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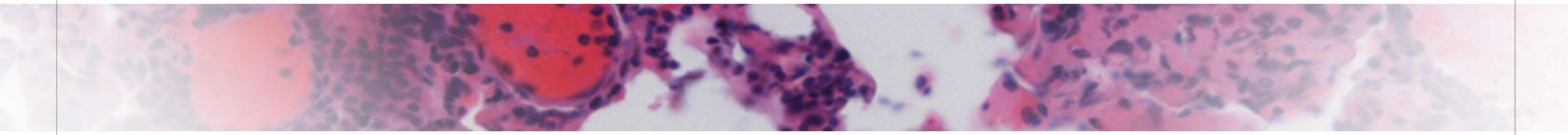

Health-Related Quality of Life in Patients with Relapsed/Refractory Cutaneous T-cell Lymphoma Treated by Lacutamab: **Patient-Reported Outcomes from the Phase 2 TELLOMAK Trial**

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NCI Cancer Center
A Cancer Center Designated by the National Cancer Institute

Health-Related Quality of Life in Patients with Relapsed/Refractory Cutaneous T-cell Lymphoma Treated by Lacutamab: **Patient-Reported Outcomes from the Phase 2 TELLOMAK Trial**

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Clinicaltrials.gov: NCT03902184

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Introduction

LACUTAMAB

- Lacutamab is a first in class depleting antibody targeting KIR3DL2.

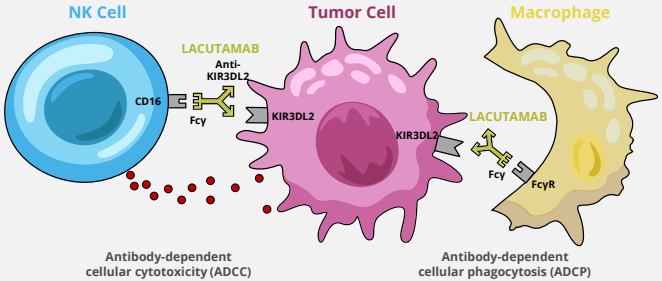


Figure 1: Lacutamab Mechanism of Action

- Orphan drug designation for the treatment of CTCL (EMA and FDA), PRIME (EMA) and Fast Track (FDA) designation for SS patients who have been treated by at least 2 prior systemic therapy.

TELLOMAK trial - NCT03902184

- Lacutamab is in development for the treatment of T-cell Lymphoma including CTCL (Sezary Syndrome [SS] and Mycosis Fungoides [MF]) in the Phase 2 TELLOMAK study:

Cohort 1 SS (N~60)	Cohorts MF (N~100) KIR3DL2 ≥ 1% or KIR3DL2 < 1%

Treatment
- Lacutamab Q1W for 5 wks, Q2W for 10 administrations then Q4W until disease progression or unacceptable toxicity

Key Eligibility Criteria
- Relapsed and/or refractory stage IVA, IVB SS (B2 blood by central flow at screening) or stage IB-IV MF
- At least 2 prior systemic therapies including mogamulizumab for SS patients
- No evidence of large cell transformation (LCT), based on central histologic evaluation at screening

Study Endpoints
- Primary endpoint: global ORR
- Secondary endpoints: PFS, OS, DoR, safety and tolerability, PK & immunogenicity
- Patient-reported Quality of Life assessed by SKINDEX-29 questionnaire, pruritus assessed by VAS

- Clinical Efficacy and Safety Data confirms the robust clinical activity of lacutamab with a favorable safety profile*. Long-term Follow-up of key study endpoints is ongoing.
- Here, we focus on Quality of Life, a key secondary endpoint.

