SAL
Studienallianz
Leukämie

AMLCG
AML
Cooperative Group

Study Alliance Leukemia/AML Cooperative Group: Achievements and news

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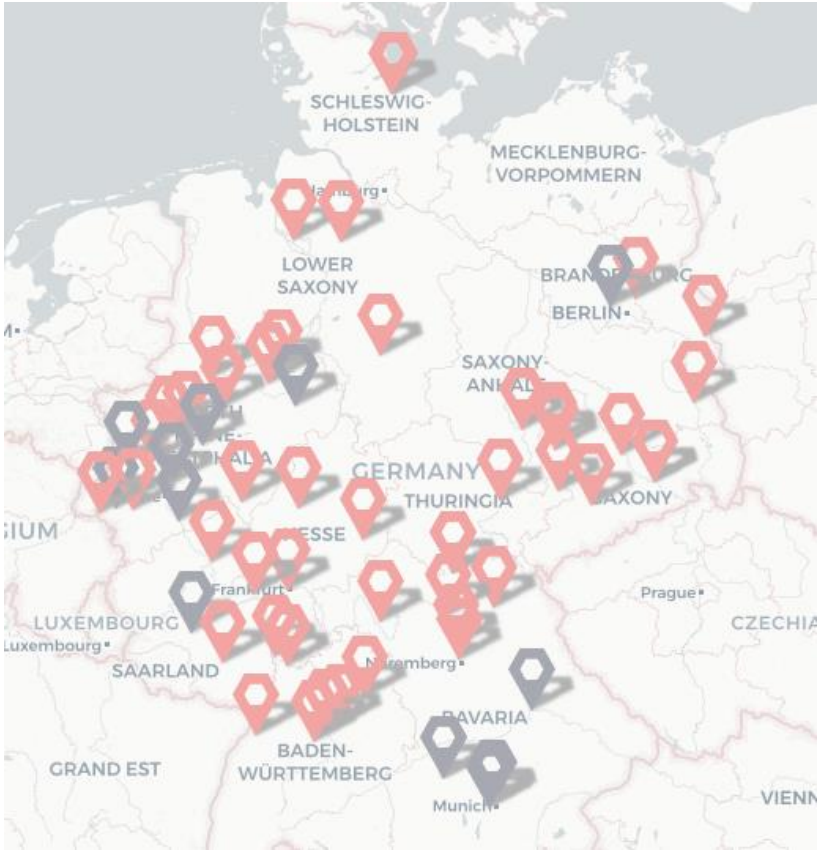
Study Sites

