Assessing the Patient Experience of Nipocalimab: Exit Interviews From the Phase 2 Randomized Placebo-Controlled Study in Sjögren's Disease

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Key Takeaways

- **Although symptomatic experiences were heterogenous, 5 core symptoms of SjD emerged as most frequently experienced by participants: mouth dryness, eye dryness, fatigue, joint pain, and, for female participants, vaginal dryness**
- **Most participants were satisfied or very satisfied with study treatment, driven by perceived symptom and HRQoL improvements**
- **Qualitative exit interviews provided rich insights into the participant experience of SjD overall, in addition to their experience of the DAHLIAS clinical trial and study treatment**
- **This research adds to the body of evidence regarding the symptoms, functional impacts, and HRQoL impacts of individuals living with SjD, providing qualitative insights from a subset of clinical trial participants**
- **Findings identify frequently reported symptoms and impacts that are most salient to the patient experience and can be used to better contextualize and inform clinical trial endpoints**

Background

- Sjögren's disease (SjD) is a chronic, progressive autoimmune disease characterized by a heterogeneous range of symptoms and manifestations[1]
- Commonly experienced symptoms include mouth dryness, eye dryness, fatigue, joint pain, and vaginal dryness, which may substantially affect patients' health-related quality of life (HRQoL)[1,2]
- Patients may experience impacts across multiple domains of daily life, including physical functioning, activities of daily living (ADL), emotional and social well-being, work, and overall HRQoL[2,3]
- Despite the substantial burden associated with SjD, there remains a high unmet need for new treatment options[1,2]
- The Phase 2 DAHLIAS study (NCT04968912) was a multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of nipocalimab, a treatment being developed for SjD
  - Participants were randomly assigned 1:1:1 to receive intravenous nipocalimab at 5 mg/kg or 15 mg/kg or placebo[4]
- Within-trial qualitative exit interviews were conducted, in alignment with regulatory guidance on patient-focused drug development, to assess patient experience[5]

Objectives

To assess patient experience with treatment, satisfaction with treatment, and experience of change in symptoms or impacts over the course of the phase 2 DAHLIAS trial

Methods

Study Design

- All enrolled participants of the Phase 2 DAHLIAS study were invited to participate in the qualitative exit interview (**Figure 1**)
- Interviews were conducted within 2 weeks after the Week 24 end-of-treatment visit; participants who discontinued early were eligible after Week 2
  - In special circumstances, interviews were conducted up to Week 30 safety visit
- One-to-one, semi-structured interviews of up to 60 minutes were conducted in participants' local language via telephone/teleconference; interviews were audio recorded, transcribed verbatim, and translated into English when required

Open-ended questions and probes explored:

- SjD symptoms and symptom changes
- Impact on daily life/HRQoL
- Treatment experience and satisfaction

- Thematic analysis was conducted using NVivo v1.6 by 3 qualitative researchers independent of the clinical trial.
- Participants and researchers were blinded to treatment assignment

Figure 1. DAHLIAS Clinical Trial and Exit Interview Sub-Study[a]

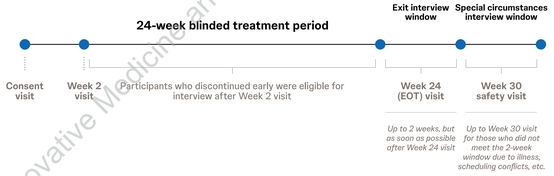


*Figure adapted from the DAHLIAS clinical trial and exit interview sub-study materials. [a]One participant completed an interview but discontinued the trial early. **EOT**=End of treatment, **HRQoL**=health-related quality of life, **SjD**=Sjögren's disease.*

Results

Exit interview participant profile

- Of 163 DAHLIAS participants, 49 (30.1%) completed the exit interview
- At baseline, 57.1% had moderate and 34.7% had severe SjD (**Table 1**)

Table 1. Demographic and baseline characteristics of participants completing exit interviews[a]