* ASH 2023 (SS) and ASCO 2024 (MF)

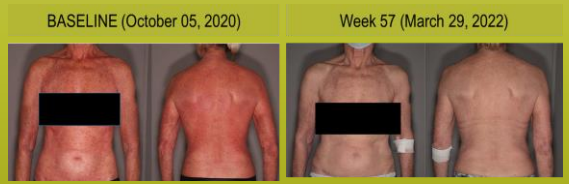
Quality of Life

Rationale

- Patients with advanced and heavily pretreated relapsed/refractory CTCL have poor health-related quality of life (HRQoL) and limited treatment options.
- Patients suffer from debilitating itching, skin redness which, together with their underlying disease has a profound effect on social wellbeing and a major impact on QoL.

Patient case

Global PR at W5, global CR from W37



Quality of Life in TELLOMAK

- Assessments were performed at baseline, W5 then Q8W until week 45 then Q12W, and reported with descriptive statistics, focusing on two measures:

Pruritus

By VAS

- Presence and severity assessed using a 10-point **visual analogue scale (VAS**) ranging from 0 (no itch) to 10 (worst imaginable itch).

HRQoL

By Skindex-29

- **Skindex-29** questionnaire inquiries about how often during the previous 4 weeks the patient experienced the effect described in each item, grouped into 3 domains (Symptoms, Functioning and Emotions).
- Domains and overall score are expressed on a 100-point scale, with higher scores indicating worse QoL.

TELLOMAK - Baseline Characteristics

* SS DCO 01MAY23 **MF DCO 13OCT23

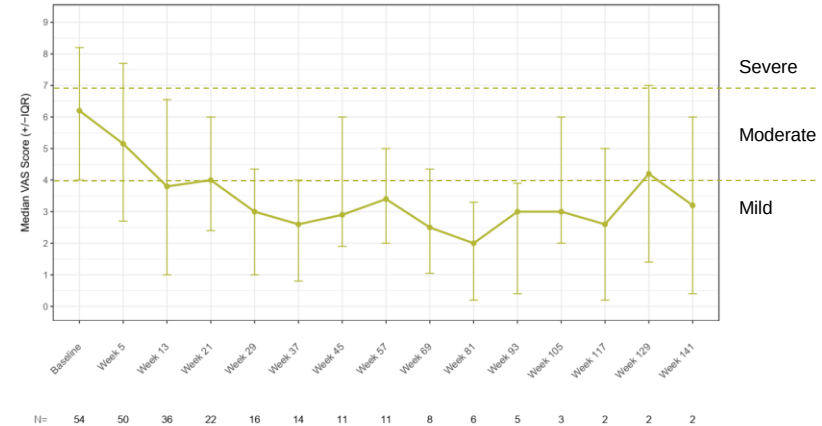
Patient Characteristics	Cohort SS* N=56	Cohorts MF** N=107
Age in years, median (range)	69 (42-86)	62 (19-82)
Male, n (%)	34 (60.7)	72 (67.3)
Stage at screening, I-II n (%) III-IV n (%) **T4, n (%)**	0 (0.0) 56 (100) **38 (67.9)**	82 (76.6) 25 (23.4) **17 (15.9)**
Follow-up in months, median (95% CI)	14.4 (9.0-18.4)	11.8 (9.9, 13.8)
ORR, % (95% CI)	37.5 (26.0-50.6)	16.8 (10.9, 25.0)
PFS in months, median (95%CI)	8.0 (4.7-21.2)	10.2 (6.5, 16.8)
VAS at baseline, median, IQR	**6.2 (4.0; 8.2)**	**6.0 (3.2; 8.2)**
Skindex-29 at baseline, median, IRQ Global score Low <25, n (%) Mild (25-32), n (%) Moderate (32-44), n (%) **Severe >44, n (%)**	**52.7 (30.0; 63.3)** 7 (12.5) 7 (12.5) 6 (10.7) **32 (57.1)**	**56.3 (35.8; 67.7)** 12 (11.2) 7 (6.5) 10 (9.3) **64 (59.8)**

