

17<sup>TH</sup>



# INTERNATIONAL SYMPOSIUM SJÖGREN'S DISEASE

SEPTEMBER 29<sup>TH</sup> - OCTOBER 2<sup>ND</sup>

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MAISON INTERNATIONALE  
CITÉ UNIVERSITAIRE



# AB-101, an Outpatient-Administered Allogeneic NK Cell Therapy, Combined with Rituximab Generates Robust Efficacy Responses in 11 Patients with Sjögren Disease

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## Disclosures

- *Guillermo. Valenzuela, MD*: AbbVie, Alexion, Amgen, Artiva Bio, AstraZeneca, BMS, Boehringer Ingelheim, Celgene, Centocor, Esaote, Exagen, Genentech, Gilead, Global Healthy Living Foundation, Horizon, Image Analysis Group, Janssen, Lilly, Mallinckrodt, Merck, Novartis, Pfizer, Pharmacia, Radius, Regeneron, Sandoz, Sanofi, Takeda, and UCB



## AB-101 (AlloNK<sup>®</sup>) in Sjögren Disease (SjD), a B-cell Driven Disease

### Unmet Need:

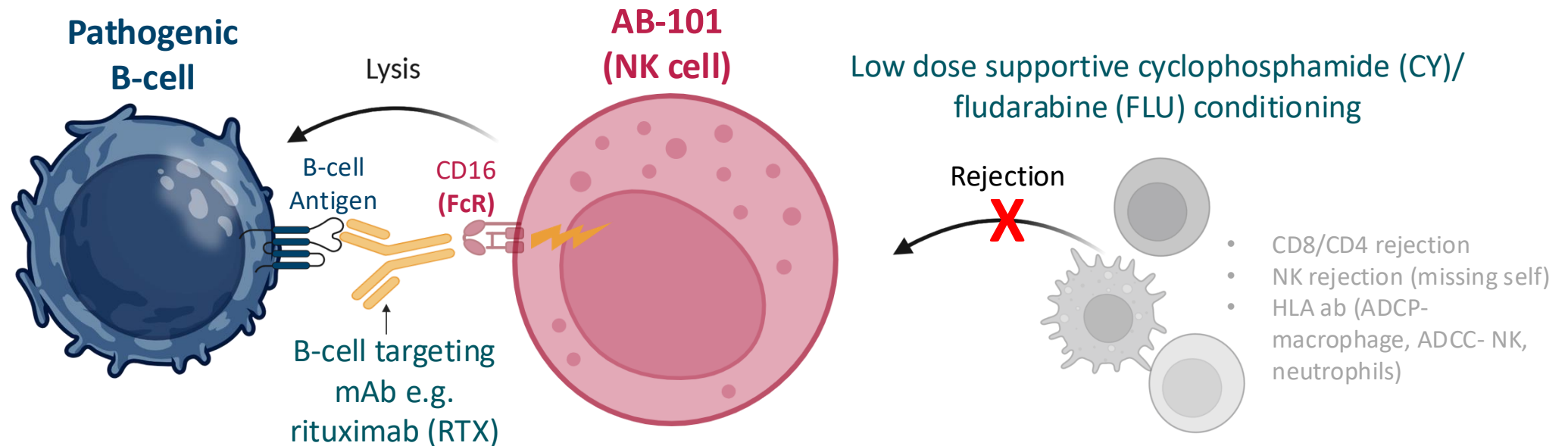
- Significant systemic manifestations may accompany characteristic dryness of the mouth and eyes
- No approved therapies
  - Current therapies include steroids, rituximab (RTX), and hyperimmune gamma globulin (IVIg) used off-label
- Symptomatic treatments for dryness do not address the underlying cause of disease

### B cells in SjD:

- B cells shown to play important roles in pathogenesis, e.g. autoantibody production
- Agents targeting B-cell pathways have shown efficacy in SjD clinical trials:
  - Ianalumab (anti-BAFF-R mAb), Ph3
  - Telitacicept (BAFF/APRIL inhibitor), Ph3 (China)
  - Nipocalimab (FcRn antagonist), Ph2
- While these agents have shown benefits on ClinESSDAI and ESSDAI scores, improvements in ESSPRI and salivary function have been modest at best