SAL Studienallianz Leukämie | AMLCG AML Cooperative Group

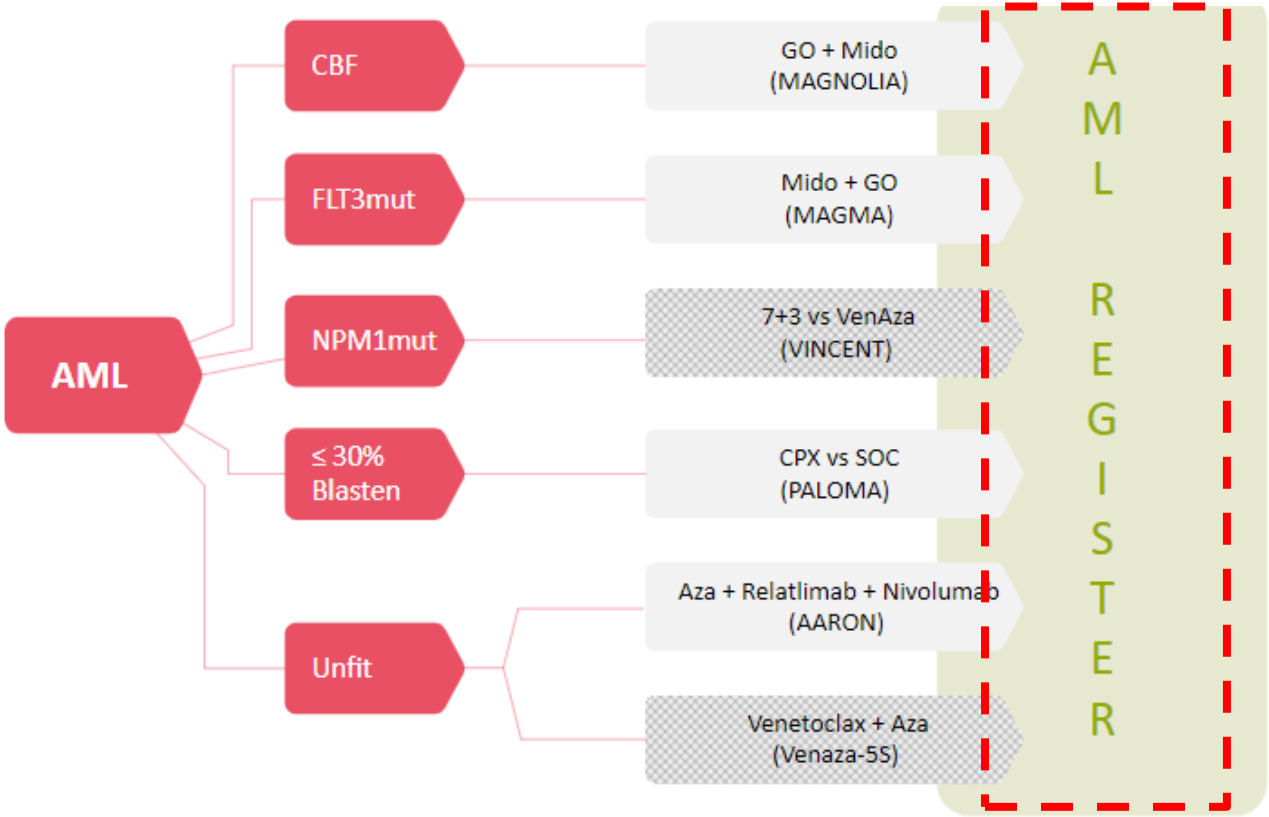


SAL Site
n=46

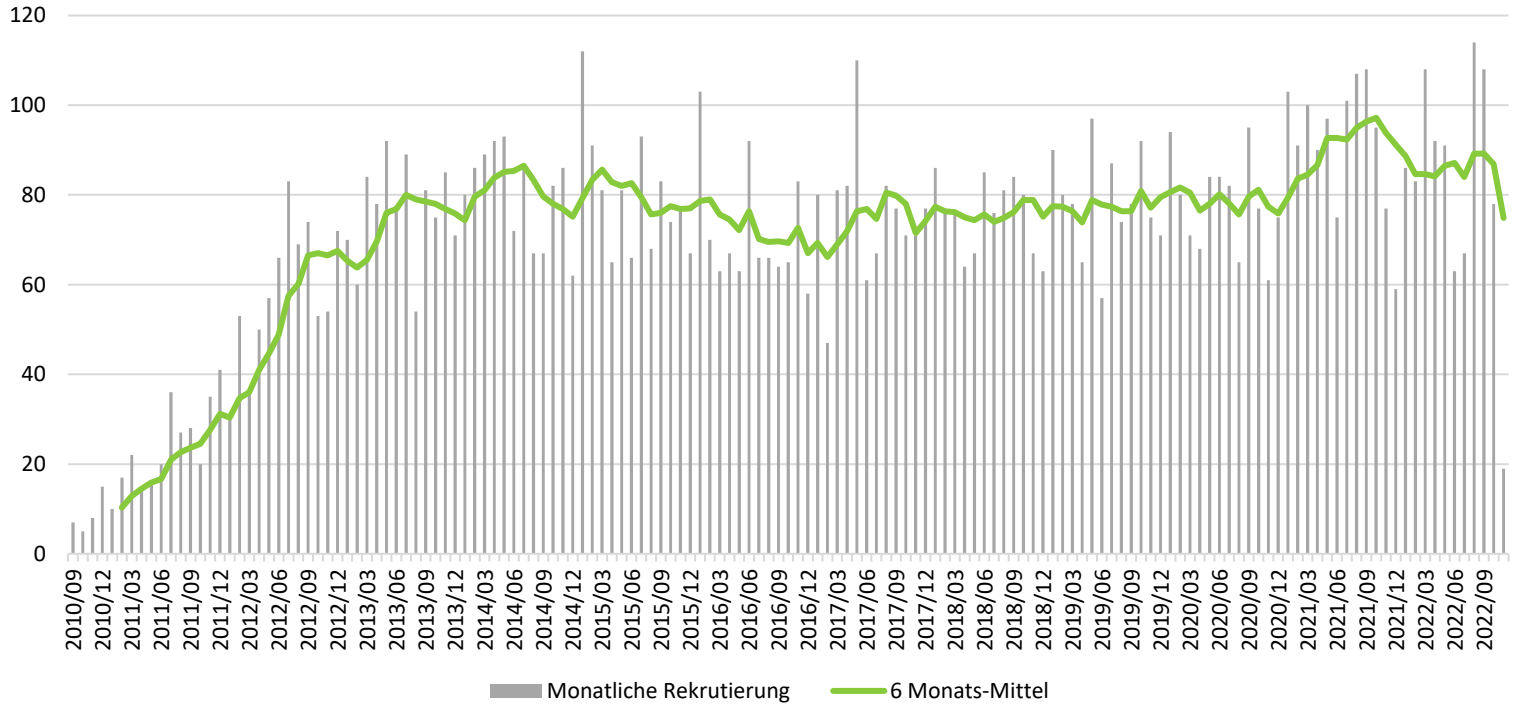
AMLCG Site
n=22

www.aml-germany.com

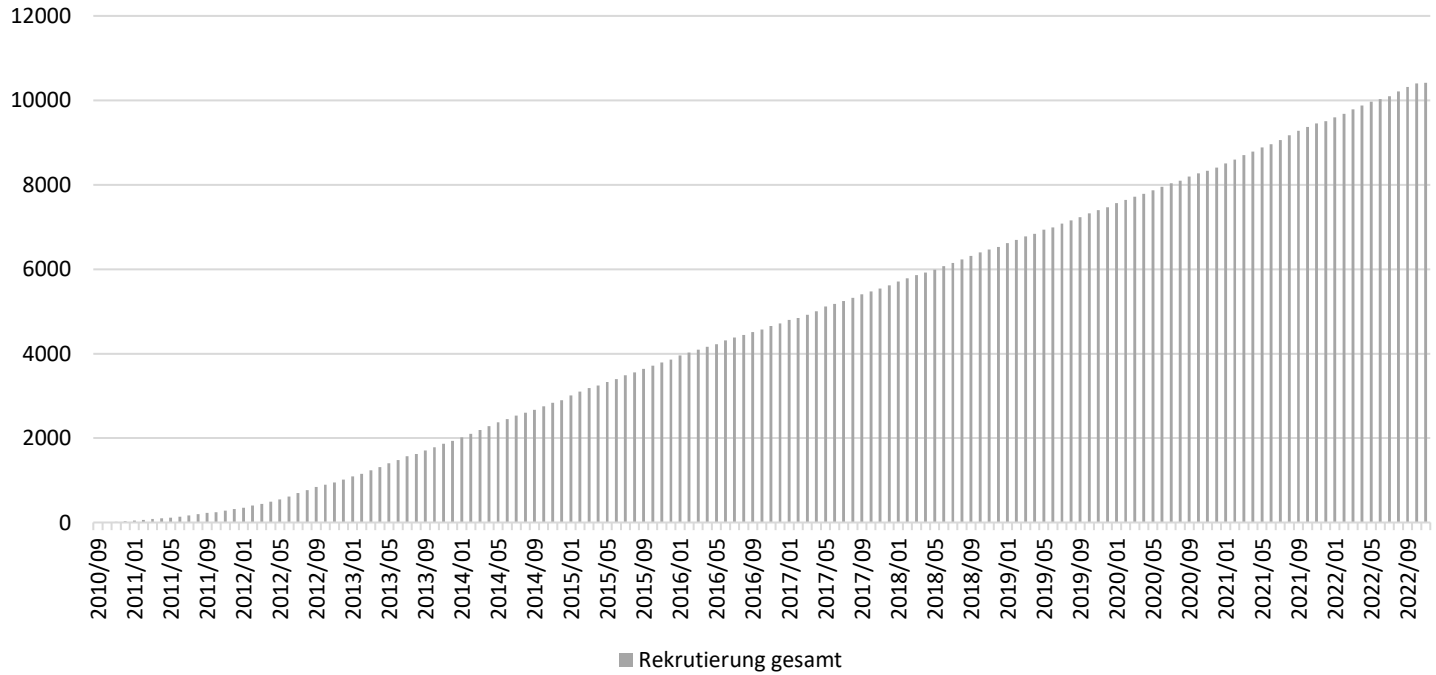
Joint AML Registry of SAL and AMLCG



AML Registry: Monthly Recruitment

