

# AB-101, an Allogeneic NK Cell Therapy, Combined with Rituximab was Highly Effective in Severe Sjögren Disease: Experience in First Patient Treated

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# Disclosures

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- *Norman Gaylis, MD, MACR, FACP*: Primary Investigator, AbbVie, Alumis, Artiva, Boehringer, BMS, GSK, Hoffman LaRoche, Sanofi, SetPoint, Spyre, Takeda, Head of Rheumatology Division Cencora, Scientific Advisory Board Inmedix

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

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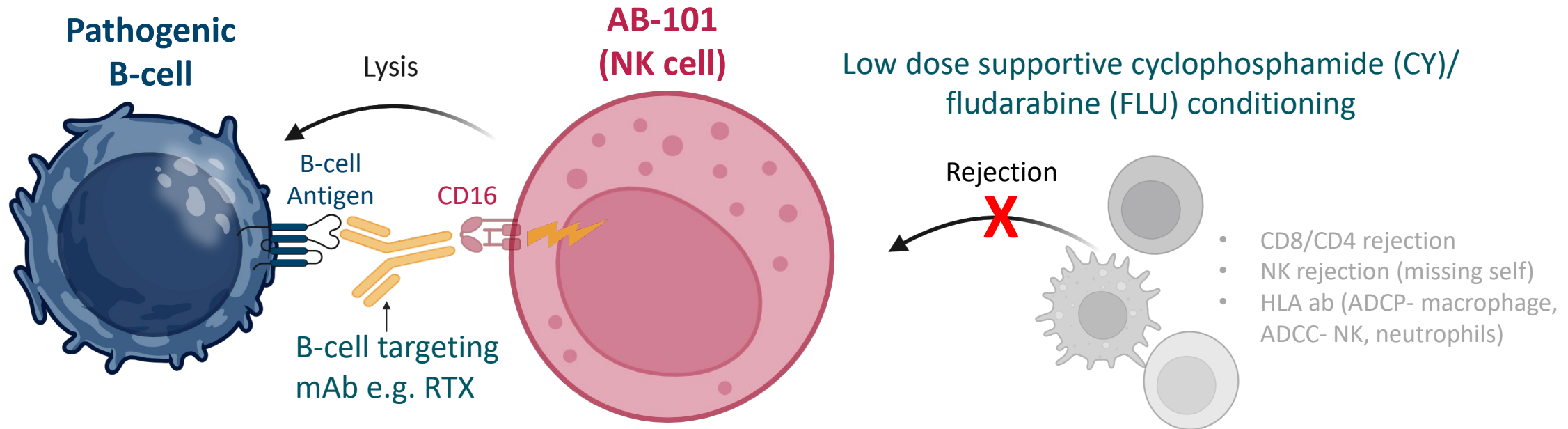
## Unmet Need:

- Significant systemic manifestations may accompany dryness of the mouth and eyes
- No approved therapies
  - Current therapies include steroids, rituximab (RTX), and hyperimmune gamma globulin (IVIg)
- Symptomatic treatments 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 improvements in ClinESSDAI and ESSDAI, improvements in ESSPRI have been modest