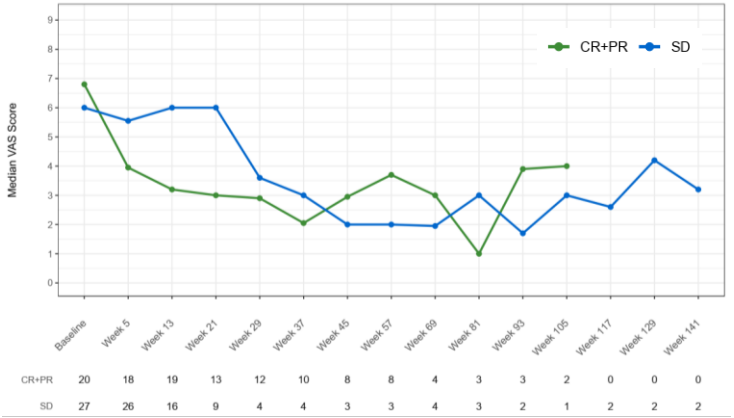
IQR interquartile range

Pruritus in Sezary Syndrome

- Pruritus elevated at baseline (VAS 6.2) with 25% of patients having very severe score VAS>8.2
- **Early** decrease of itch intensity starting from W5
- **Deep** and clinically meaningful decrease ≥2 points in VAS scale from W13 (VAS<4, mild pruritus) maintained over time
- **Improvement** is observed not only -and earlier- in responder patients but as well -and later on- in SS patients with stable disease

VAS





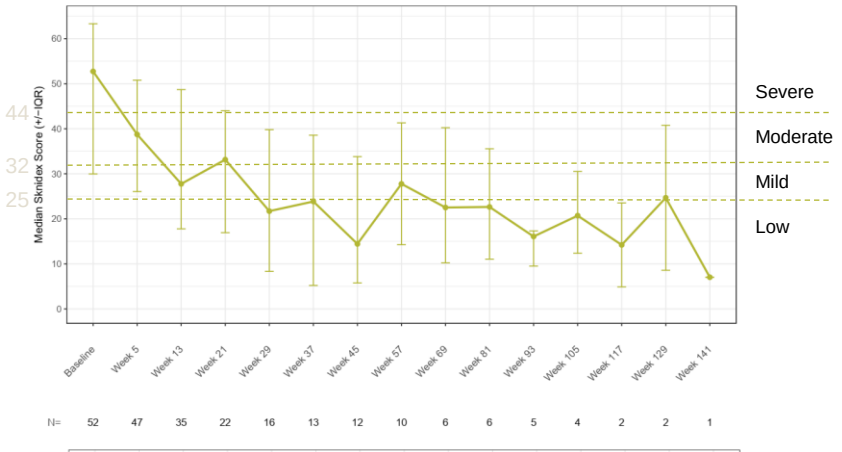
IQR interquartile range

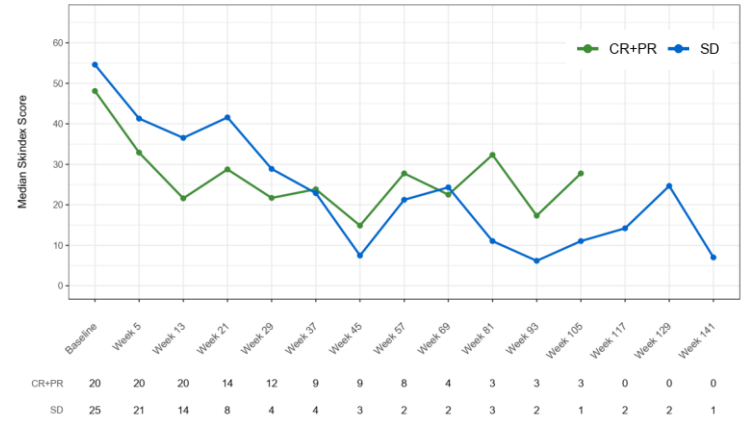
*PD pts are not represented in the graph by response