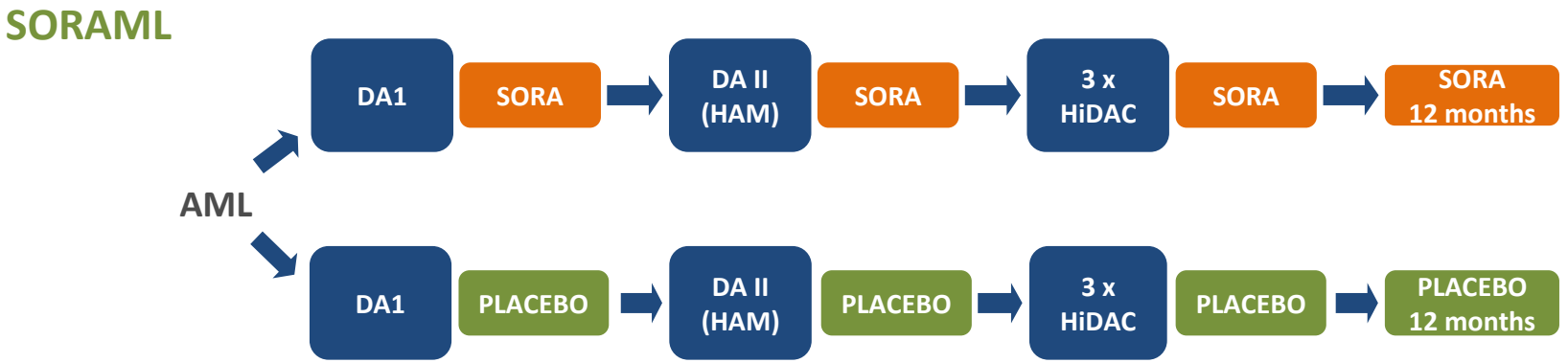


AML Registry: Cumulative Recruitment



Main Achievements from the Past

Sorafenib in combination with chemo: SORAML Trial

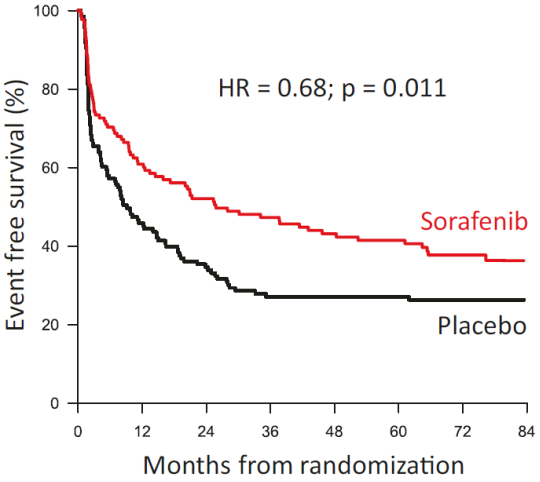


ARA-C, cytarabine; DA, daunorubicin; HAM, high-dose cytarabine and mitoxantrone; HiDAC, high-dose cytarabine; SORA, sorafenib

