616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Novel Therapies for Elderly Patients with AML

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Randomized Phase 2 Trial of Lirilumab (anti-KIR monoclonal antibody, mAb) As Maintenance Treatment in Elderly Patients (pts) with Acute Myeloid Leukemia (AML): Results of the Effikir Trial

Norbert Vey[1], Pierre-Yves Dumas, MD[2*], Christian Recher, MD, PhD[3], Lauris Gastaud, MD[4*], et al.

The authors of the study conclude that:

Single agent lirilumab administered for up to 24 cycles was well tolerated. Lirilumab did not result in a statistically significant improvement of LFS in the challenging setting of maintenance in AML in elderly pts. Immune-pharmacological studies will be presented. Potential hypotheses relevant for AML and lirilumab monotherapy (e.g. dosage/schedule optimization, partial desensitization by continuous KIR blockade leading to an impaired immunosurveillance by NK cells) for the non-significant trends will be discussed.

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Phase 1/2 Study of Venetoclax with Low-Dose Cytarabine in Treatment-Naive, Elderly Patients with Acute Myeloid Leukemia Unfit for Intensive Chemotherapy: 1-Year Outcomes

Andrew Wei, MBBS, PhD, FRACP, FRCPA[1], Stephen A. Strickland, MD, MSCI[2], Gail J. Roboz, MD[3], Jing-Zhou Hou, et al.

The authors of the study conclude that:

The safety profile of VEN 600 mg/day plus LDAC was acceptable for elderly patients with treatment-naive AML who were ineligible for intensive chemotherapy. After ≥1 year of follow-up, the observed median OS was 11.4 months. This cohort included 44% (27/61) of patients with AHDs. Corelations of specified AML mutations with response and duration should be confirmed in later trials. Due to the observced CR/CRi rate of 62%, extended duration of response, and encouraging OS in a cohort of patients with particularly poor-

risk features, the 600-mg dose of VEN combined with LDAC is being tested in an ongoing phase 3 study.

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Results of a Phase 3 Study of Elderly Patients with Newly Diagnosed AML Treated with Sapacitabine and Decitabine Administered in Alternating Cycles

Hagop M. Kantarjian, MD[1], Kebede H. Begna, MD[2], Jessica K. Altman, MD[3,4], Stuart L. Goldberg, MD[5], et al.

The authors of the study conclude that:

The regimen of sapacitabine administered in alternating cycles with decitabine was active and well tolerated but it did not significantly improve overall survival as compared to decitabine monotherapy. Further analyses are being conducted to characterize the subgroups of patients who appeared to have benefited from this treatment regimen and the potential cost savings associated with the use of an oral drug.

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Phase II Study of CPX-351 (Cytarabine: Daunorubicin) Liposome Injection in Patients (Pts) with Newly Diagnosed Acute Myeloid Leukemia (AML) at High Risk for Induction Mortality

Gautam Borthakur, MD[1], Hagop M. Kantarjian, MD[1], Courtney D. DiNardo, MD, MSc[1], Naval Daver, MD[1], E et al.

The authors of the study conclude that:

In a very high-risk elderly cohort of newly diagnosed pts with AML, CPX-351 induction yielded promising remission rates at all 3 doses tested. The efficacy, toxicity and early mortality profile favors the use of

CPX-351 at 75u/m2 on days 1, 3 and 5 as the preferred induction schedule. Presence of TP53 mutation or T-AML potentially defines groups with low probabilities of response.

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BST-236, a Novel Cytarabine Pro-Drug, Enables Safe and Effective Administration of High Dose Cytarabine to Older or Unfit Patients with Acute Leukemia. Results of a Phase I/II Study

Tsila Zuckerman, MD[1,2*], Ron Ram, MD[3,4], Maya Koren-Michowitz, MD[5], Luiza Akria, MD[6*], et al.

The authors of the study conclude that:

This Phase I/II study demonstrates that BST-236, a cytarabine pro-drug, is able to safely deliver high-dose cytarabine to older and unfit patients (median age 78) with no significant typical cytarabine toxicities other than "on-target" hematological events. Moreover, the general wellbeing of the patients during and after administration, as noted by the treating physicians, was exceptionally improved compared to intensive therapy. The good safety profile, accompanied by the high response rates and significantly prolonged survival of the older and unfit newly-diagnosed population, most of them refractory to HMA, is highly encouraging. A phase II study is planned to confirm these results.

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GMI-1271 Improves Efficacy and Safety of Chemotherapy in R/R and Newly Diagnosed Older Patients with AML: Results of a Phase 1/2 Study

Daniel J. DeAngelo, MD, PhD[1], Brian A Jonas, MD, PhD[2], Jane L. Liesveld, MD[3], Dale L. Bixby[4*], et al.

The authors of the study conclude that:

The addition of GMI-1271 to chemotherapy was well tolerated with high remission rate, low induction mortality, and low rate of mucositis suggesting improved tolerance of chemotherapy. In R/R AML, correlative studies showed blasts expressing the E-sel ligand were predictive of response. Initial survival outcomes are promising and updated survival outcomes will be presented at ASH. FDA granted Breakthrough Therapy Designation to GMI-1271 for treatment of adults with R/R AML and randomized trials are planned.