Poster ID: Tre-P-30

French real-life retrospective study in patients with Mycosis Fungoides and Sézary Syndrome treated by Mogamulizumab

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Background

Mogamulizumab is a defucosylated monoclonal antibody targeting the C-C chemokine receptor 4 (CCR4) and approved for the treatment of adult patients with mycosis fungoides (MF) and Sézary syndrome (SS) who have received at least one prior systemic therapy.
The efficacy of mogamulizumab was demonstrated in the open-label, phase 3 MAVORIC clinical trial[1] comparing mogamulizumab to vorinostat.

This retrospective observational study was conducted in 14 French centres to further assess efficacy and safety of mogamulizumab in a real-life setting.

Methods

Settings: data collection from medical records of MF and SS patients treated with mogamulizumab between February 2014 and March 2020 in 14 French centres.

Patients:

- Treated or having been treated with mogamulizumab, including 20 patients of the MAVORIC trial still alive at the end of the trial;
- No objection to personal data collection.

Primary endpoint: efficacy based on the percentage of patients achieving complete (CR) or partial (PR) response according to the Global Response Score for MF/SS[2,3] at mogamulizumab best response (overall response rate - ORR).

Secondary endpoints:

- Responses per compartments (blood, skin, viscera, lymph nodes) at mogamulizumab best response;
- Safety: number and type of adverse events.

Results

Table 1. Baseline characteristics

	Mycosis Fongoides (n=55)	Sézary syndrome (n=69)	Total population (n=124)
Age group			
• < 65 years (n, %)	19 35%	20 29%	39 32%
• ≥ 65 years (n, %)	36 65%	49 71%	85 68%
Sex			
Male (n, %)	30 55%	32 46%	62 50%
Female (n, %)	25 45%	37 54%	62 50%
Time from initial diagnostics (years) (m ± SD)	4.8 ± 3.4	2.8 ± 3.1	3.7 ± 3.4
Number of previous systemic therapies (m ± SD; median)	4.7 ± 3.0 4.0	3.6 ± 2.8 3.0	3.6 ± 2.8 3.0

Figure 1A. Disease stages at mogamulizumab initiation: clinical stages in total population (n=119)

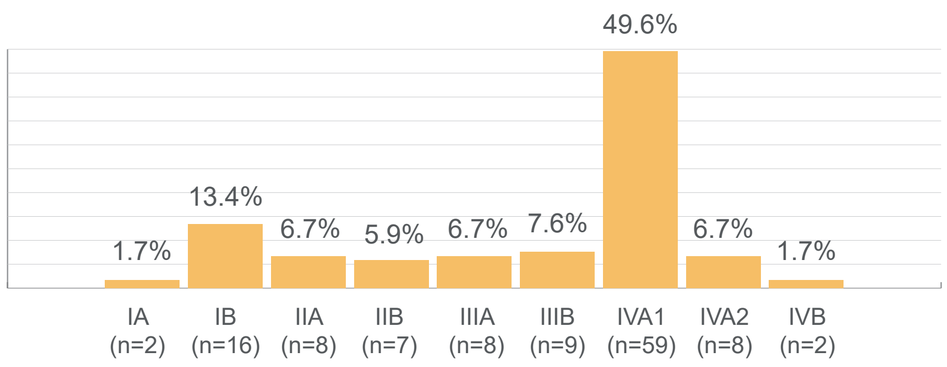
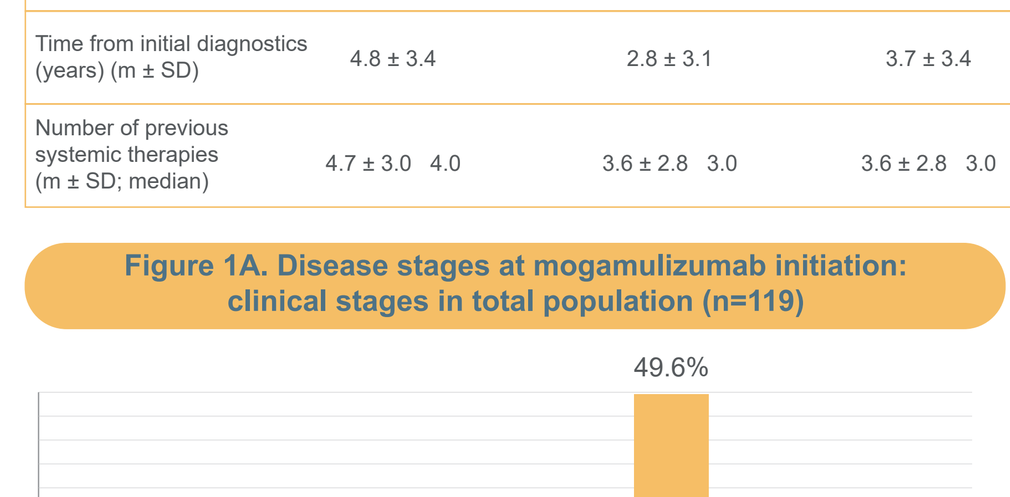


Figure 1B. TNMB stages in total population (n=119)