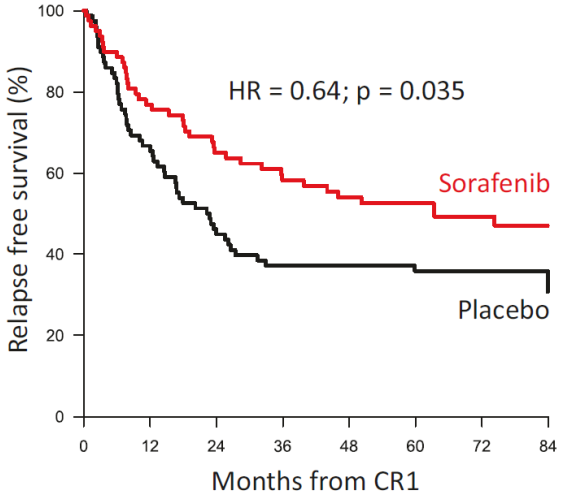
Röllig et al., Leukemia 2021

Sorafenib in combination with chemo: SORAML Trial

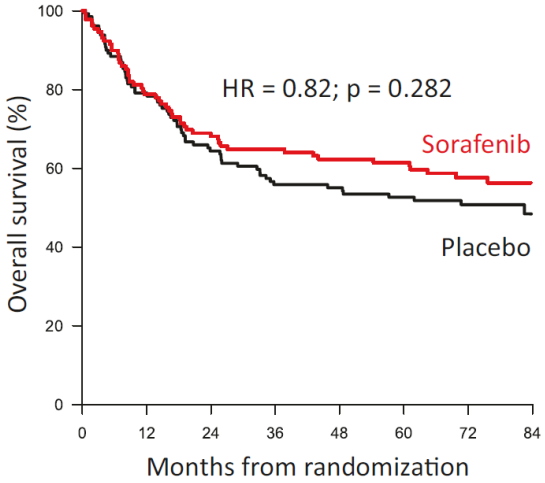
EFS



RFS

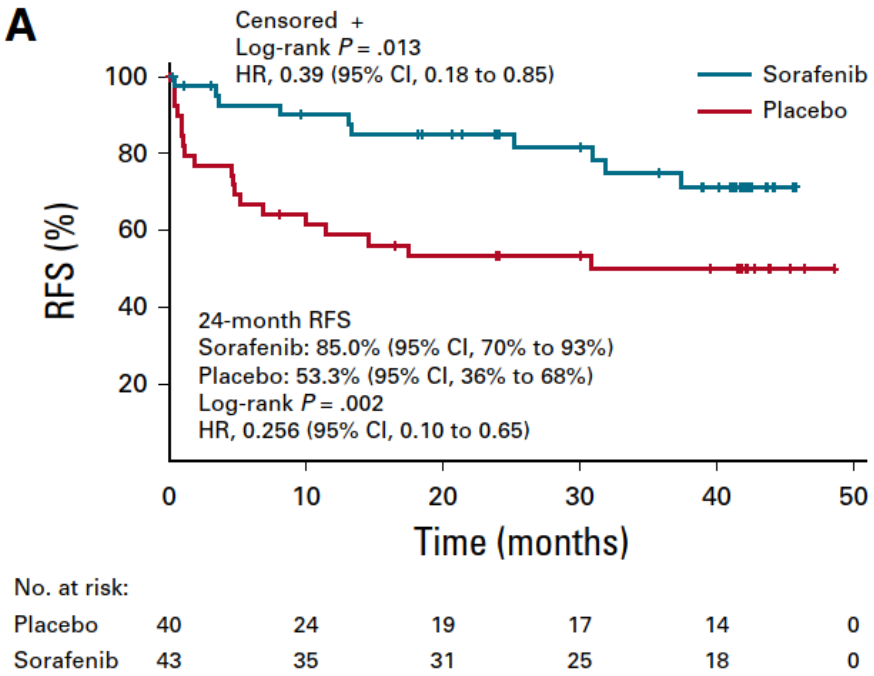


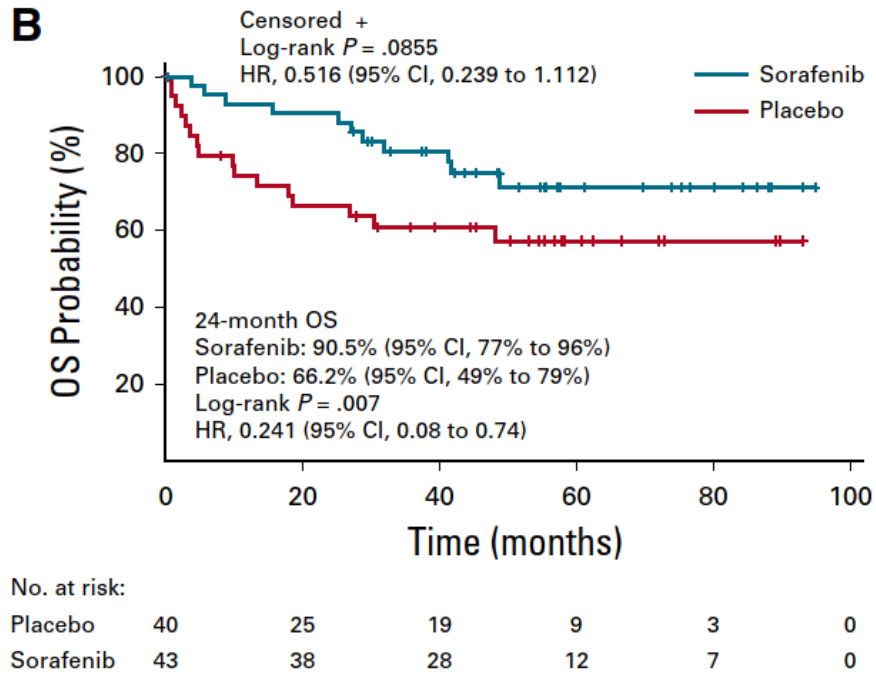
OS



Röllig et al., Leukemia 2021

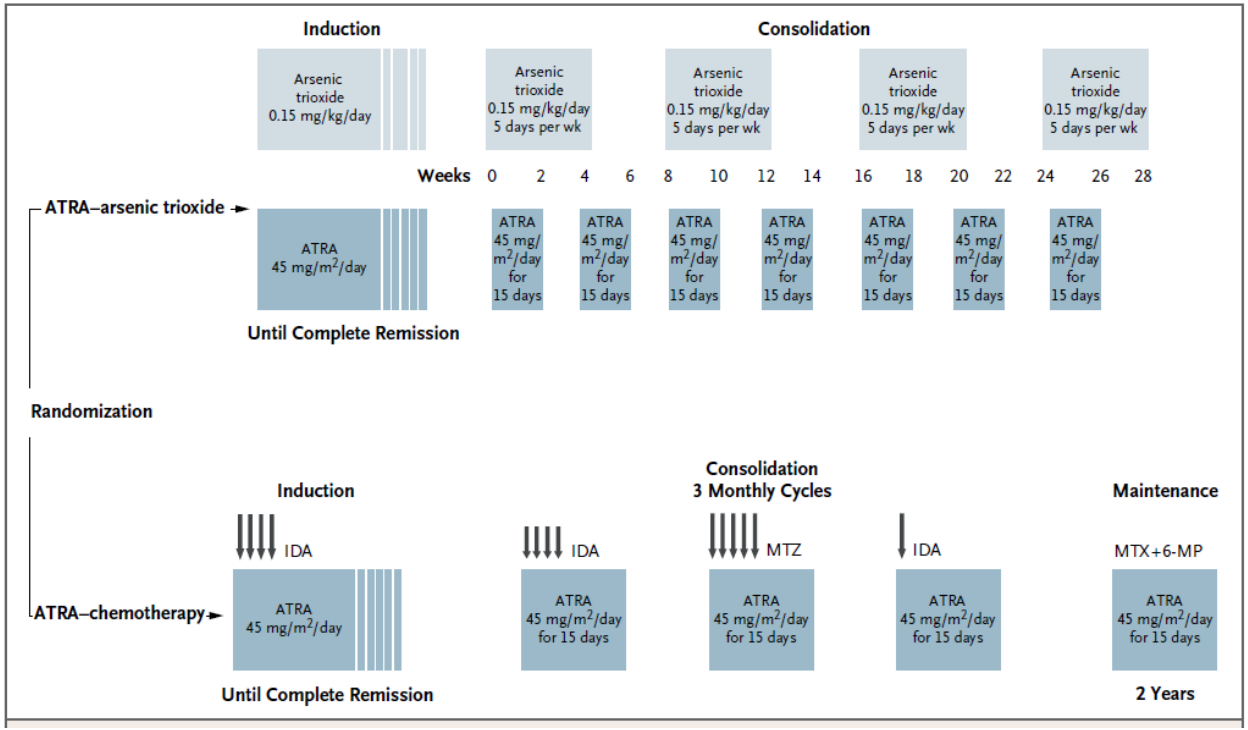
Sorafenib maintenance post allo HCT prolongs RFS and OS significantly





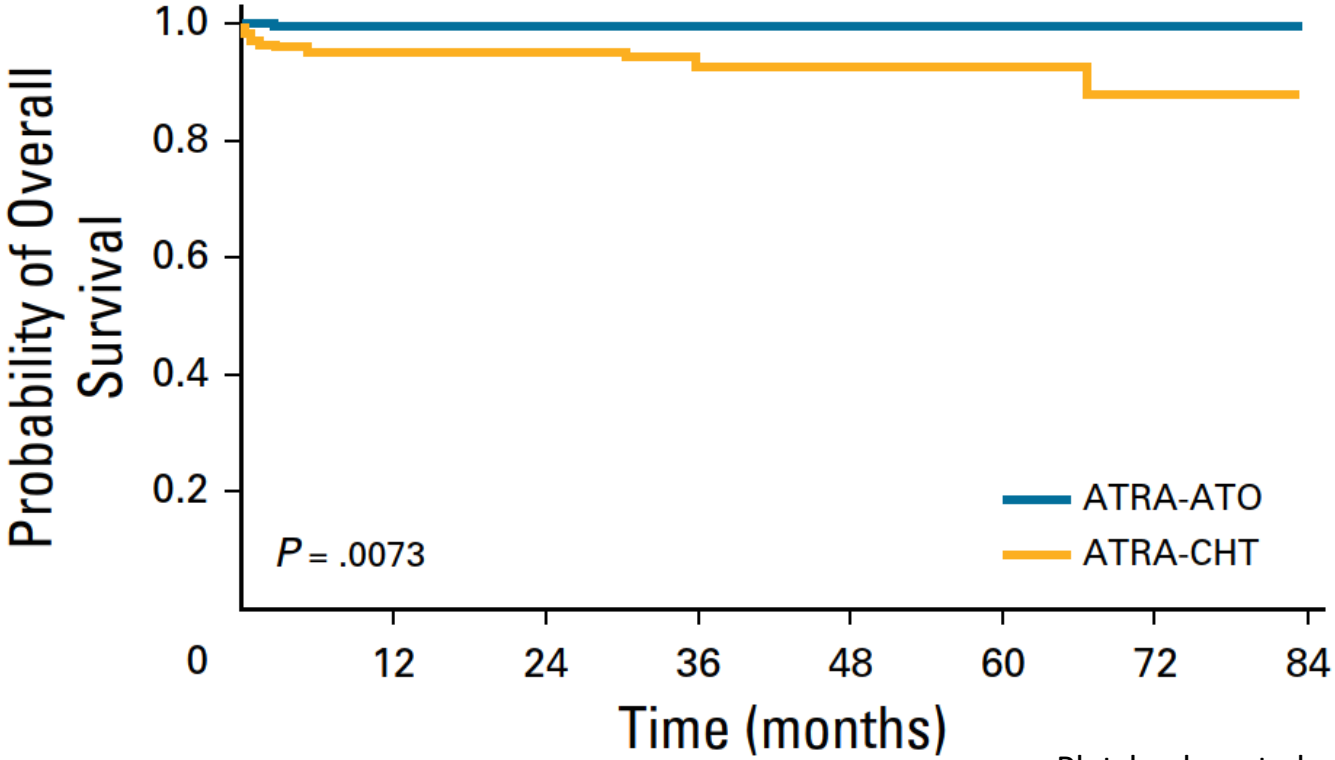
Burchert et al., J Clin Oncol 2020

Therapie APL (M3)