## AB-101 + Rituximab (RTX) in Rheumatological Diseases

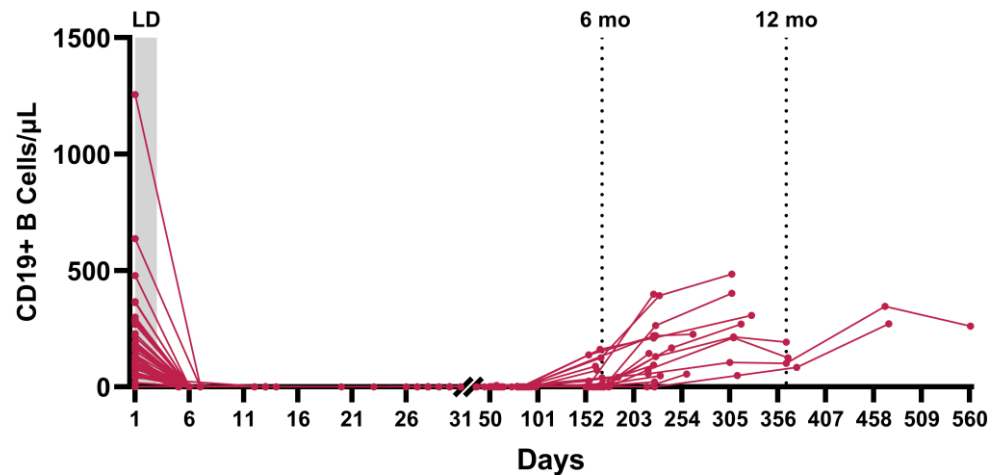


- Allogeneic, **non-genetically modified NK cells** from cord blood selected for **high affinity CD16 variant**
- Cryopreserved, **off-the-shelf**, investigational therapy
- **Outpatient-administered** with most patients treated in non-academic, community sites

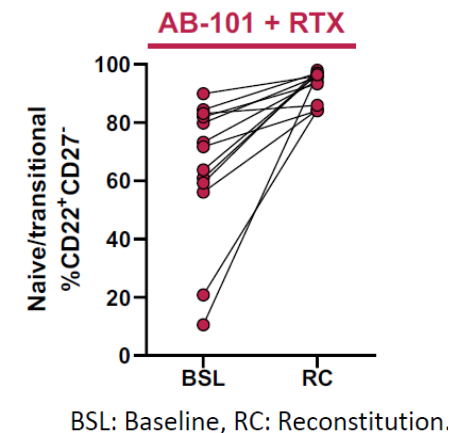


## Complete B-Cell Depletion with AB-101 + RTX Across Autoimmune Diseases *Demonstrates B-cell Reset*

Uniform and consistent B-cell depletion observed by Day 13 in all 51 patients with autoimmune diseases



B-cell reconstitution with increase in naïve/transitional B cells (n=13)



- B-cell reconstitution after AB-101 + RTX demonstrated an increase in naïve B cells (N=13)
- Studies with RTX showed correlation between higher proportion of naïve/transitional cells with a good response in RA patients<sup>1,2</sup>



## Basket Study: Design and Dosing

**Design:** Ph2a study single-arm study of AB-101+ RTX in four B-cell dependent autoimmune diseases (RA; SjD; SSc; IIM).

### **Dosing (All IV and outpatient):**

- Conditioning: cyclophosphamide + fludarabine
- Rituximab: 1000 mg x 2 doses given 2 weeks apart
- AB-101 (each dose): 4 billion cells