Skindex-29 in SS

- **Severe** global score at baseline (52.7)
- **Early** decrease to moderate score starting from W5
- **Continuous** and deep decrease to mild or low score maintained over time (i.e. 27.8 at W13 then 14.4 at W45)
- **Improvement** is observed not only in responder patients but as well as in SS patients with stable disease

Skindex-29



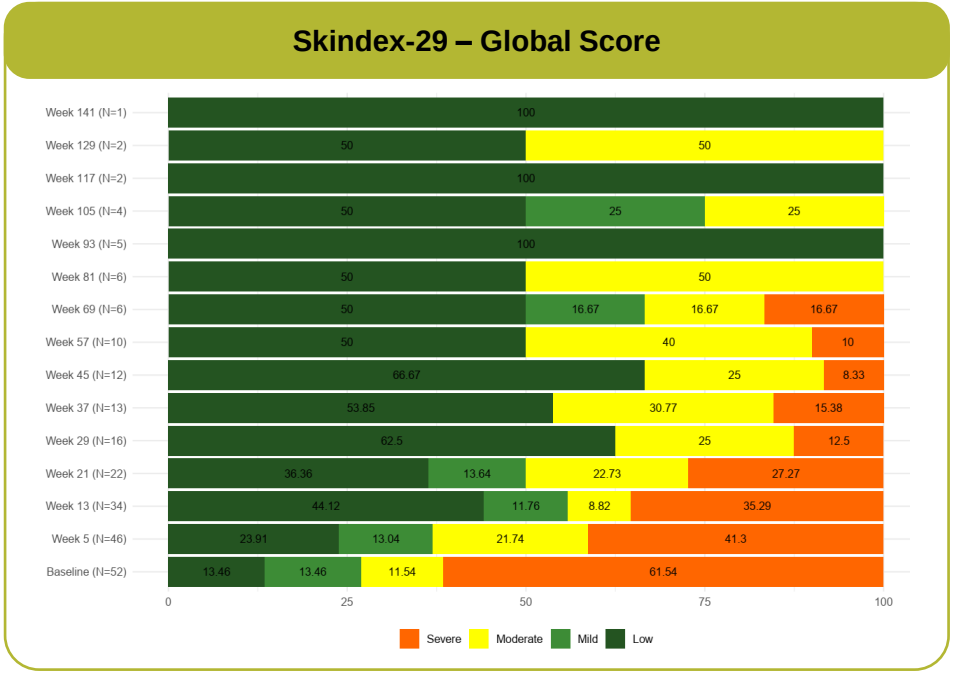


IQR interquartile range

*PD pts are not represented in the graph by response

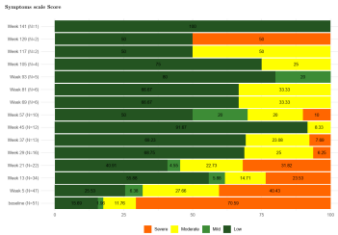
Skindex-29 in SS and by domain

- **Severe** global scores for most (61.5%) of the patients at baseline decreasing down to <20% of patients from W29 and none from W81

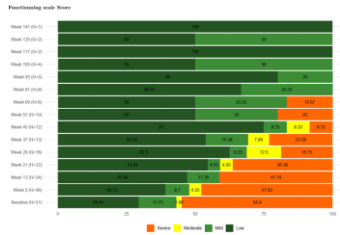


- Severe scores reported **in all 3 domains** for majority of patients at baseline, with improvement observed in all 3 domains, and more pronounced on functioning and symptoms