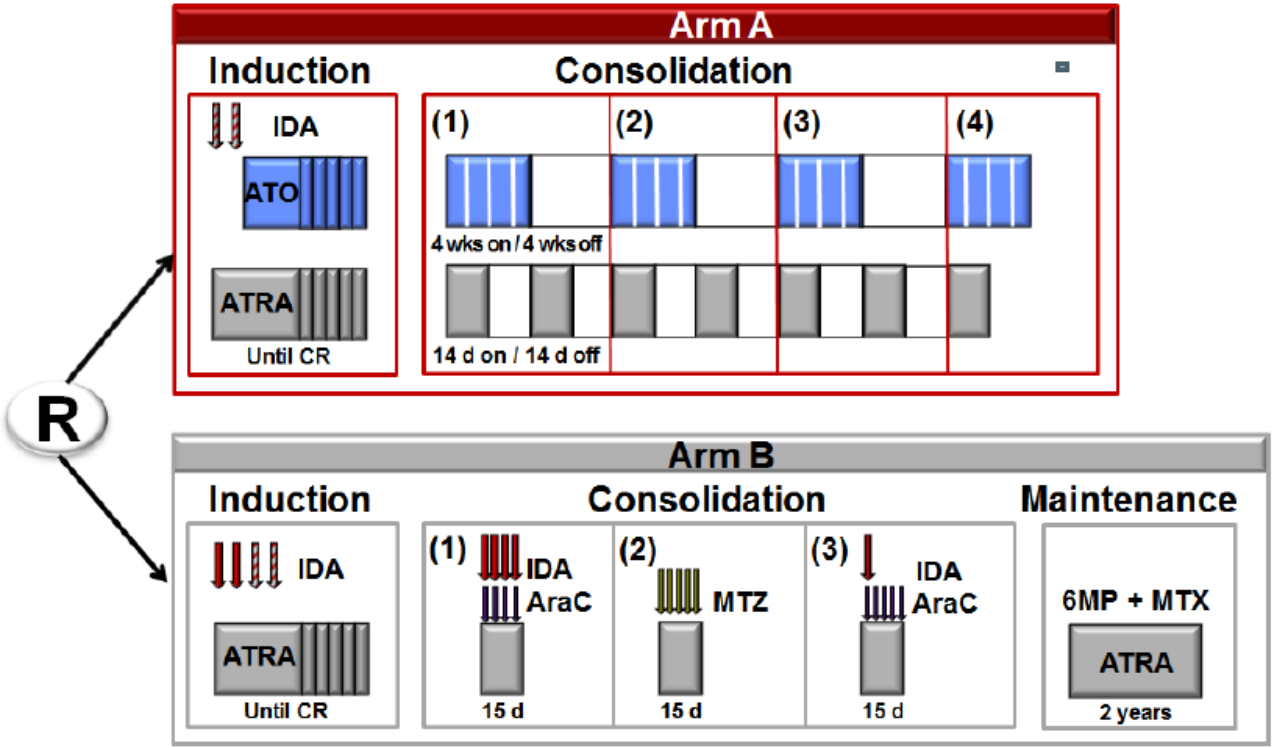
Lo Coco et al., NEJM 2013

Non-High-Risk APL:
Arsenic-ATRA ist non-inferior to Chemo-ATRA



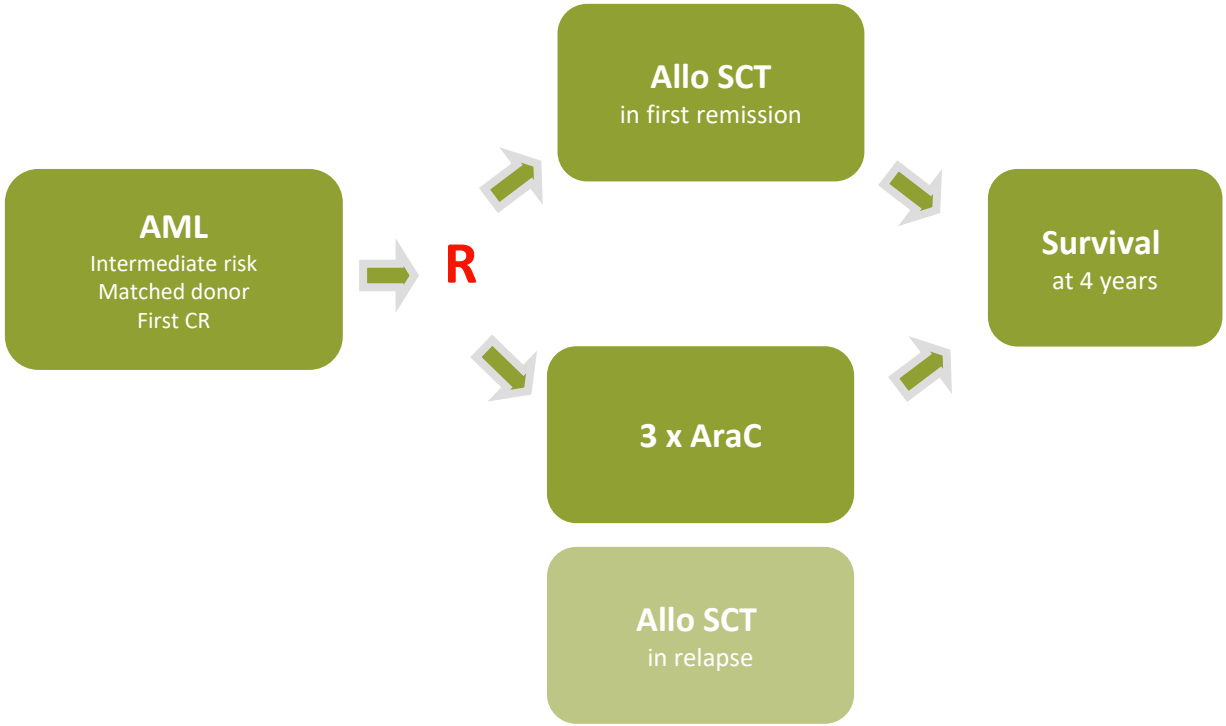
Platzbecker et al., J Clin Oncol 2017

APOLLO: Arsenic versus AIDA in High-Risk APL



Ara-C versus allo HCT in Intermediate-Risk AML in 1st CR

(ETAL1 Trial)