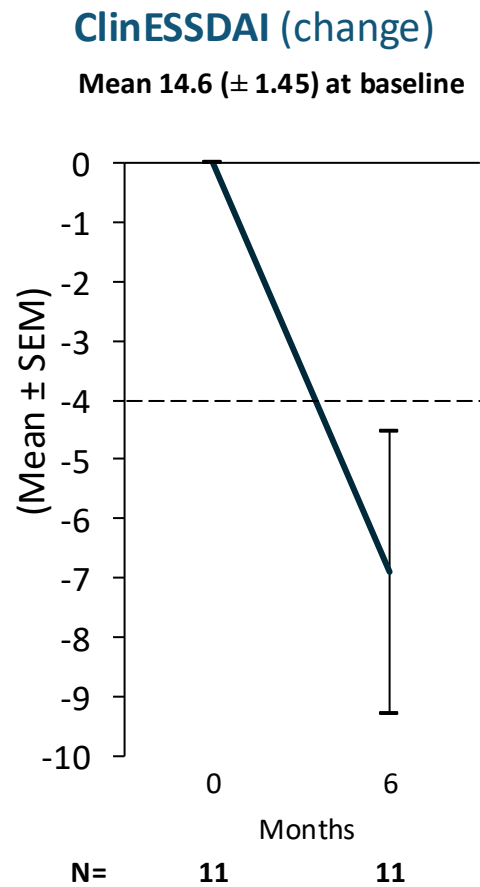


## SjD Cohort: Demographics, Disease Severity

- Number: First 11 subjects with at least 6-month follow-up
- Disease characteristics: ***long-standing disease, high disease activity and refractory to SoC***
  - ❑ Age: Mean 53.6 years
  - ❑ Sex: 100% female
  - ❑ Disease duration: Mean **12.2 years**
  - ❑ Prior therapy: Refractory to SoC (csDMARDs, glucocorticoids, immunosuppressives, biologics)
  - ❑ Concomitant meds: No concomitant csDMARDs or immunosuppressives at baseline
  - ❑ (BASELINE) Disease activity:
    - **ClinESSDAI** - mean **14.6** (*severe*)
    - **ESSPRI** - mean **8.0** (*high*)
    - Salivary flow - 82% with hyposalivation (stimulated salivary flow  $\leq 0.7$  mL/min)



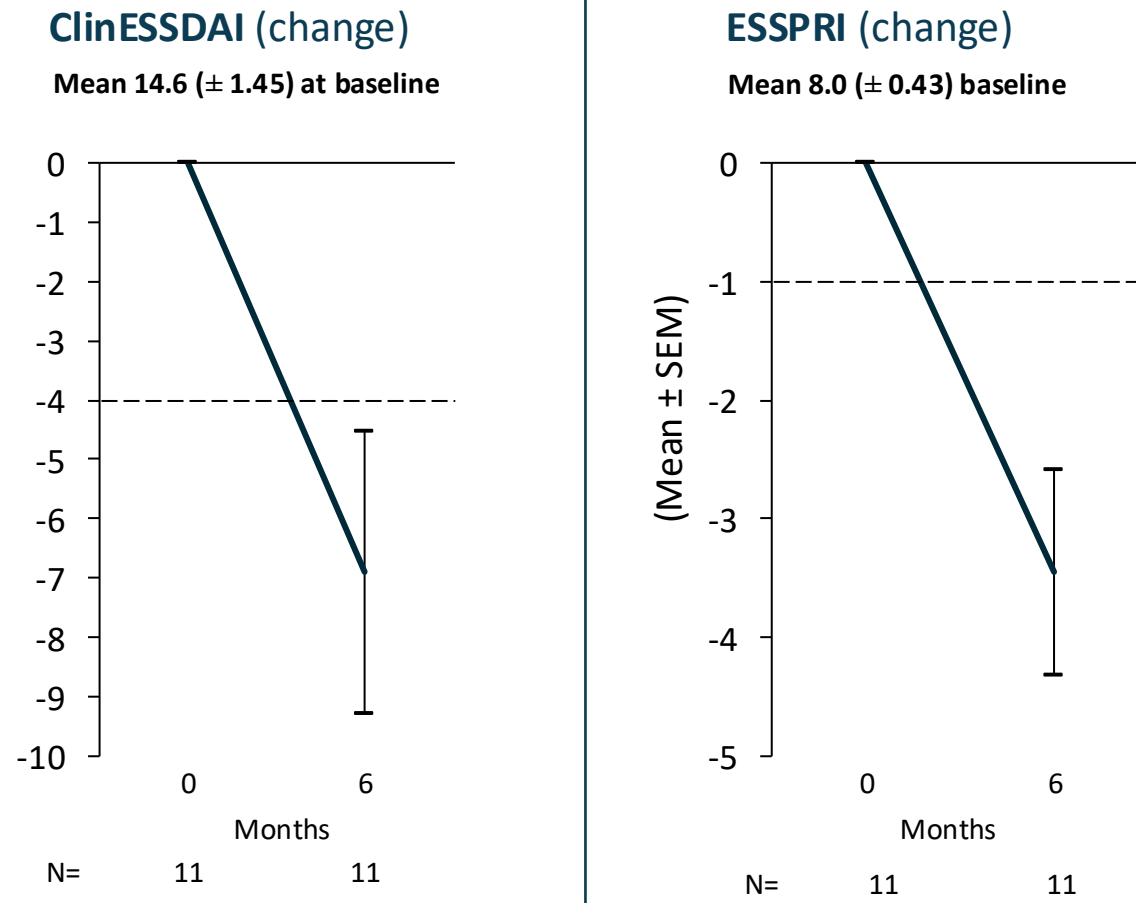
## Improvement in Clinical Scores – ClinESSDAI and ESSPRI