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



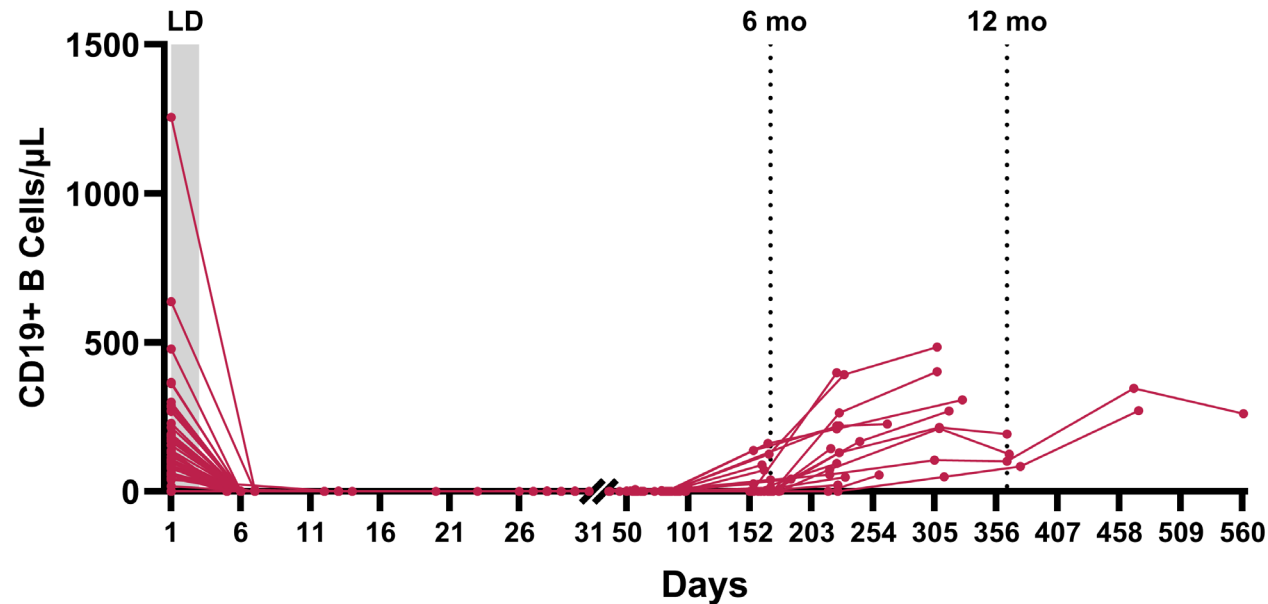
- Allogeneic, non-genetically modified NK cells from cord blood selected for high affinity CD16 variant.
- Cryopreserved, off-the-shelf, investigational therapy.
- Outpatient-administered with most patients treated in non-academic, community sites.

# Complete B-Cell Depletion with AB-101 + RTX Across Autoimmune Diseases

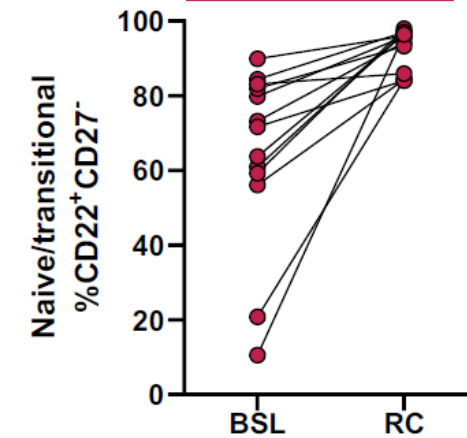
## *Demonstrates Resetting of the Immune System*

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)



AB-101 + RTX



BSL: Baseline, RC: Reconstitution.

- 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>

# SjD Case Report (AB-101-05): Dosing, Demographics, Disease Severity

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*AB-101-05: Ph2a study of AB-101+ RTX after lymphocyte conditioning in four rheumatologic diseases*

- **Dosing (IV):**
  - **CY** (1000 mg x 1) + **FLU** (30 mg/m<sup>2</sup> x 3)
  - **RTX:** 1000 mg x 2, 2 weeks apart
  - **AB-101:** 1 billion or 4 billion cells x 3, weekly
- **Indications:** Rheumatoid Arthritis (RA); Sjogren Disease (SjD); Systemic Sclerosis (SSc); Idiopathic Inflammatory Myopathies (IIM)
- **Primary objective:** Safety and tolerability
- **Secondary objective:** Preliminary efficacy