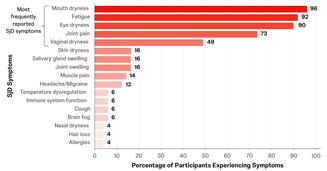
Characteristics	Total interview sample (N=49)
Age, years, mean (SD)	48.6 (11.08)
Sex, female, n (%)	46 (93.9)
Country, n (%)	
Poland	23 (46.9)
United States	16 (32.7)
Germany	5 (10.2)
Taiwan	2 (4.1)
France	2 (4.1)
Japan	1 (2.0)
Baseline SjD severity, n (%)	
Mild	2 (4.1)
Moderate	28 (57.1)
Severe	17 (34.7)
Very severe	2 (4.1)

*[a]Overall, characteristics of participants who competed the exit interviews were largely representative of the total DAHLIAS population[4]. **SD**=standard deviation, **SjD**=Sjögren's disease.*

Participant-reported SjD symptoms

- A broad and heterogeneous symptom burden was reported, with 25 SjD symptoms identified across interviews (**Figure 2**)
- Five core SjD symptoms emerged as the most frequently reported: mouth dryness, eye dryness, fatigue, joint pain, and vaginal dryness (**Figure 2**)

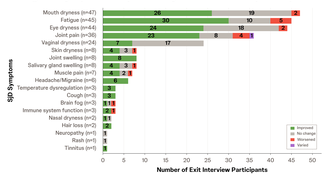
Figure 2. Frequency of participant-reported SjD symptoms (N=49)



SjD=Sjögren's disease.

- Improvement was the most commonly reported direction of change among majority of the core symptoms (**Figure 3**)

Figure 3. Change in symptoms reported by exit interview participants[a]



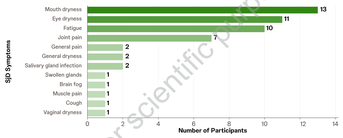
*[a]Since the start of the trial. **SjD**=Sjögren's disease.*

Symptoms participants considered important to change and symptoms affected by daily life and HRQoL

Symptoms considered most important to change

- Participants mostly prioritized core SjD symptoms as key targets for improvement, highlighting the importance of patient-reported priorities when evaluating treatment benefit (**Figure 4**)
- Overall improvement in SjD was meaningful to participants, with benefits reflected in reduced symptom burden, fewer limitations in daily functioning, and better emotional well-being

Figure 4. Most important symptoms that participants wanted to change as a result of treatment[a,b]

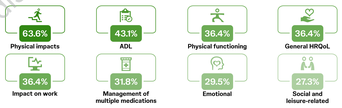


*[a]Participants could describe more than one "most important" change. [b]Twenty-nine participants were asked; two participants did not respond to the questions. **SjD**=Sjögren's disease.*

Symptoms affected by daily life and HRQoL

- SjD symptom improvements were associated with better physical functioning, ADL, emotional/social well-being, work, and overall HRQoL (**Figure 5**)

Figure 5. Frequency of SjD related impacts

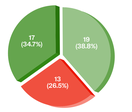


***ADL**=activities of daily living, **HRQoL**=health-related quality of life, **SjD**=Sjögren's disease.*

Participants' reported overall level of satisfaction

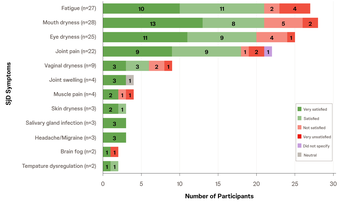
- **73.5%** of participants were satisfied or very satisfied with the study drug (**Figure 6**)
- Perceived treatment effectiveness was the key driver of satisfaction, with efficacy described in terms of improved symptoms and HRQoL (**Figure 7**)
- The biggest advantage of the study drug was perceived efficacy, while time burden associated with receiving the study drug was identified as the biggest disadvantage

Figure 6. Participants' reported overall level of satisfaction[a,b]



[a]Participant responses to the questions "How would you describe your overall level of satisfaction with the study drug?" Very satisfied, satisfied, not satisfied or very unsatisfied". [b]As the data were blinded, participants may have received the placebo or active treatment.