*Dashed lines indicate minimal clinically important improvement*



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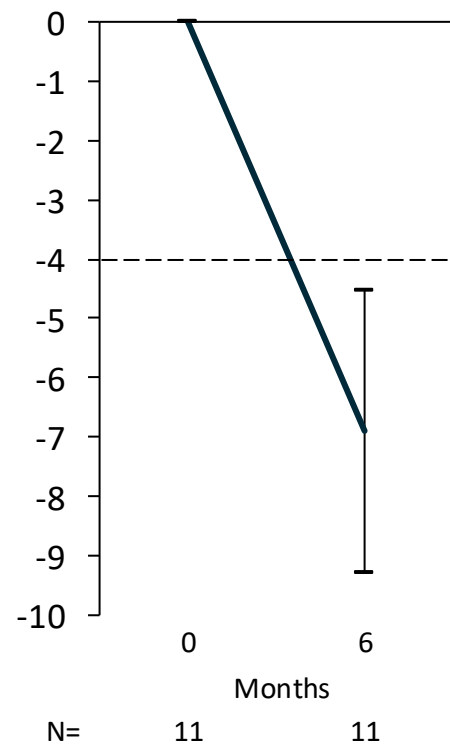
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## Improvement in Clinical Scores – ClinESSDAI and ESSPRI

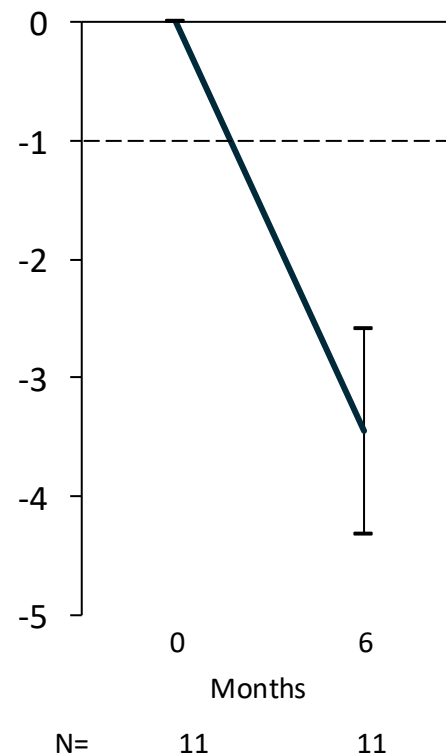
### ClinESSDAI (change)

Mean 14.6 ( $\pm 1.45$ ) at baseline



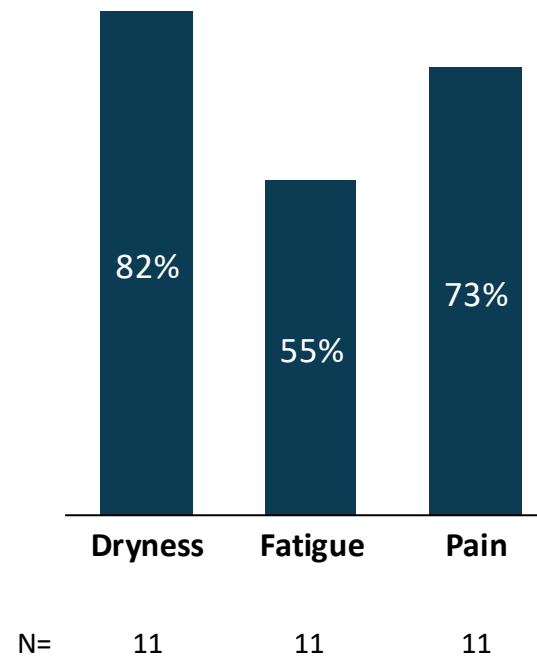
### ESSPRI (change)