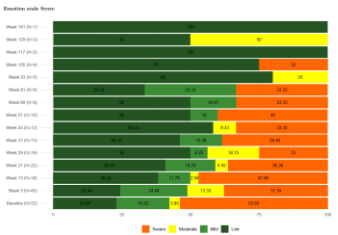
Symptoms



Functioning



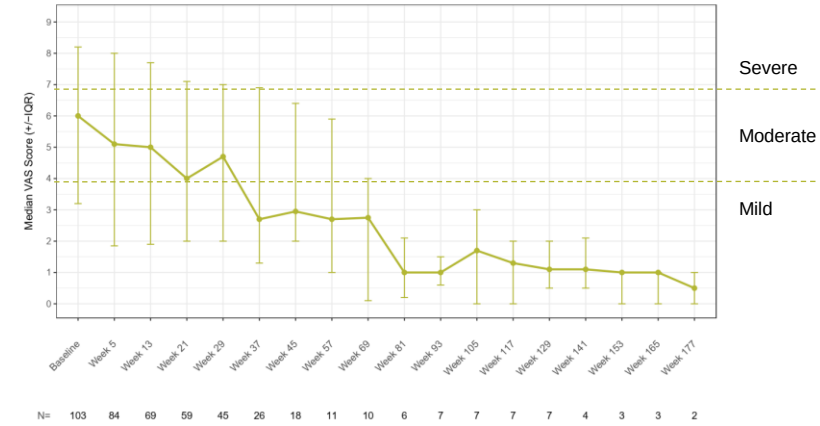
Emotions



Pruritus in Mycosis Fungoides

- Pruritus elevated at baseline (VAS=6) with 25% of patients having very severe score of VAS>8.2
- **Early** and slight improvement of itch intensity from W5 (VAS=5)
- **Continuous** and deeper clinically meaningful decrease from W37 (VAS<4, mild pruritus) maintained over time
- **Improvement** is observed early in responder patients but also later in MF patients with stable disease

VAS



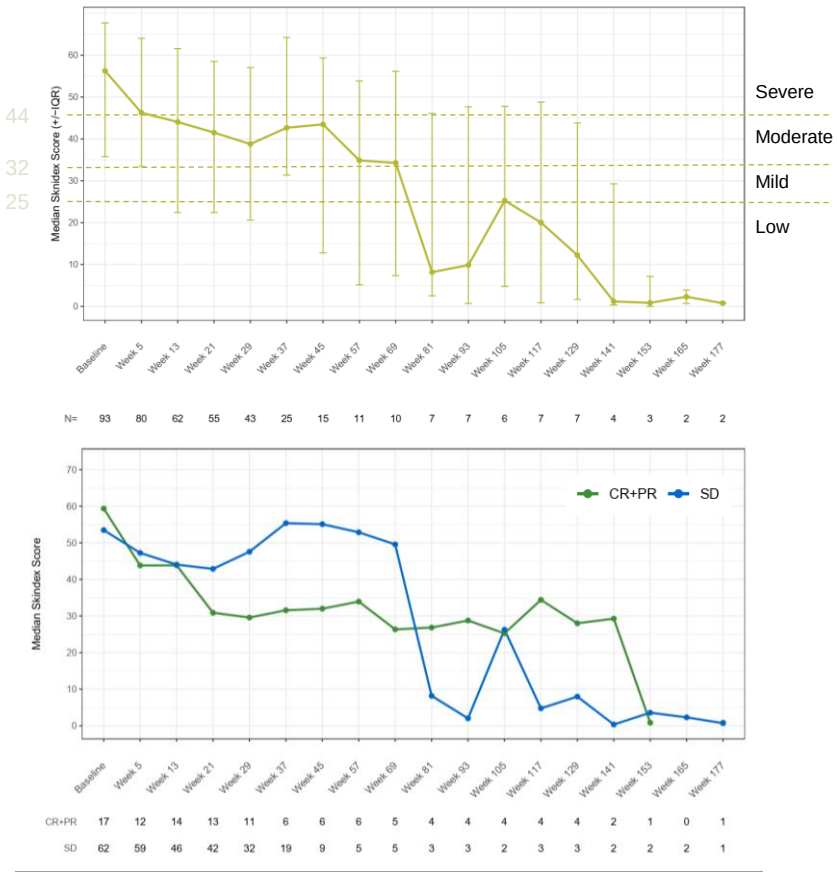
IQR interquartile range

*PD pts are not represented in the graph by response

Skindex-29 in MF

- **Severe** global score at baseline (56.3)
- **Early** slight decrease starting from W5 (46.3)
- **Continuous** and deeper decrease to moderate score from W13 (eg 38.8 at W29) then low score
- **Improvement** is observed earlier in responder patients and also later in MF patients with stable disease

