RS-2024-00332815

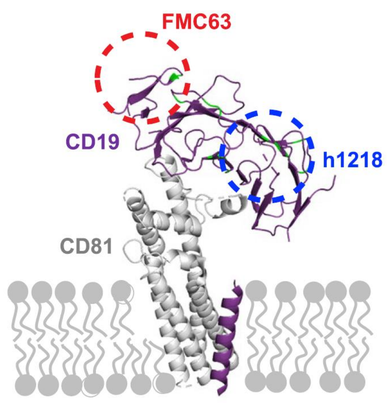
Phase 2 clinical study of innovative CD19-targeted CAR-T

Innovative Therapeutic Antibody
AbClon

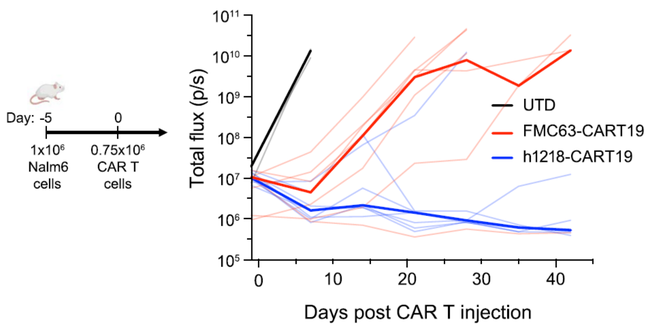
Disease Area	***Relapsed or refractory B-cell non-Hodgkin lymphoma***
Product Type	Autologous CAR-T (chimeric antigen receptor-T) cell therapy
Indication	• Diffuse large B-cell lymphoma (not otherwise specified, DLBCL, NOS) • Grade 3B follicular lymphoma (FL3B) • High-grade B-cell lymphoma (HGBCL) • Primary mediastinal large B-cell lymphoma (PMBCL)
Target	CD19
Mechanism of Action	• A novel h1218 based anti-CD19 CAR-T (AT101) • h1218 binds to a membrane-proximal epitope of CD19 compared to FMC63 • h1218 has fast on and off-rates (fly-kiss) to target binding
Competitiveness	• Enhanced CAR-T efficacy: Outstanding long-lasting efficacy, leading to increased OS and PFS • New epitope: Opportunities for r/r NHL patients, even those who do not respond to current CAR-T therapies • Humanized antibody (h1218) based CAR-T: Lower immunogenicity and higher CAR-T cell persistency • Automated and closed manufacturing process: Easy to control and keep quality • Exclusive IP rights
Development Stage	**Phase II**
Route of Administration	IV infusion

Key Data

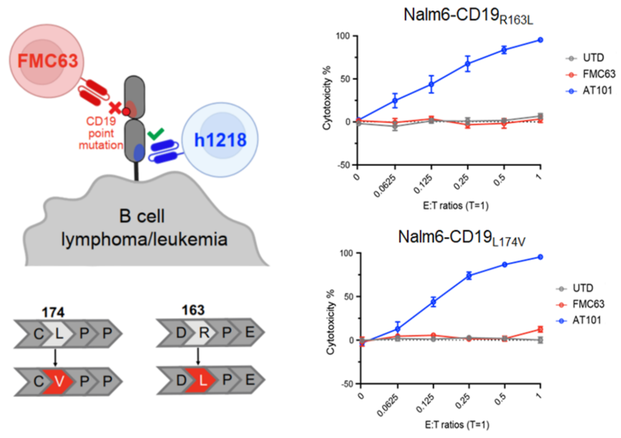
Identification of new epitope at a proximal region