Mean 8.0 ( $\pm 0.43$ ) baseline



### ESSPRI at Week 24 – response by domain

(% with  $\geq 1$  point  
improvement)



Dashed lines indicate minimal clinically important improvement



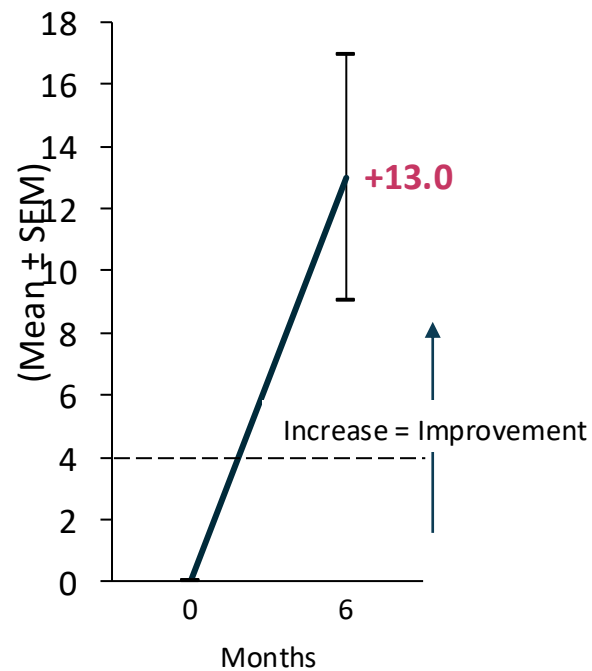
## Improvement in Patient-Reported Outcomes

----- Min. Point Change  
for Response

### FACIT-F (fatigue)

Mean 18.1 ( $\pm 2.9$ )

baseline (severe fatigue)



N 11 11  
=

*Dashed lines indicate minimal clinically important improvement*



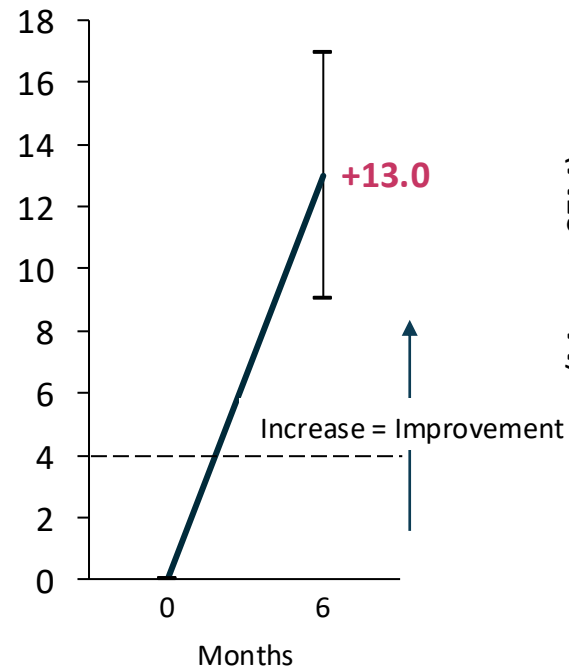
## Improvement in Patient-Reported and Functional Outcomes

----- Min. Point Change  
for Response

### FACIT-F (change)

Mean 18.1 ( $\pm$  2.9)