Skindex-29



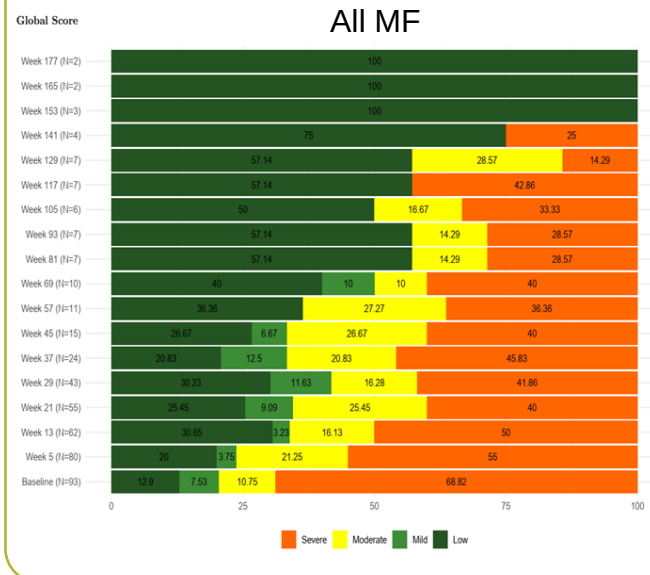
IQR interquartile range

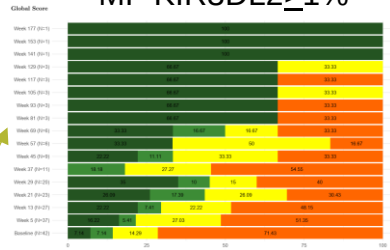
*PD pts are not represented in the graph by response

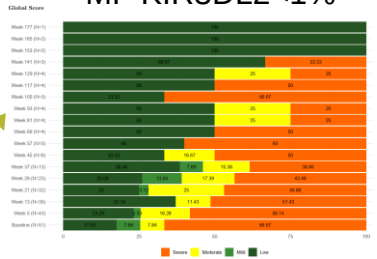
Skindex-29 in MF

- **Severe** global scores for most (68.8%) of the patients at baseline decreasing to 40% or less of the patients from W45
- Severe score reported regardless of KIR3DL2 expression for majority of MF patients at baseline
- Severe score were reported **in all 3 domains** for majority of MF patients at baseline with improvement observed in all 3 domains

