Acute Myeloid Leukemia: Clinical Studies: Immunotherapy and New Agents

25 A Phase 1 First-in-Human Study of AMG 330, an Anti-CD33 Bispecific T-Cell Engager (BiTE®) Antibody Construct, in Relapsed/Refractory Acute Myeloid Leukemia (R/R AML)

Farhad Ravandi, et al.

The Abstract concludes: *Preliminary data of AMG 330 dosed up to 480 µg/d provide encouraging early evidence of tolerability and anti-leukemic activity in heavily pre-treated patients with R/R AML. Expected CRS was mitigated through step-up dosing, corticosteroid pretreatment, IV fluids, tocilizumab, and drug interruption if needed; most patients had short periods of CRS which responded well to treatment. A 2-step approach will be used in the future to quickly achieve the target dose and optimize clinical response. Regarding pharmacodynamics, to date, 2 CRs and 2 CRis have been observed at target doses of 120 and 240 µg/d. As nearly all patients were substantially cytopenic at baseline, it is challenging to evaluate the impact of AMG 330 on cytopenias. Of note, both CR patients had a complete recovery of blood counts after one cycle of treatment. These promising data validate the use of the BiTE® platform to target CD33.*

26 Maturing Clinical Profile of IMGN779, a Next-Generation CD33-Targeting Antibody-Drug Conjugate, in Patients with Relapsed or Refractory Acute Myeloid Leukemia

Jorge E. Cortes, MD, et al.

The Abstract concludes: *IMGN779 continues to display manageable tolerability and antileukemia activity in patients with relapsed or refractory AML, characterized by an adverse event profile that is consistent with the underlying disease and/or comorbidity. PK exposures and PD CD33 saturation continue to increase with dose and support further escalation of both Q2W and QW dosing schedules, which is ongoing.*

27 A Phase I, First-in-Human Study Evaluating the Safety and Preliminary Antileukemia Activity of IMGN632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Patients with Relapsed/Refractory Acute Myeloid Leukemia and Other CD123-Positive Hematologic Malignancies

Naval G. Daver, et al.

The Abstract concludes: *Objective responses (CR and CRis) were seen in one third of relapsed/refractory AML patients during the initial stages of dose escalation in this first-in-human clinical trial with IMGN632, a*

novel CD123-targeting ADC. No dose limiting toxicities have been observed, and PK and PD data support continued dose escalation, which is ongoing.

28 Outcomes Following Hematopoietic Stem Cell Transplantation in Patients Treated with Chemotherapy with or without Gemtuzumab Ozogamicin for Acute Myeloid Leukemia

Cécile Pautas, et al.

The Abstract concludes: *Similar post-transplant outcomes were observed in patients with AML treated with standard chemotherapy with and without GO. The use of GO was not associated with an excess of VOD events after HSCT. The results suggest that the administration of GO as part of induction and consolidation chemotherapy for AML does not induce excess post-transplant mortality and thus does not preclude the use of transplant as consolidation treatment following induction or salvage treatment.*

29 Phase II Trial of a Peptide Vaccine, Ocv-501 in Elderly Patients with Acute Myeloid Leukemia

Masaki Yamaguchi, et al.

The Abstract concludes: *There was no significant difference in DFS between OCV-501- and placebo-treated patients. OCV-501 was found to be generally safe and well-tolerated in elderly AML patients.*

30 Zella 201: A Biomarker-Guided Phase II Study of Alvocidib Followed By Cytarabine and Mitoxantrone in MCL-1 Dependent Relapsed/Refractory Acute Myeloid Leukemia (AML)

Joshua F Zeidner, et al.

The Abstract concludes: *Our findings indicate that alvocidib given beforecytarabine and mitoxantrone in MCL-1-dependent AML has clinical activity, particularly in those refractory to frontline therapy. Given these findings, stage 2 of the Zella 201 trial has been initiated,randomizing patients to alvocidib, cytarabine, and mitoxantrone versus cytarabine and mitoxantrone alone in MCL-1 dependent R/R AML. Furthermore, a Phase Ib study of alvocidib followed by 7+3 induction in newly diagnosed AML (Zella 101) is being conducted.*

oncoletter
ONLINEPORTAL FÜR ONKOLOGIE UND ONKOLOGISCHE HÄMATOLOGIE