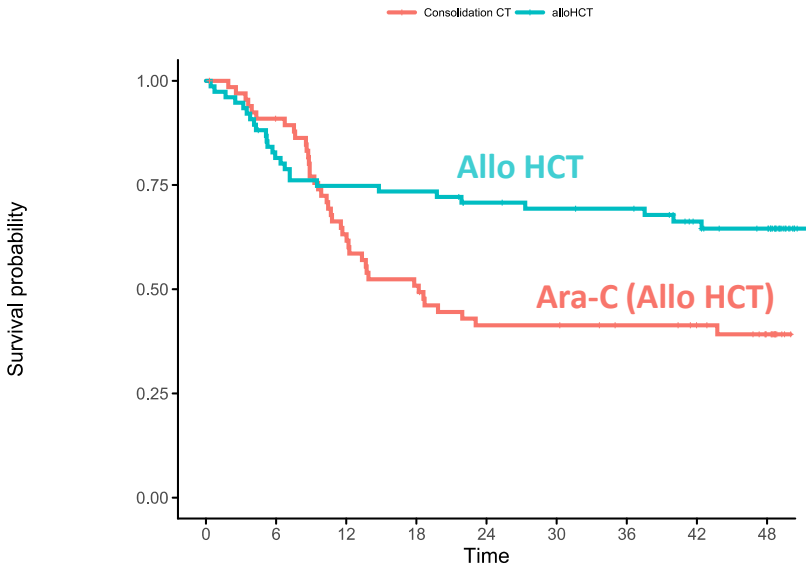


Bornhäuser et al., ASH 2021; in press

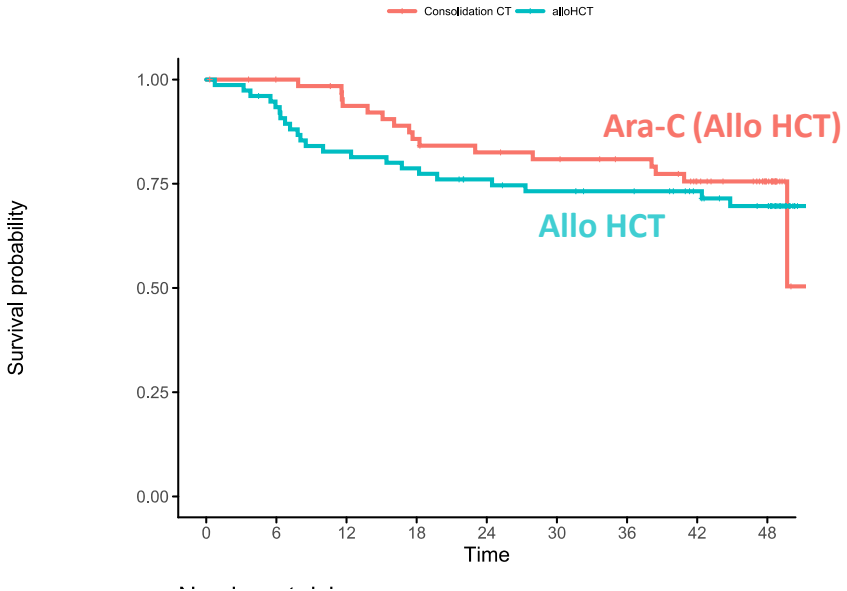
Ara-C versus allo HCT in Intermediate-Risk AML in 1st CR

(ETAL1 Trial)

Relapse-free survival



Overall survival



Bornhäuser et al., ASH 2021; in press

Ara-C versus allo HCT in Intermediate-Risk AML in 1st CR

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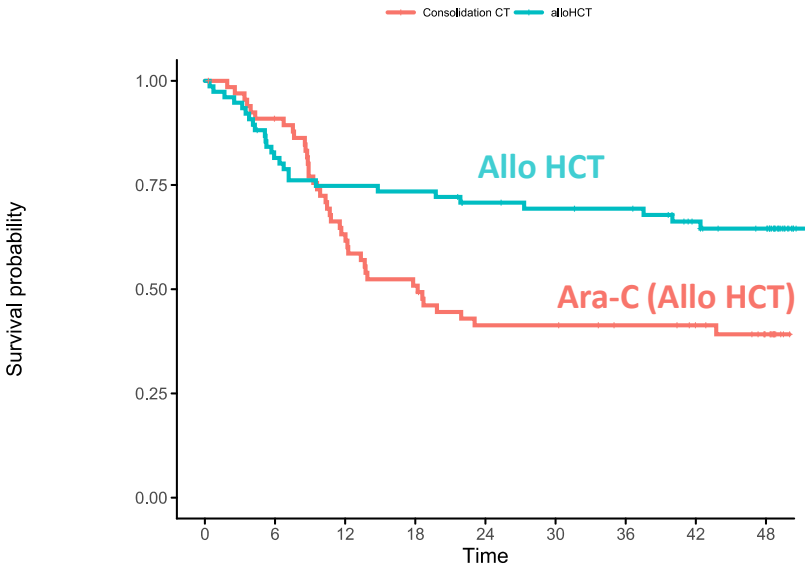
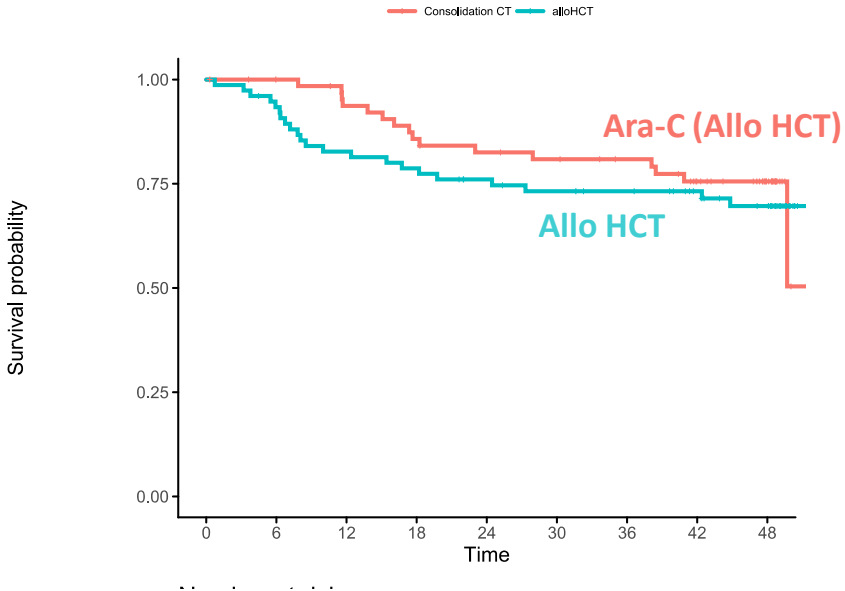
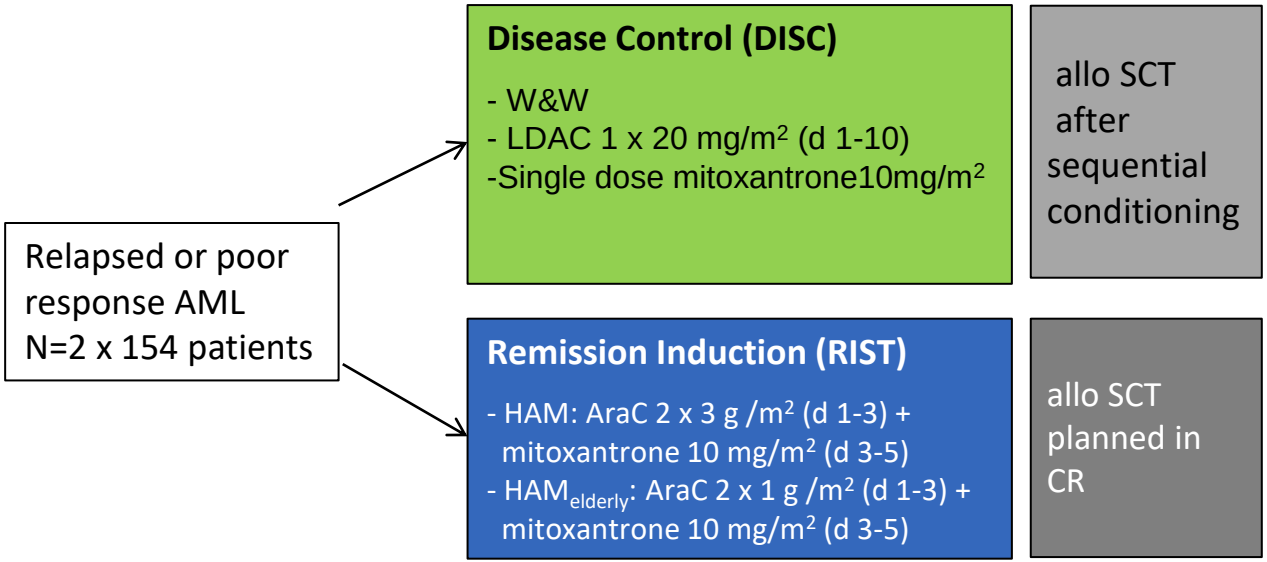