Figure 7. Participants' reported overall level of satisfaction with individual symptom change

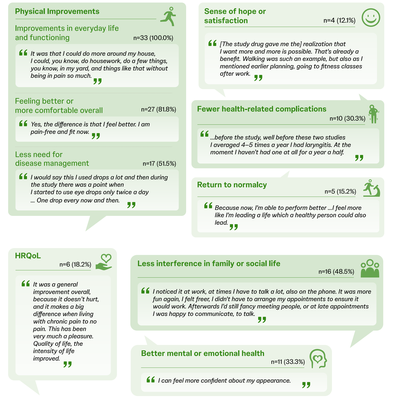


SjD=Sjögren's disease.

Improvements in HRQoL

- Improvements in symptoms were associated with beneficial impacts across key HRQoL domains, including physical, social, and emotional well-being (**Figure 8**)

Figure 8. Improvements in HRQoL by interview participants

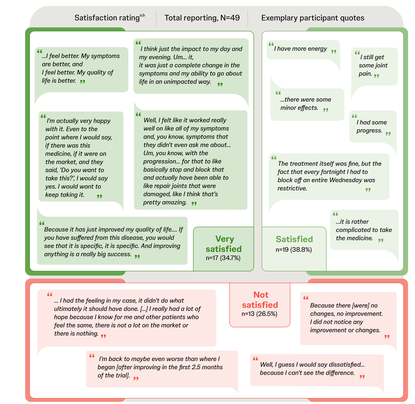


*[a]Total number of participants who discussed improved HRQoL. [b]Participants could indicate more than 1 type of HRQoL improvement. **HRQoL**=health-related quality of life.*

Qualitative context for treatment satisfaction

- Treatment satisfaction was driven by perceived improvements in symptoms, HRQoL, energy, and daily functioning, whereas dissatisfaction reflected limited or absent improvement and ongoing symptoms or treatment burden (**Figure 9**)

Figure 9. Participant description of their level of satisfaction



[a]As treatment allocation was blinded, it is unknown which participants received treatment versus placebo. [b]None of the participants reported "Very Unsatisfied."

PRESENTED AT: The American College of Rheumatology (ACR) Convergence 2026; November 6–11, 2026; Orlando, Florida, USA. **REFERENCES: 1.** Baldini C, et al. *Nat Rev Rheumatol.* 2024;20:473–491. **2.** Hamilton KM, et al. *RMD Open.* 2017;3:e000443. **3.** Meijer JM, et al. *Rheumatology (Oxford).* 2012;51:1281–1294. **4.** Noaiseh G, et al. *Lancet.* 2025;406:2435–2448. **5.** US FDA. Patient-focused drug development: methods to identify what is important to patients guidance for industry. February 2022. https://www.fda.gov/media/131230/download. 2022. **ACKNOWLEDGMENTS:** Medical writing support was provided by Rajani Thakur, PhD, of SIRO Medical Writing Pvt. Ltd., India, under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). Anthony Gaba, PhD, of Janssen and Johnson, provided additional editorial support. Layout design and formatting for this presentation were provided by Sanjita Warang of SIRO Medical Writing Pvt. Ltd., India (funded by Johnson & Johnson). **DISCLOSURES: Ghaith Noaiseh** has consulted for argenx, Vor Bio, Amgen, First Tracks (formerly Anaptys), Bristol Myers Squibb, Galapagos, Gilead, Johnson & Johnson, Eli Lilly, MSD, Novartis, Pfizer, Sanofi, and UCB. **Jennifer Clegg, Traci Abraham,** and **Coleen Del Rosario** are employees of Clinical Outcomes Solutions. **Claire Burbridge** was employed with Clinical Outcomes Solutions when this study was performed. **Harman Dhatt, Kayla Scippa, Jonathan J. Hubbard** and **Kim Campbell** are employees of Johnson & Johnson and may hold stock/stock options in Johnson & Johnson. **FUNDING:** This work was funded by Johnson & Johnson. **PREVIOUSLY PRESENTED AT:** The 17th International Symposium on Sjögren's Disease (ISSJD); September 28–October 2, 2026; Paris, France.