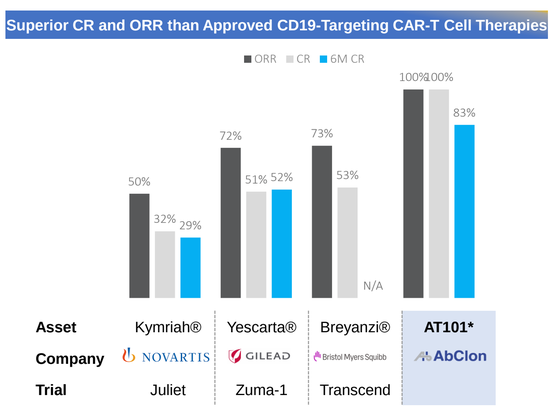
Persistent efficacy led by fly-kiss MoA



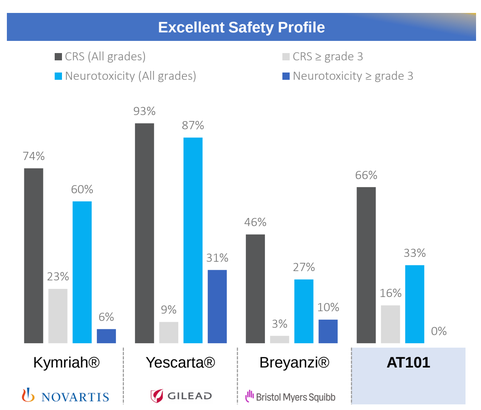
Overcome CD19-FMC63 epitope loss resistance



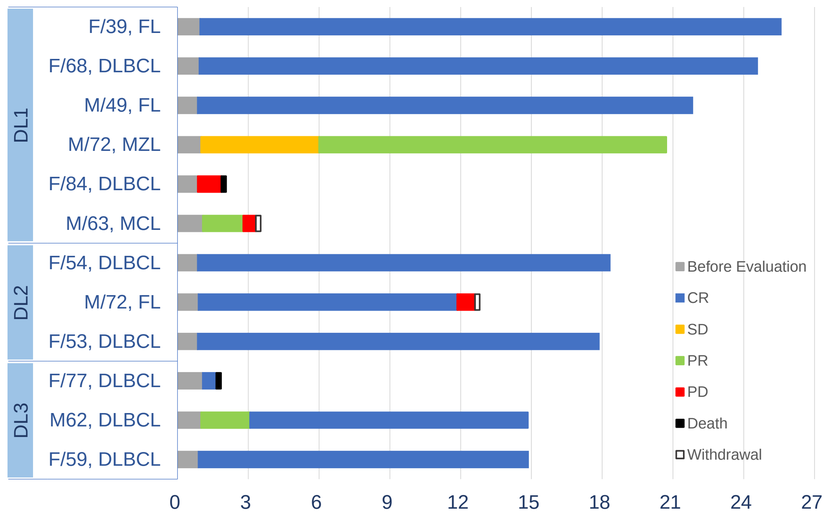
Overall response rate



Adverse events



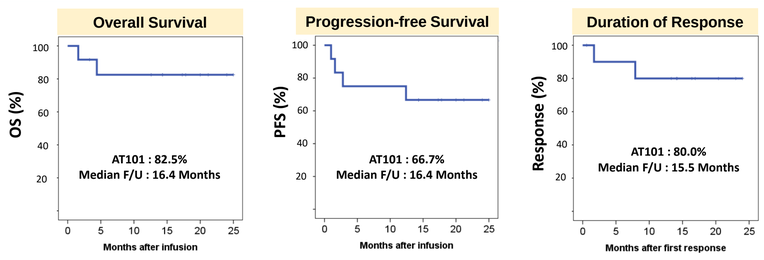
Response duration



▪ *Cut-off: May 02, 2024*
▪ *No AT101 related death*

Survival

➢ 12 patients of Phase 1 (DL1=6, DL2=3, DL3=3)
➢ Among 9 patients who had the CR, **77.8% maintained the CR over 12 months**.



➢ At median follow-up of 16.4 months, AT101 showed **82.5% of the overall survival (OS) rate** and **66.7% of the progression-free survival (PFS) rate**. The mPFS and mOS were not reached.

• Phase II study (NCT05338931)
➢ Title: Safety, Tolerability, and Efficacy of AT101 in Patients With Relapsed or Refractory B-cell Non-Hodgkin's Lymphoma
➢ First Patient In: 2023.10.17
➢ Enrollment: 82
➢ Trial Institutions: Seven Institutions (Asan Medical Center and 6 others)

IP	KR102136063B1, US11534462B2, US20230099646A1, EP3722313A4, JP7089806B2, CN111465616B, CA3083936C, AU2018379502A1