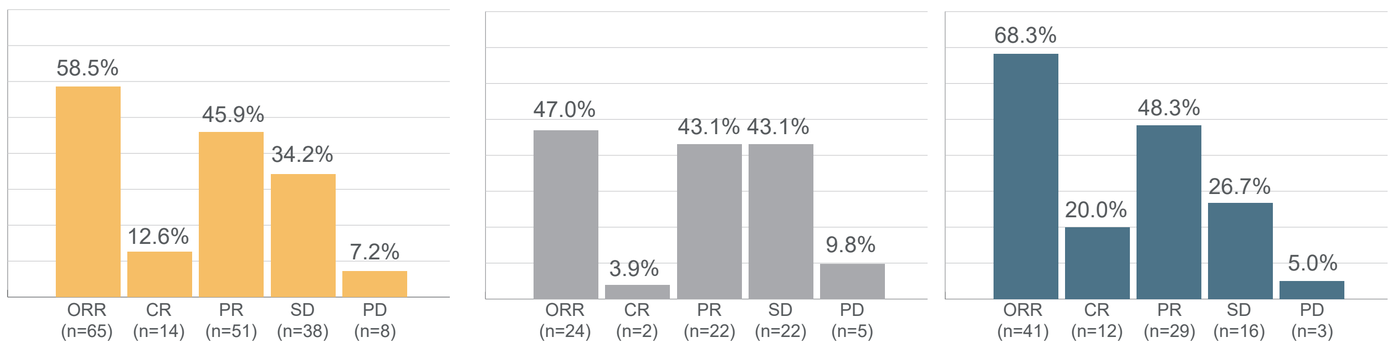


Biological data

- 8/72* (11%) patients with cell transformation

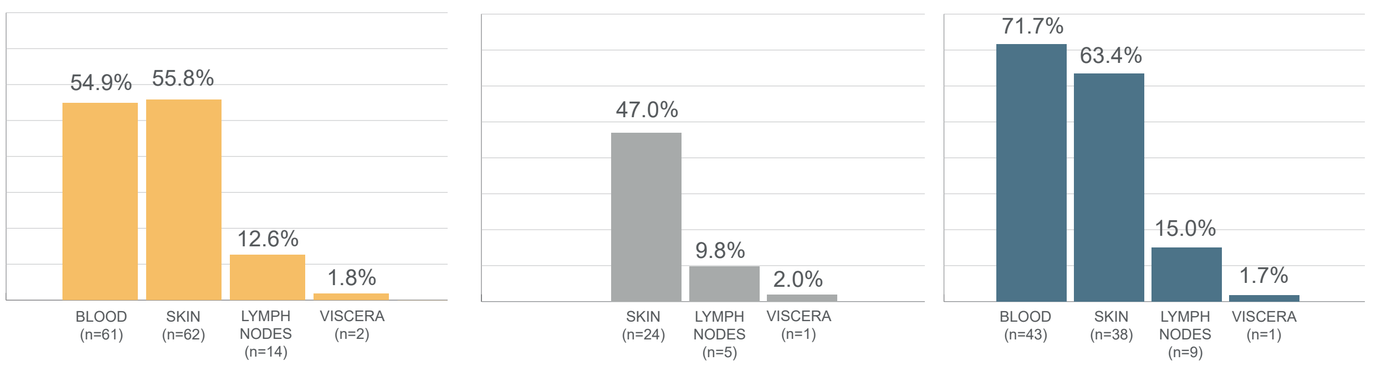
*Based on available data

Figure 2. Best overall response obtained with mogamulizumab



Time to best response: 2.4 months (median)

Figure 3. Compartment response at mogamulizumab best response: CR + PR in blood, skin, lymph nodes and viscera



N.B. Due to limited number of patients with lymph nodes or viscera involvement, the NA data represent 76/111 (68%) in lymph nodes and 99/111 (89%) in viscera.

Table 2. Safety

Adverse Events (AE) occurence	n	%
Skin and subcutaneous tissue disorders	45	**24%**
• Rash / Drug eruption	23	12%
Blood and lymphatic system disorders	39	**21%**
• Lymphopenia	29	16%
• Thrompocytopenia	5	3%
General disorders and administration site conditions	30	**16%**
• Asthenia	25	13%
• Pyrexia	5	3%
Infusion-Related Reactions	**17**	**9%**
Gastrointestinal disorders	14	8%
Metabolism and nutrition disorders	11	6%
Musculoskeletal and connective tissue disorders	8	4%
Hepatobiliary disorders	7	4%
Respiratory, thoracic and mediastinal disorders	3	2%
Nervous system disorders	3	2%
Investigations	2	1%
Infections and infestations	2	1%
Immune system disorders	1	<1%
Ear and labyrinth disorders	1	<1%
Renal and urinary disorders	1	<1%
Endocrine disorders	1	<1%

Infusion-Related Reactions (IRR) (n=17)*	n	%
Cycle 1 - Infusion 1	15	88%
Cycle 1 - Infusion 2	2	12%
IRR < 24h	17	100%
Grade 3	3	18%
Interrupted infusion	2	12%
Mogamulizumab discontinuation	0	0%

*17 IRR occured in 15/124 patients (12%).

7 patients passed away (6%) due to:

- Treatment-related: 0
- Disease progressions: 5 (Stage IIB: 1 ; Stage IVA1: 3 ; Stage IVA2: 1)
- Sepsis: 2

Acknowledgments

Research implementation was performed by CEN CRO (Dijon, France), and was funded by Kyowa Kirin, Inc.

References

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Conclusion

- **This real-life survey shows both a significant ORR (59% in total population) and a favourable safety profile in MF and SS patients treated with mogamulizumab.**
- **The shown data are consistent with those observed in MAVORIC study:**
  - **Best overall global response vs MAVORIC: = 47% vs 21% in MF; 68% vs 37% in SS**
  - **IRR in total population vs MAVORIC: 12% vs 34%**
  - **Most common AE: Rash, IRR, asthenia and lymphopenia**