Overall survival



Bornhäuser et al., ASH 2021; in press

ASAP/ETAL-3: Immediate allogeneic SCT or Preceding Re-Induction?



AML-CG

PI: J. Schetelig

SAL Study Alliance Leukemia

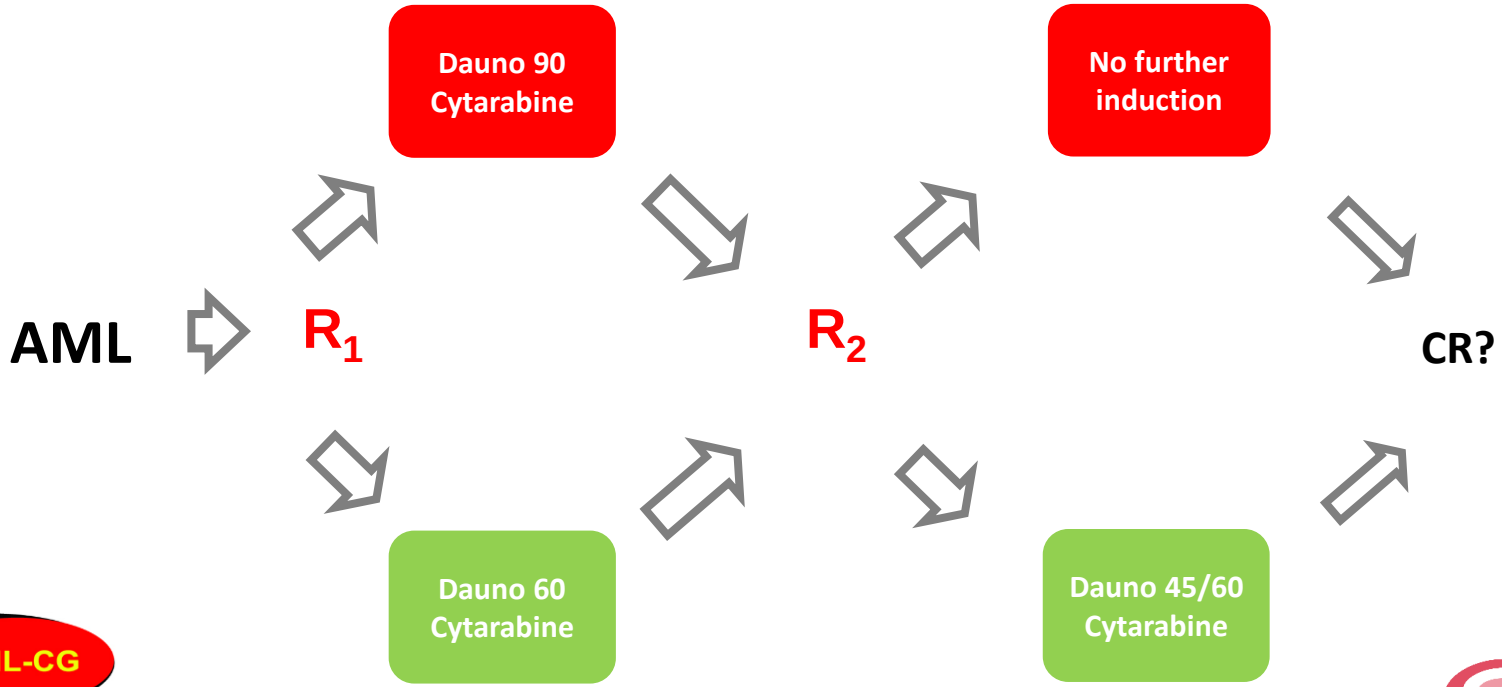
4 In Patients with Relapsed/Refractory AML Sequential Conditioning and Immediate Allogeneic Stem Cell Transplantation (allo-HCT) Results in Similar Overall and Leukemia-Free Survival Compared to Intensive Remission Induction Chemotherapy Followed By Allo-HCT: Results from the Randomized Phase III ASAP Trial

Program: General Sessions
Session: Plenary Scientific Session
Hematology Disease Topics & Pathways:
MDS, clinical trials, AML, adult, Acute Myeloid Malignancies, Research, Clinical Research, Chronic Myeloid Malignancies, Diseases, therapy sequence, Therapies, Myeloid Malignancies, Human, Study Population