*See also: EULAR Late Breaker 06Jun 12:00 Room N3: AB-101, an Outpatient-Administered Allogeneic NK Cell Therapy Combined with Rituximab, Generates Robust Clinical Efficacy Responses Comparable with Autologous CAR T in 32 Patients with Rheumatologic Diseases. Presenter: Norman Gaylis*

# SjD Case Report (AB-101-05): Dosing, Demographics, Disease Severity

AB-101+ RTX after lymphocyte conditioning with CY/FLU

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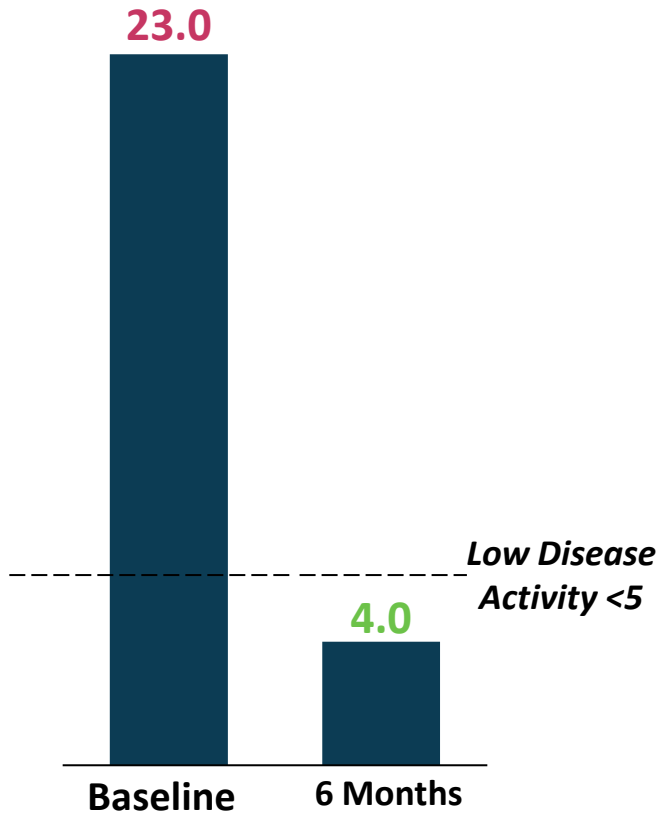
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\*EULAR Late Breaker 06Jun 12:00 Room N3: AB-101, an Outpatient-Administered Allogeneic NK Cell Therapy Combined with Rituximab, Generates Robust Clinical Efficacy Responses Comparable with Autologous CAR T in 32 Patients with Rheumatologic Diseases. Dr. Gaylis

- **Age:** 40y
- **Sex:** Female
- **Disease Duration:** 12.5y
- **Autoab:** **Anti-SSA/Ro (52/60)+, anti-SSB/La+**
- **Prior Rx:** Hydroxychloroquine, Azathioprine
- **Concomitant immunomodulators:** **None**
- **Baseline disease activity:**
  - **ClinESSDAI:** 23 (*high activity*)
  - **ESSPRI:** 5.67 (*high activity*)
  - **Stimulated salivary flow (SSF):** 0.5 mL/min (*hyposalivation*)