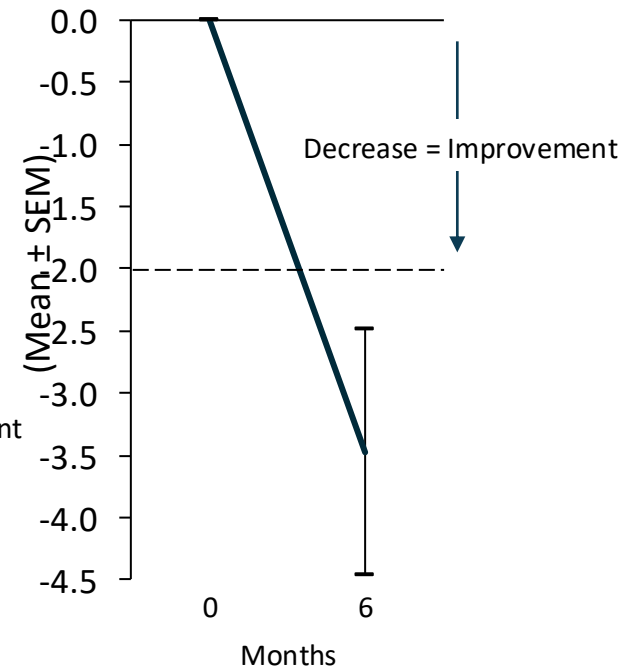
baseline (severe fatigue)



N= 11 11

### Patient Global (change)

Mean 7.21 ( $\pm$  0.82) baseline



N 11 11

=

Dashed lines indicate minimal clinically important improvement

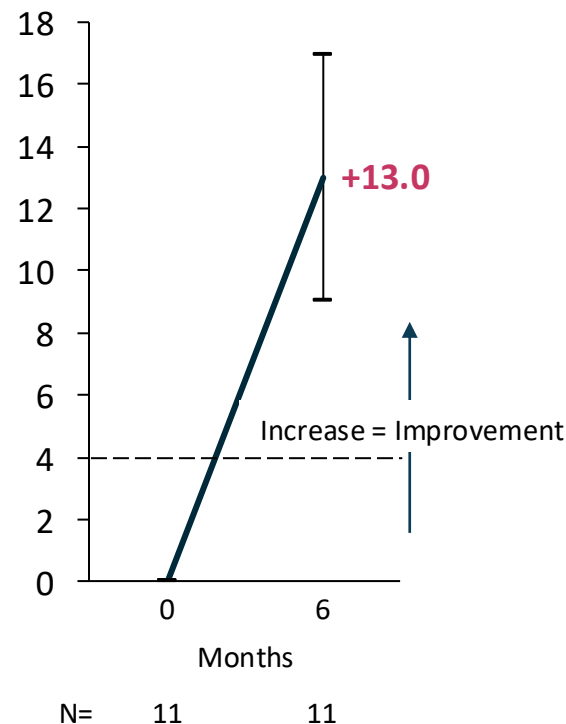


## Improvement in Patient-Reported and Functional Outcomes

----- Min. Point Change  
for Response

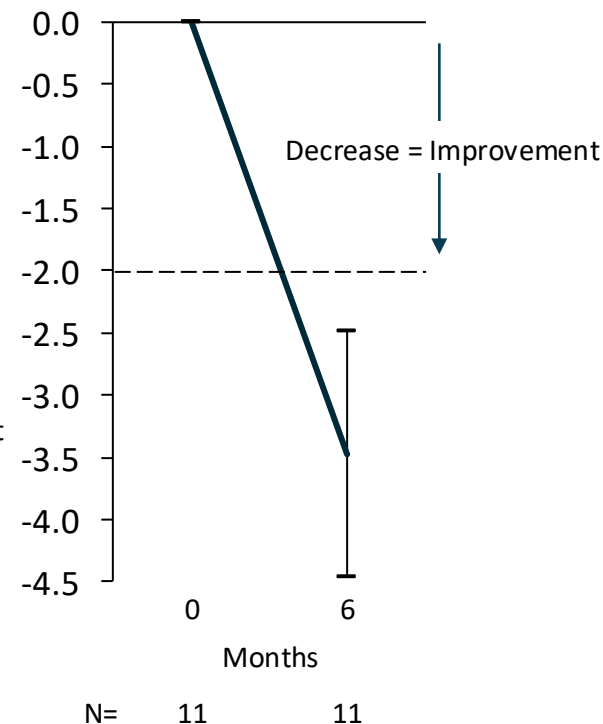
### FACIT-F (change)

