OSHO#069: Randomized phase III study comparing the OSHO arm to the standard intergroup arm - Efficacy of allogeneic stem cell transplantation in comparison to a second consolidation chemotherapy in elderly patients with newly diagnosed Acute Myeloid Leukemia (AML) in the age over 60 years

Publication of Results on clinicaltrials.gov

To whom it may concern:

The **"Randomized phase III study comparing the OSHO arm to the standard intergroup arm"**, registered on clincaltrials.gov (NCT01497002) is no ACT (applicable clinical trial) following the definition of clincaltrials.gov and thus not required to post results within a year of completion.

However, the authors clearly see the need to make the results publicly available and intend to do so following the acceptance of the main publication, which is currently under review by a major journal. Since the ICMJE-guidelines state that it is not possible to publish previously published results in a high-ranking journal, publication of the results on clincaltrials.gov will be delayed as indicated above.

For the time being, the abstract from the manuscript submitted for publication is cited below:

Different treatment strategies versus a common standard arm (CSA) in patients with newly diagnosed AML over the age of 60 years: a randomized German Intergroup study

Summary

A randomized intergroup trial comparing more intensive treatment strategies to a common standard arm 3+7 (CSA) was conducted in patients with non-M3 AML.

Untreated patients ≥60 years were allocated to the CSA (n=132) or to the study group arms (n=1154) of the AMLCG (TAD/HAM versus HAM/HAM ± G-CSF followed by TAD and maintenance) and the OSHO (intermediate-dose ara-C/mitoxantrone followed by ara-C/mitoxantrone).

Median age of the 1147 eligible patients was 69 (range 60-87) years. CR/CRi status at 90 days was not significantly different between the CSA [54% (95%CI:45-64)] and the study group arms [53% (95%CI:47-60) and 59% (95%CI:58-63)]. The five-year event-free survival (EFS) probability (primary endpoint) was 6.2% (95%CI:2.7-4.0) in the CSA, 7.6% (95%CI:4.5 to 12.8) in group A and 11.1% (95%CI:9.0 – 13.7) in B. The 5-year OS was 17.2% (95%CI:11.0-26.9), 17.0% (95%CI:2.0-23.9) and 19.5% (95%CI:16.7-22.8) in CSA, group A and B, respectively. Neither study group differed significantly from the

CSA regarding EFS, OS or relapse-free survival. In multivariate analyses, allocation to the treatment strategy was not significantly associated with the time-to-event endpoints.

The evaluation of more intensive treatment strategies did not show clinically relevant outcome differences when compared to CSA, but an overall improvement in comparison to previous publications."

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