming dose followed by escalating weekly doses to identify a recommended dose and regimen
 - Part B dose expansion will further evaluate safety, PK, PD, and clinical activity at selected dose levels from Part A and will explore alternative dosing schedules
- CLN-978 is administered during a 4-week treatment phase, followed by longitudinal assessments through Week 48, with optional long-term follow-up

Figure 2. OUTRACE Sjögren's (CLN-978-SJ-101) is a Phase 1b, multicenter, open-label, dose-escalation and dose-expansion study

ACR, American College of Rheumatology; D, day; DL, dose level; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; EULAR, European Alliance of Associations for Rheumatology; PD, pharmacodynamics; PK, pharmacokinetics; SC, subcutaneous; SjD, Sjögren's disease; SoC, standard of care. ^aUp to 3 additional patients may be added following cohort review by the Safety Review Committee. ^bDose level to be determined based on Part A findings.

	Study objective	Endpoint(s)
Primary	To evaluate safety and tolerability of CLN-978	Incidence and severity of AEs, serious AEs, and AEs of special interest
Secondary	To evaluate the PK of CLN-978	Serum concentrations of CLN-978
	To evaluate the PD of CLN-978	Change from baseline in B lymphocyte cell numbers in peripheral blood
	To evaluate the immunogenicity of CLN-978	Detection of anti-drug antibodies
Exploratory	To evaluate CLN-978 biomarkers	PD markers of B cell depletion
	To evaluate clinical efficacy of CLN-978	ESSDAI, ESSPRI, STAR, CRESS

AE, adverse event; CRESS, Composite of Relevant Endpoints for Sjögren's Syndrome; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EULAR, European Alliance of Associations for Rheumatology; PD, pharmacodynamics; PK, pharmacokinetics; STAR, Sjögren's Tool for Assessing Response.

Figure 3. The study is currently enrolling patients at sites in the United States, Europe, and Australia

CONCLUSIONS

- OUTRACE Sjögren's will characterize the safety, PK, and PD of CLN-978 and explore its potential to induce deep peripheral and tissue B cell depletion and improve disease activity in patients with active SjD
- This study will inform dose selection and direct further clinical development of CLN-978 in patients with SjD

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