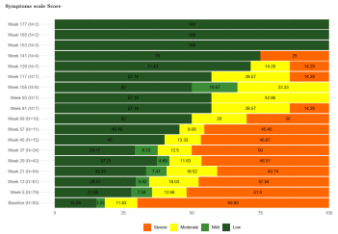
Skindex-29 – Global Score



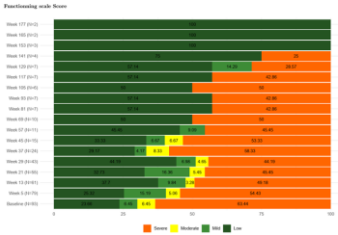




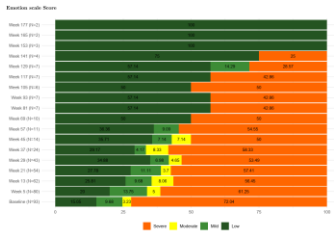
Symptoms



Functioning



Emotions



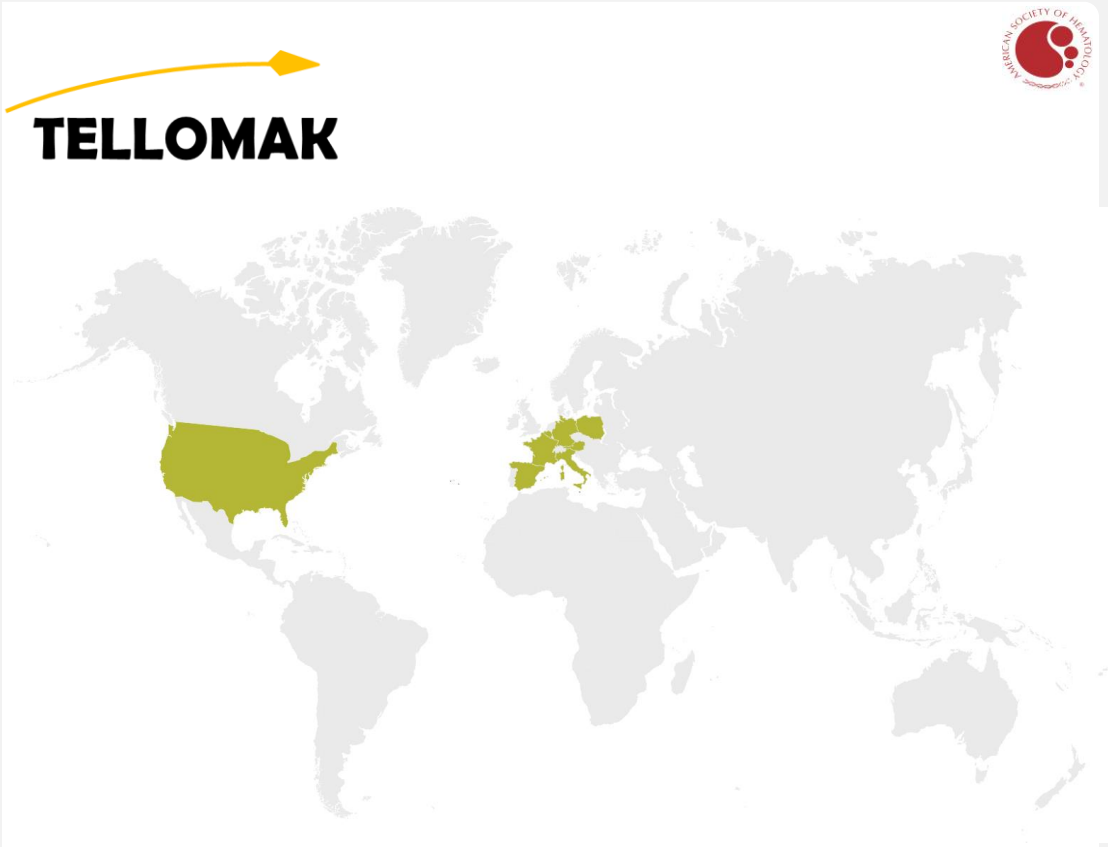
TELLOMAK Health Related Quality of Life Conclusions

- TELLOMAK is a Phase 2 study evaluating lacutamab monotherapy in CTCL. The study showed a robust clinical activity of lacutamab with a favorable safety profile.
- Quality of Life assessments in TELLOMAK focused on changes in pruritus and skindex-29 in SS and MF patients treated with lacutamab.
- Patients had high pruritus and poor QoL at baseline. Meaningful improvements from baseline in overall HRQoL and in pruritus intensity were observed, with durable improvements from Week 5 and sustained over time, not only in responder patients but as well as in patients with stable disease, who benefit from lacutamab.
- These favorable HRQoL results complement the efficacy and safety profile of lacutamab, highlighting its potential as a compelling future treatment option for CTCL patients with unmet need.

TELLOMAK
With Thanks

53 active sites

- USA (17)
- France (10)
- Germany (8)
- Spain (6)
- Italy (4)
- Belgium (3)
- Poland (3)
- Austria (2)



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Study sponsored by Innate Pharma

TELLOMAK

Acknowledgment

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