Mean 18.1 ( $\pm$  2.9)  
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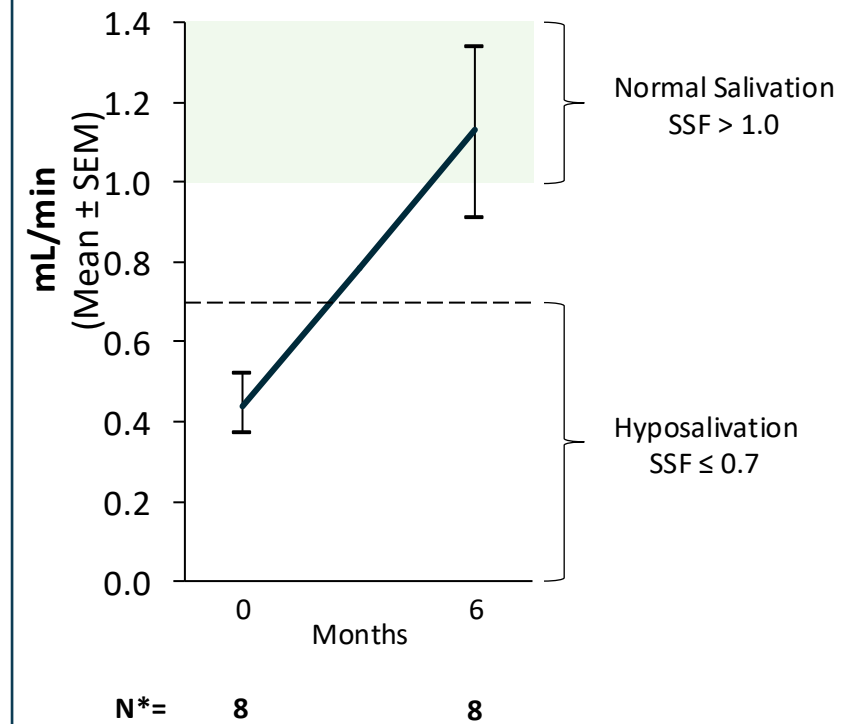


### Patient Global (change)

Mean 7.21 ( $\pm$  0.82) baseline



### Stimulated Salivary Flow (SSF)



Dashed lines indicate minimal clinically important improvement

\* Among subjects with baseline SSF  $\leq$  0.7 mL/min and month 6 data entered as of 02Jul, 2026



## Most Common AEs Consistent With Those Seen With CY/FLU or RTX

### Ph2a Basket Study Cohort (N=73)\*

- No CRS, ICANS, GvHD, or hypogammaglobulinemia<sup>1</sup>
- SAEs: 11% (n=8); 2 with serious infections – gastroenteritis; pneumonia & wound infection; none related to AB-101
- No opportunistic infections; none of the infections below related to AB-101
- No discontinuations from AEs