# ClinESSDAI and ESSPRI: Consistent Improvements Across All Domains

## ClinESSDAI

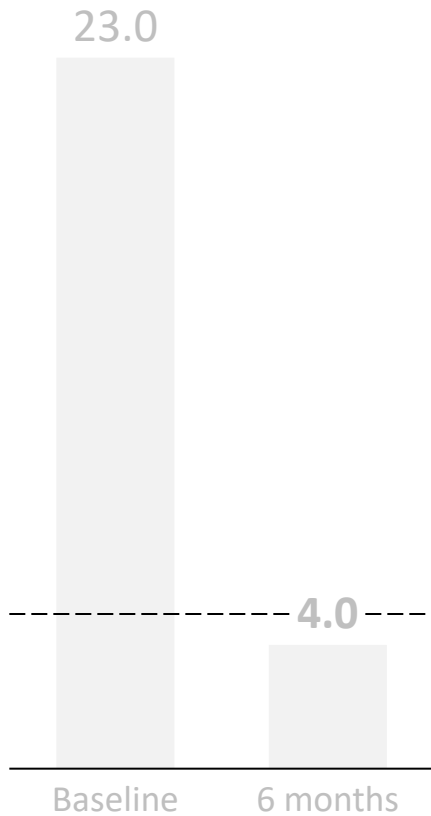


## ClinESSDAI Domains

Domain	Baseline	6 mo
<i>Constitutional</i>	2	1
<i>Articular</i>	3	0
<i>Cutaneous</i>	2	0

