

## **Final Results of the International, Randomized Phase 3 Trial HD16 By the German Hodgkin Study Group**

### **Andreas Engert, MD**

Professor of Internal Medicine, Hematology, and Oncology  
University Hospital of Cologne  
Cologne, Germany

Hello from ASH. I want to share some new data from our group, German Hodgkin Study Group. The trial is called HD16 and it is a larger prospectively randomized trial in early favorable Hodgkin lymphoma. This is based on prior trials, HD13, but particularly HD10. HD10 defined our standard of care in early favorable Hodgkin's, and that is 2 cycles of ABVD followed by 20 Gy involved-field radiotherapy (IFRT). PET-guided trials were done in the past, in particular, in early favorable and early unfavorable Hodgkin's. The trials that were done by our British colleagues was RAPID and the EORTC/LYSA Italian colleagues' H10, and there were really controversies. The British said that is possible deleting radiotherapy and the EORTC said no, that is not possible. That is why we are happy to have a trial in that particular setting because there is still discussion going on, on interim PET, and that is why we performed this trial basically in early stage Hodgkin lymphoma patients.

This is a rather simple design. In the standard arm, all patients received 2 cycles of ABVD followed by 20 Gy involved field radiation, very similar to the HD10 trial; however, a PET was done after 2 cycles of chemotherapy and no reaction in the standard arm. In the PET guided arm, patients, who were PET negative did not receive any additional radiotherapy, the PET positive ones did. This is PET negative patients after 2 cycles of ABVD, and then one group had the standard, that is additional 20 Gy involved field radiation, and the experimental group did not. You can clearly see that there is a significant difference, 7.3% difference between those patients having the standard of care, very high PFS of more than 93% and the patients just receiving ABVD 2 cycles were at 86%. That is significant and this represents a difference of 10% after 5 years. So, really, meaningful if you do not want additional radiotherapy in this setting, you will have this higher risk of sort of relapse or progress and that has to be really taken into account. What we also did, we used the PET and evaluated the impact on different Deauville scores, and there you can see the Deauville score 1-3 is much better of giving much better outcomes as compared to the Deauville score 4. After 2 cycles of ABVD, you see, the difference is more than 12%, and that means that those patients who have a Deauville score of 4 have poor prognosis and we are just in the middle of discussing what to do. Should we treat these patients more aggressively with high-dose

chemotherapy or not or just radiation? That is something we will decide in the next weeks to come.

So, in brief summary, this is the HD16 trial, it is a PET-driven international multicenter trial in early favorable Hodgkin lymphoma patients, and the trial included a total of 1150 patients. These patients were randomized between the standard of care, that is 2 cycles of ABVD followed by 20 Gy involved field radiation, and in the experimental arm, patients just had 2 cycles of ABVD. There was a significantly poorer PFS in Hodgkin lymphoma patients treated without radiation. There were no differences and that is also important in terms of toxicity between patients receiving radiotherapy or not. Overall survival was on high level, and that was in part due to the effective second-line treatment, such as high-dose chemotherapy or multi-agent chemotherapy and so forth. Overall, we used Deauville scoring by the PET, and PET positive patients with a Deauville score of 4 did much worse than those with a Deauville score of 1, 2, and 3.

**Reference:**

Fuchs M, Goergen, Kobe C, et al. PET-Guided Treatment of Early-Stage Favorable Hodgkin Lymphoma: Final Results of the International, Randomized Phase 3 Trial HD16 By the German Hodgkin Study Group. ASH 2018. Abstract 925.