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# POSTER ABSTRACTS

## 624.HODGKIN LYMPHOMAS AND T/NK CELL LYMPHOMAS: CLINICAL AND EPIDEMIOLOGICAL

### Quality of Life with Nivolumab and AVD First-Line Treatment in Hodgkin Lymphoma: Patient-Reported Outcomes from the Phase II GHSG Nivahl Trial

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Background: First-line treatment of patients with classical Hodgkin lymphoma (HL) with anti-PD1 antibodies in combination with AVD chemotherapy is highly effective across risk-groups. Based on encouraging phase II and ongoing phase III trials, anti-PD1 based first-line treatment may hence soon become a first-line treatment option. To date, no patient-reported outcome (PRO) data is available in this setting, which is crucial to comprehensively evaluate relative benefits of these novel treatment approaches. Herein, we present the preplanned PRO analysis of quality of life (QoL), fatigue and life situation of HL patients treated within the randomized GHSG phase II NIVAHL trial.
Methods: NIVAHL enrolled 109 patients aged 18-60 years with first diagnosis of early-stage unfavorable HL to receive either fully concomitant (4xN-AVD; group A) or sequential (4xN, 2xN-AVD, 2xAVD; group B) nivolumab-based 1st-line treatment, each followed by 30Gy involved-site radiotherapy (IS-RT). The primary and final analyses showed excellent efficacy and an acceptable safety profile after 1- and 3-years of follow up; details were previously published (Bröckelmann et al. *JAMA Oncol* 2020 & *JCO* 2023). Patients providing separate informed consent reported QoL and Fatigue by the EORTC QLQC30 questionnaire in addition to key sociodemographic data including employment status at baseline and after systemic treatment, radiotherapy and 1- and 3-years of follow-up (FU), respectively. Data were analyzed descriptively and time-to-recovery (TTR) calculated for resolution of fatigue (TTR-F, event defined as first documentation of a fatigue score <30 after end-of-treatment (EOT)) and return to work (TTR-W, event defined as first documentation of employment after EOT).
Results: A total of 99 patients provided a median of 4 questionnaires per patient (range 1-11), with the vast majority (85%) providing baseline and at least one questionnaire during FU. Mean fatigue score was 22 points higher (95% confidence interval, CI 16.1-27.9) than the age- and sex-matched German reference population at baseline, worsened during treatment (+38.2, 95%CI 31.4-44.9) but improved over the course of FU (1-year +10.2, 95%CI 3.7-16.6) to normal values at 3-year FU (-3.4, 95%CI -10.7 to 3.9), without any differences between treatment groups. Similar trajectories were observed for global health status/QoL as well as the different functional and symptom scales. While improvement beyond baseline (79.6, 95%CI 76.5-82.7) was observed, global health status/QoL did not improve to age- and sex-matched reference values at 1- (87.2, 95%CI 83.2-91.2) and 3-year FU (92, 95%CI 87.8-96.2). Multiple regression analysis showed a significant effect of baseline score (ß 0.28-0.56) and age (ß 0.23-0.34) but not sex (p>0.2 each) on cognitive, emotional and social functional scales as well as fatigue at 1-year of FU. At 3-years of FU the effect of age remained significant (ß 0.48-0.66) for all functional or symptom scales except resolution of dyspnea, while baseline scores had no significant effect. More detailed analysis of the different

QLQ-C30 scales is ongoing and will be presented at the meeting. Median TTR-F and TTR-W were 12.8 (95%CI 7.3-20.3) and 3.8 months (95%CI 1.4-8.0) after EOT, respectively. Cox regression analysis for TTR-F showed significant effect of baseline fatigue (HR 0.99, p=0.03) but not sex (HR 1.71, p=0.09) or age (HR 0.98, p=0.14). For TTR-W, Cox regression did not show significant effects of baseline fatigue (HR 1, p=0.93) or age (HR 0.99, p=0.69) but a trend for faster return to work in male patients (HR 1.82, p=0.06).
Conclusion: This first ever analysis of PROs after anti-PD1 based first-line HL treatment with N-AVD indicates substantial improvement of functional and symptom scales as well as global health status/QoL at last FU compared to baseline. Baseline status and age have a significant effect for improvement of functioning and symptoms at 1-year of FU. Importantly, while substantial fatigue is present at baseline, relevant improvement with resolution to age- and sex-matched reference values is observed and recovery is influenced by baseline fatigue score.

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**OffLabel Disclosure:** Nivolumab is not currently approved for first-line treatment of Hodgkin lymphoma.

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