### Most Common Treatment-Emergent AEs (≥10%)

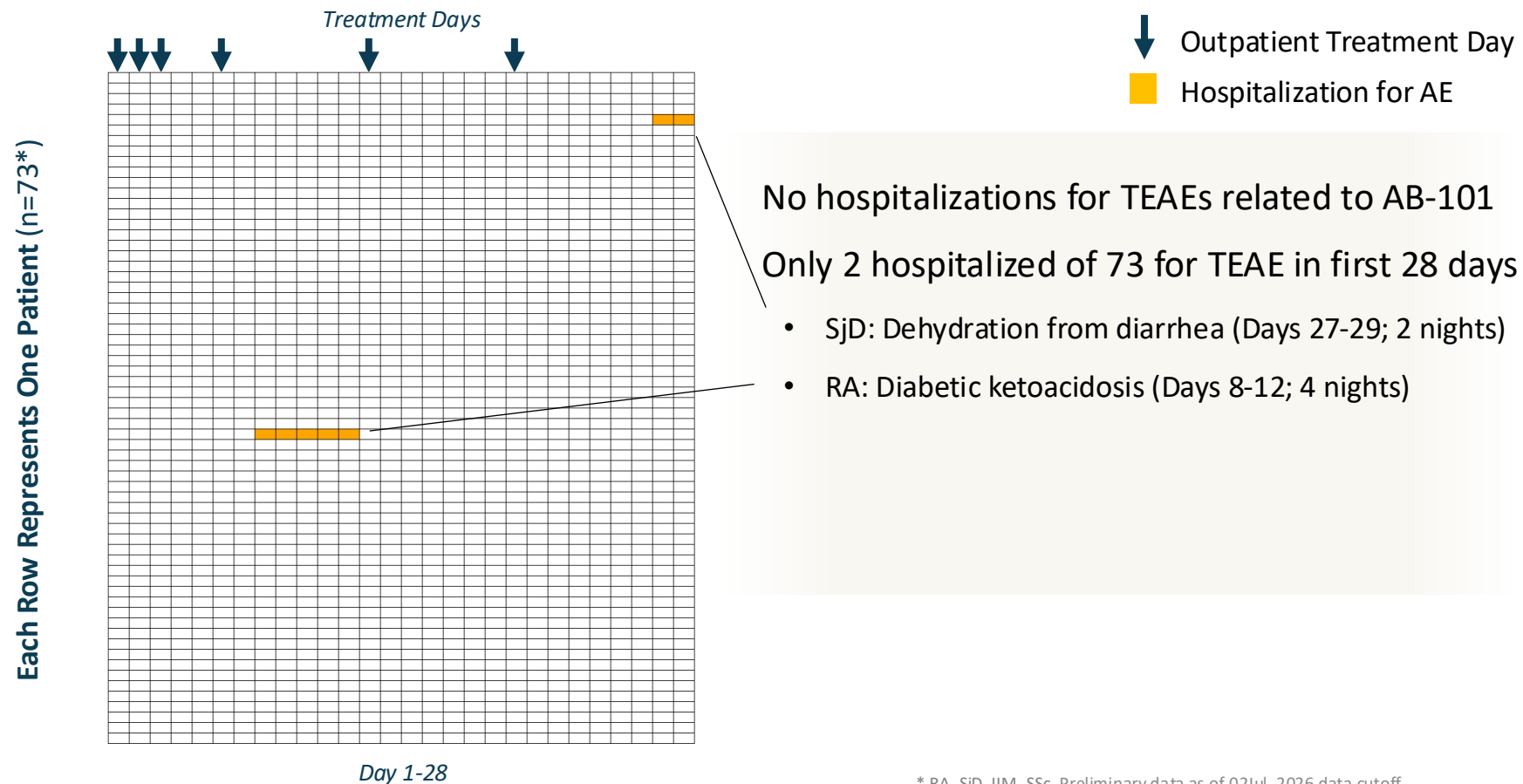
| Adverse Event | n  | %   |
|---------------|----|-----|
| Nausea        | 29 | 40% |
| Headache      | 20 | 27% |
| Lymphopenia   | 18 | 25% |
| Neutropenia   | 17 | 23% |
| Leukopenia    | 16 | 22% |
| Vomiting      | 13 | 18% |
| Alopecia      | 12 | 16% |
| Constipation  | 9  | 12% |

### Infections ≥ 5%

| Infection | n | %    |
|-----------|---|------|
| URTI      | 7 | 9.6% |
| UTI       | 4 | 5.5% |



## Very Low Hospitalization Rates Consistent with Ability to Treat in Outpatient Settings





## AB-101: Summary in Sjogren Disease (SjD)

- Novel, off the shelf, non-genetically modified, investigational, allogeneic NK cell therapy
- Administered in an outpatient setting with a targeting antibody, rituximab (RTX)
- Highly effective in a cohort of patients with severe SjD
  - Rapid, clinically meaningful improvements in systemic disease, symptoms, and salivary function
  - Exceeds those seen with RTX alone in published literature
- Safety profile as observed with CY/FLU or RTX but without CAR T-associated toxicities<sup>1,2</sup>

AB-101 offers a potential deep B-cell depletion option for refractory autoimmune diseases that is suitable for outpatient administration

<sup>1</sup> Yang C, Nguyen J, Yen Y. Complete spectrum of adverse events associated with chimeric antigen receptor (CAR)-T cell therapies. J Biomed Sci. 2023 Oct 21;30(1):89. doi: 10.1186/s12929-023-00982-8.

<sup>2</sup> Müller, F., Hagen, M., Wirsching, A. et al. CD19 CAR-T cells for treatment-refractory autoimmune diseases: the phase 1/2 CASTLE basket trial. Nat Med 32, 1142–1151 (2026).

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**Thank You to Our Patients and Their Families**