# ClinESSDAI and ESSPRI: Consistent Improvements Across All Domains

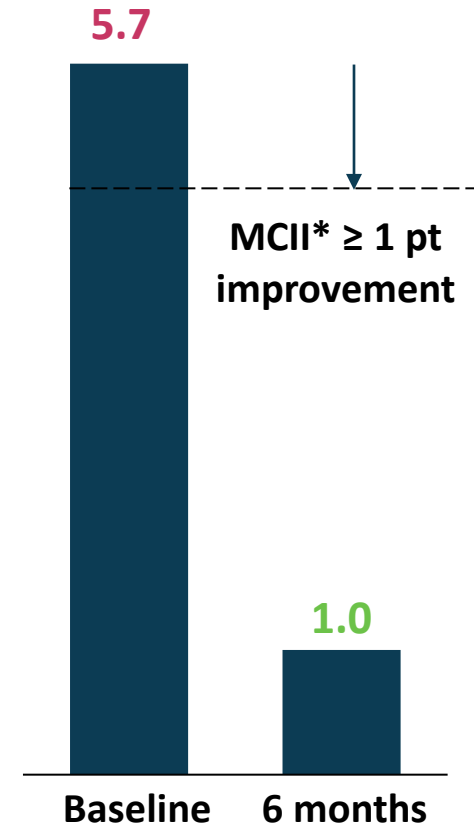
## ClinESSDAI



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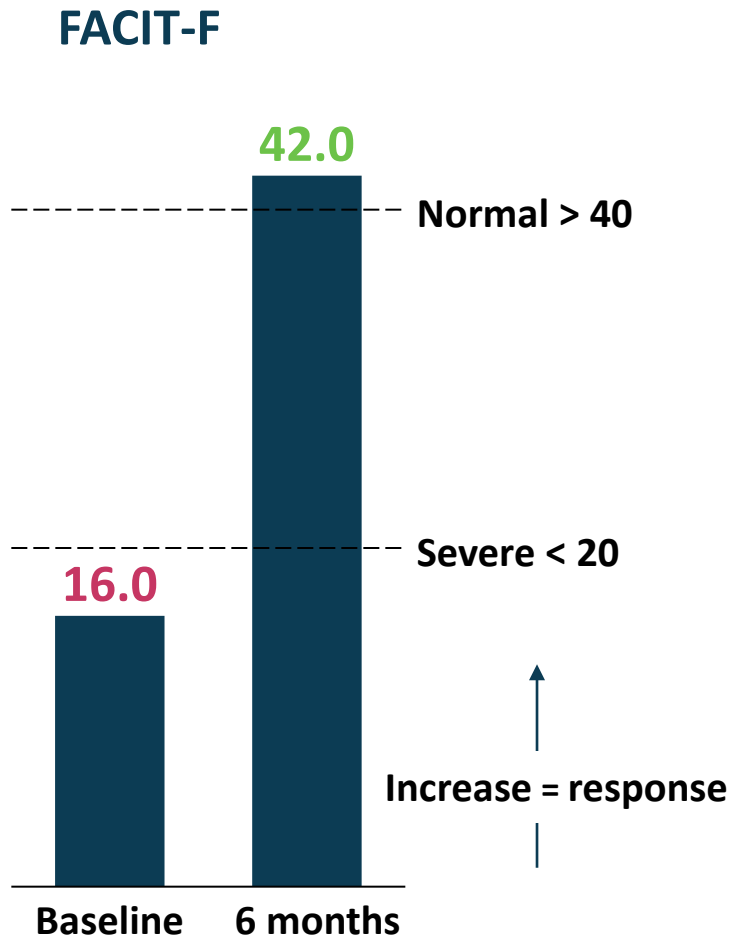
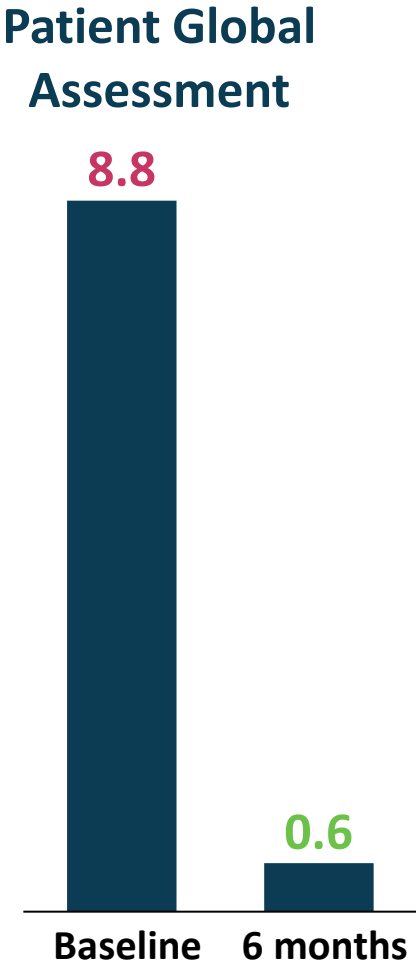
## ESSPRI



