P1148 REAL WORLD DATA (RWD) AMONG FOLLICULAR LYMPHOMA (FL) PATIENTS IN GERMANY WITH AT LEAST TWO PRIOR LINES OF SYSTEMIC THERAPY AND COMPARISON WITH CLINICAL DATA FOR MOSUNETUZUMAB

**Topic:** 18. Indolent and mantle-cell non-Hodgkin lymphoma - Clinical

**Aims:** This study summarizes RWD in pts with 3L+ FL utilizing the Tumor Registry Lymphatic Neoplasms extension (TLNext) and plans to perform a matching-adjusted indirect comparison (MAIC) between the M SAT and TLNext.

**Methods:** TLN was a multicenter, longitudinal, observational, prospective cohort study collecting data from medical charts of pts with lymphoid B-cell neoplasms receiving care at office-based hematology practices in Germany (NCT00889798; Knauf et al. 2019). Patients were enrolled between 2009–14 and followed for up to 5 years. TLNext collected additional data up to November 2021 from consented pts originally enrolled in TLN as well as additional newly-consented pts with 3L+ FL. Baseline characteristics, treatment patterns, and outcomes were summarized for pts with 3L+ FL in TLNext. A MAIC is planned between the M SAT and a TLNext cohort selected by applying key eligibility criteria from the M SAT. An index line of therapy (LoT) will be selected for all pts with more than one known relapse or refractory status (Table). Latest recorded LoT was selected as the index therapy for every patient. Compared to M SAT, the TLNext cohort was slightly older and had more female pts. A higher proportion of pts in TLNext had received only 2 prior LoT. Overall, M SAT had a higher proportion of pts with factors known to be associated with poorer outcomes in 3L+ FL, e.g. refractory to prior anti-CD20 therapy, double-refractory to prior anti-CD20 therapy and alkylator therapy. The most common regimens in the TLNext cohort were bendamustine-like regimens (34%), PI3K-like regimens (15%), and anti-CD20 mono-therapy (14%). Comparative MAIC analyses are ongoing.

**Results:** TLNext included 69 pts who had received 112 documented LoTs in 3L+ FL. Median follow-up was 40 months from the start of the 3rd LoT. 65 pts had received an anti-CD20 therapy and an alkylator therapy prior to index therapy and had a known relapse or refractory status (Table). Latest recorded LoT was selected as the index therapy for every patient. Compared to M SAT, the TLNext cohort was slightly older and had more female pts. A higher proportion of pts in TLNext had received only 2 prior LoT. Overall, M SAT had a higher proportion of pts with factors known to be associated with poorer outcomes in 3L+ FL, e.g. refractory to prior anti-CD20 therapy, double-refractory to prior anti-CD20 therapy and alkylator therapy. The most common regimens in the TLNext cohort were bendamustine-like regimens (34%), PI3K-like regimens (15%), and anti-CD20 mono-therapy (14%). Comparative MAIC analyses are ongoing.

**Image:**

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| Table: Baseline characteristics and key prognostic factors at index therapy in the mosunetuzumab SAT and TLNext |
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|                                                                                                           |
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|                                                                                                           |
| | Sample size | Mosunetuzumab SAT | TLNext cohort |
| | Follow-up (months, median) | 18 | 18 |
| | Age (years, mean, SD) | 60.0 (12.0) | 69.1 (11.9) |
| | Female (n, %) | 35 (38.9) | 37 (56.9) |
| | POD24 (n, %) | 47 (52.2) | 33 (50.8) |
| | Prior lines of systemic therapy (n, %) | | |
| | 2 | 34 (37.8) | 42 (64.6) |
| | 3 | 28 (31.1) | 14 (21.5) |
| | ≥4 | 28 (31.1) | 9 (13.8) |
| | Time (months) since initial diagnosis to (index) therapy (mean, SD) | 94.5 (59.2) | 87.4 (62.3) |
| | Refractory¹ to prior anti-CD20 therapy (n, %) | 71 (78.9) | 42 (64.6) |
| | Refractory¹ to prior alkylator therapy (n, %) | 51 (56.7) | 29 (44.6) |
| | Refractory¹ to last prior systemic therapy (n, %) | 62 (68.9) | 30 (48.2) |
| | Double refractory¹,² (n, %) | 48 (53.3) | 28 (43.1) |
| | ECOG performance status (n, %) | | |
| | 0-1 | 90 (100.0) | 21 (32.3) |
| | ≥2 | 2 (3.1) | 42 (64.6) |
| | Unknown/not available | | |
| | Elevated LDH (n, %) | 35 (38.9) | 20 (30.8)³ |
| | Received therapy in clinical trial (n, %) | 90 (100.0) | 7 (10.8)⁴ |
| | Treatments (n, %) | | |
| | Mosunetuzumab | 90 (100.0) | 22 (33.8) |
| | Bendamustine-like +/- anti-CD20 | | 10 (15.4) |
| | PI3Kδ-like +/- anti-CD20 | | 9 (13.8) |
| | Anti-CD20 monotherapy | | 5 (7.7) |
| | LEN-like +/- anti-CD20 | | 4 (6.2) |
| | DHAP-like +/- anti-CD20 | | 15 (23.1) |
| | Other | | |

DHAP = regimen containing dexamethasone, high-dose cytarabine and cisplatin. ECOG = Eastern Cooperative Oncology Group. LDH = lactate dehydrogenase. LEN = lenalidomide. PI3Kδ = phosphoinositide 3-kinase inhibitor. POD24 = progression of disease within 24 months of initiating first systemic therapy for FL. SAT = single-arm trial. SD = standard deviation. TLNext = Updated extension Tumor Registry Lymphatic Neoplasms.

¹ Refractory status to a given therapy is defined as lack of complete or partial response as best response to the given therapy or progression within 6 months from the last treatment of the given therapy.

² Double refractory is defined as refractory to prior anti-CD20 and an alkylator therapy.

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Summary/Conclusion: TLNext represents a real-world 3L+ FL cohort from Germany that provides relevant context for the M SAT. TLNext outcomes data will be re-weighted using the MAIC approach to generate a descriptive benchmark for outcomes observed in M SAT. While comparisons between clinical trials and RWD carry several limitations pertaining to measurement, reporting of data, and choice of analytical approach to conduct the comparison, RWD from TLNext may be useful to describe a benchmark for clinical practice in 3L+ FL in Germany and globally prior to the availability of randomized evidence on newer treatment options like mosunetuzumab.