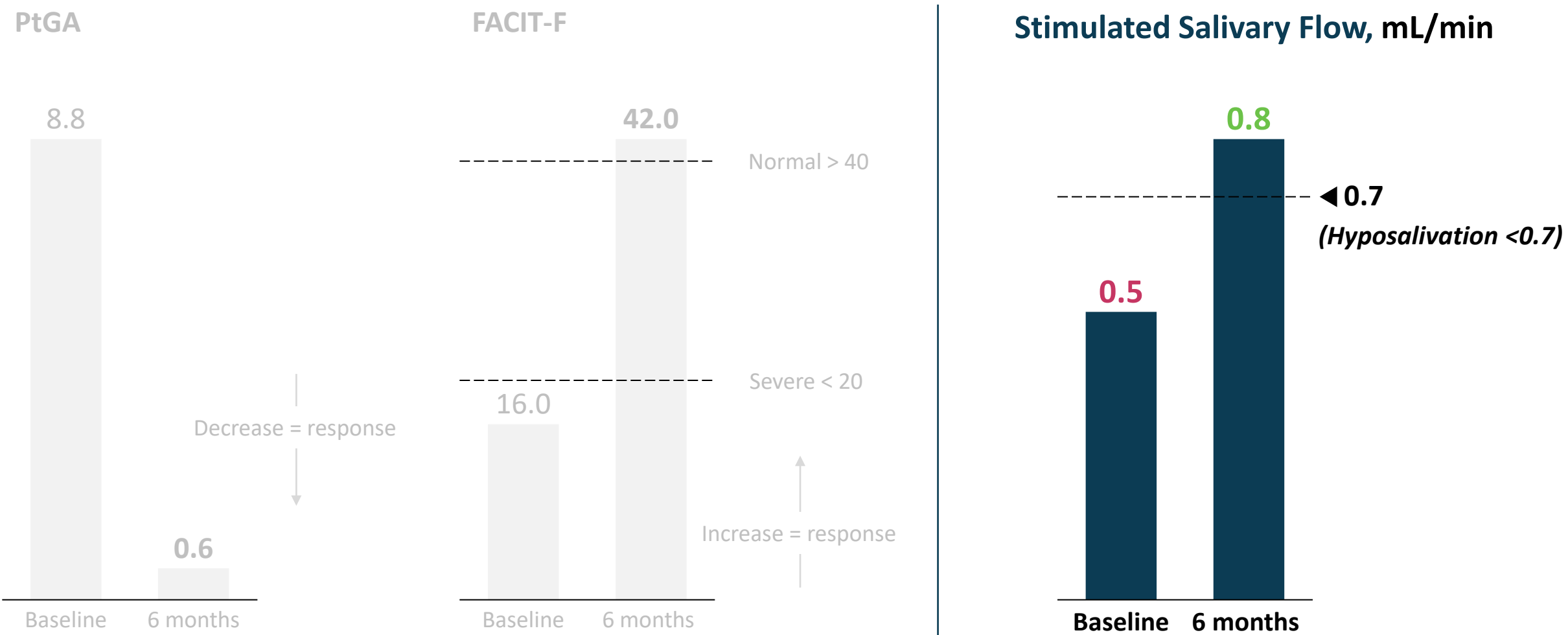
## ESSPRI Domains

Domain	Baseline	6 mo
<i>Dryness</i>	7	1
<i>Fatigue</i>	2	1
<i>Pain</i>	8	1

# Patient Global Assessment, FACIT-F (Fatigue), and Salivary Function Improved



# Patient Global Assessment, FACIT-F (Fatigue), and Salivary Function Improved



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

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## Safety in Patient with SjD

- No CRS, ICANS, GvHD, or hypogammaglobulinemia<sup>1</sup>
- No SAEs
- Treatment emergent AEs:
  - Nausea (Grade 1)
  - Vomiting (Grade 1)
  - Headache (Grade 1)
- Subject still in study after 10 months of follow-up
- Safety profile consistent with broader cohort

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## Ph2a Basket Study Cohort (N=46)

- No CRS, ICANS, GvHD, or hypogammaglobulinemia<sup>1</sup>
- SAEs: 13% (n=6), none related to AB-101
- Treatment emergent AEs >10%, (rounded):
  - Nausea, n=20 (44%)
  - Headache, n=13 (28%)
  - Leukopenia, n=12 (26%)
  - Neutropenia, n=12 (26%)
  - Lymphopenia, n=11 (24%)
  - Alopecia, n=10 (22%)
  - Vomiting, n=7 (15%)
  - Diarrhoea, n=5 (11%)
  - Fatigue, n=5 (11%)
  - URI, n=5 (11%)
- Grade 3+ AEs ≥ 5%: lymphopenia (6.5%), neutropenia (6.5%), none related to AB-101
- Infections: URI, n=5 (11%), UTI, n=1 (2%), Staph. wound infection, n=1 (2%), gastroenteritis, n=1 (2%); none AB-101-related
- No opportunistic infections
- No discontinuations

# Summary

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- AB-101 is a novel, off the shelf, non-genetically modified, investigational, allogeneic NK cell therapy
- Administered in an outpatient setting with a targeting antibody
- Highly effective in the first patient treated with severe SjD
  - Rapid, clinically meaningful responses demonstrated
  - 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</sup>
- Currently >70 autoimmune patients treated, with AEs consistent with above\*
- AB-101 offers a potential deep B-cell depletion option suitable for community setting adoption

*\*EULAR Late Breaker 06Jun 12:00 Room N3: Gaylis, et al. AB-101, an Outpatient-Administered Allogeneic NK Cell Therapy Combined with Rituximab, Generates Robust Clinical Efficacy Responses Comparable with Autologous CAR T in 31 Patients with Rheumatologic Diseases.*

<sup>1</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).

# Thank You to Our Patients and Their Families

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