Sunday, December 11, 2022, 2:00 PM-4:00 PM

Matthias Stelljes, Prof. Dr. med.[1], Jan Moritz Middeke, MD[2], Gesine Bug, MD[3*], Eva-Maria Wagner, MD[4*], Lutz Peter Mueller, MD[5*], Schmid Christoph[6*], Stefan W. Krause, MD[7*], Wolfgang Bethge, MD[8*], Edgar Jost[9*], Uwe Platzbecker, MD[10*], Stefan Klein, MD[11], Jörg Schubert[12*], Judith Niederland[13*], Martin Kaufmann, MD[14], Kerstin Schäfer-Eckart[15*], Markus Schaich, MD[16*], Henning Baldauf[17*], Friedrich Stölzel[18*], Cathleen Petzold, PhD[17*], Christoph Röllig, MD, MSC[19*], Nael Alakel, MD[20*], Björn Steffen, MD[21*], Beate Hauptrock[22*], Christian Reicherts, MD[23*], Christoph Schliemann, MD[24*], Hubert Serve, MD[21], Alexander H. Schmidt, MD, PhD[25], Martin Bornhäuser, MD[26*], Jan-Henrik Mikesch, PD, MD[24*] and **Johannes Schetelig, MD, MSc**[17,20]*

DaunoDouble: 7+3 with 90 or 60 Dauno and Double or Single Induction?



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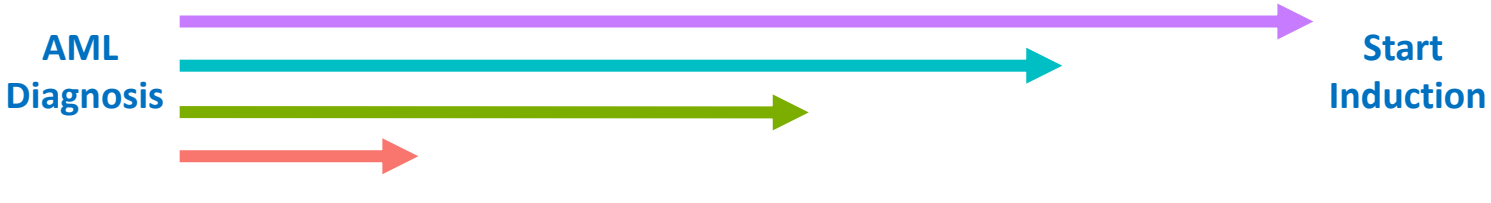
217 Single Versus Double Induction with "7+3" Containing 60 Versus 90 Mg Daunorubicin for Newly Diagnosed AML: Results from the Randomized Controlled SAL Dauno-Double Trial

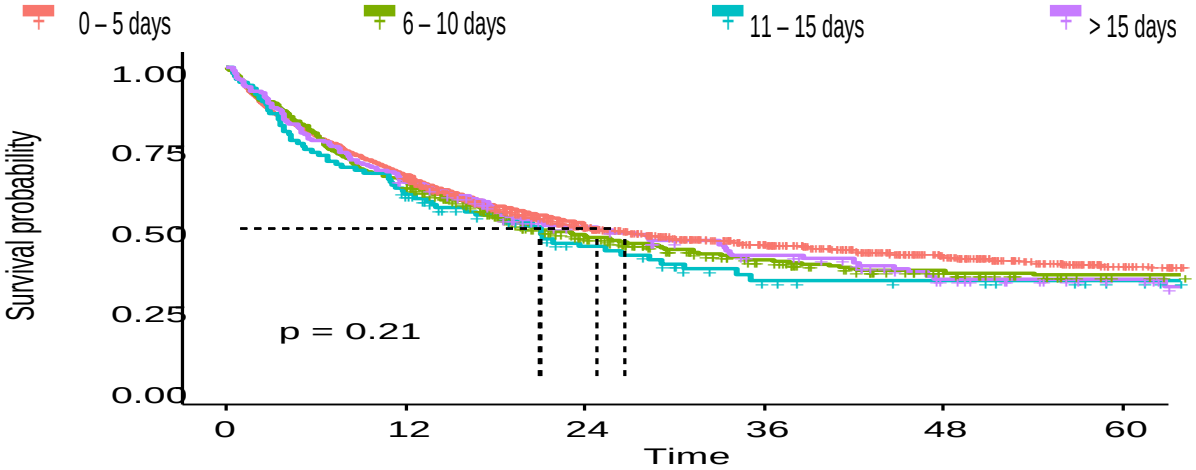
Program: Oral and Poster Abstracts
Type: Oral
Session: 615. Acute Myeloid Leukemias: Commercially Available Therapies, Excluding Transplantation and Cellular Immunotherapies: New Approaches to Combination Chemotherapy and Venetoclax Plus Hypomethylating Agent Therapy in AML
Hematology Disease Topics & Pathways:
adult, Clinical Practice (Health Services and Quality), Combination therapy, Therapies, therapy sequence, Study Population, Human

Saturday, December 10, 2022: 2:00 PM

Christoph Röllig, MD, MSC[1*], *Björn Steffen, MD*[2*], *Christoph Schliemann, MD*[3*], *Jan-Henrik Mikesch, PD, MD*[3*], *Nael Alakel, MD*[4*], *Regina Herbst, MD*[5*], *Mathias Haenel, MD*[6*], *Richard Noppeney, MD*[7*], *Maher Hanoun, MD, PhD*[8*], *Martin Kaufmann, MD*[9], *Zdenek Racil, MD*[10*], *Kerstin Schäfer-Eckart*[11*], *Tim Sauer, MD*[12*], *Andreas Neubauer, MD*[13], *Claudia D. Baldus, MD*[14*], *Jolana Mertova*[15*], *Edgar Jost*[16*], *Dirk Niemann, MD*[17*], *Jan Novak*[18*], *Stefan W. Krause, MD*[19*], *Sebastian Scholl, MD*[20*], *Andreas Hochhaus*[21], *Gerhard Held, Professor Dr*[22*], *Tomáš Szotkowski, MD, PhD*[23*], *Christoph Schmid, MD*[24*], *Andreas Rank, MD*[25*], *Lars Fransecky, MD*[26*], *Michael Kramer, MSc*[27*], *Frank Fiebig*[28*], *Annett Haake*[28*], *Friedrich Stoelzel, MD*[29], *Johannes Schetelig, MD, MSc*[30], *Jan Moritz Middeke, MD*[29*], *Uwe Platzbecker, MD*[31*], *Christian Thiede, MD*[27], *Carsten Müller-Tidow, MD*[12*], *Wolfgang E. Berdel, MD*[32], *Hubert Serve, MD*[2], *Gerhard Ehninger, MD*[33], *Jiří Mayer, MD*[34] *and Martin Bornhaeuser, MD*[35]

Time from Diagnosis to Treatment does not influence long-term prognosis

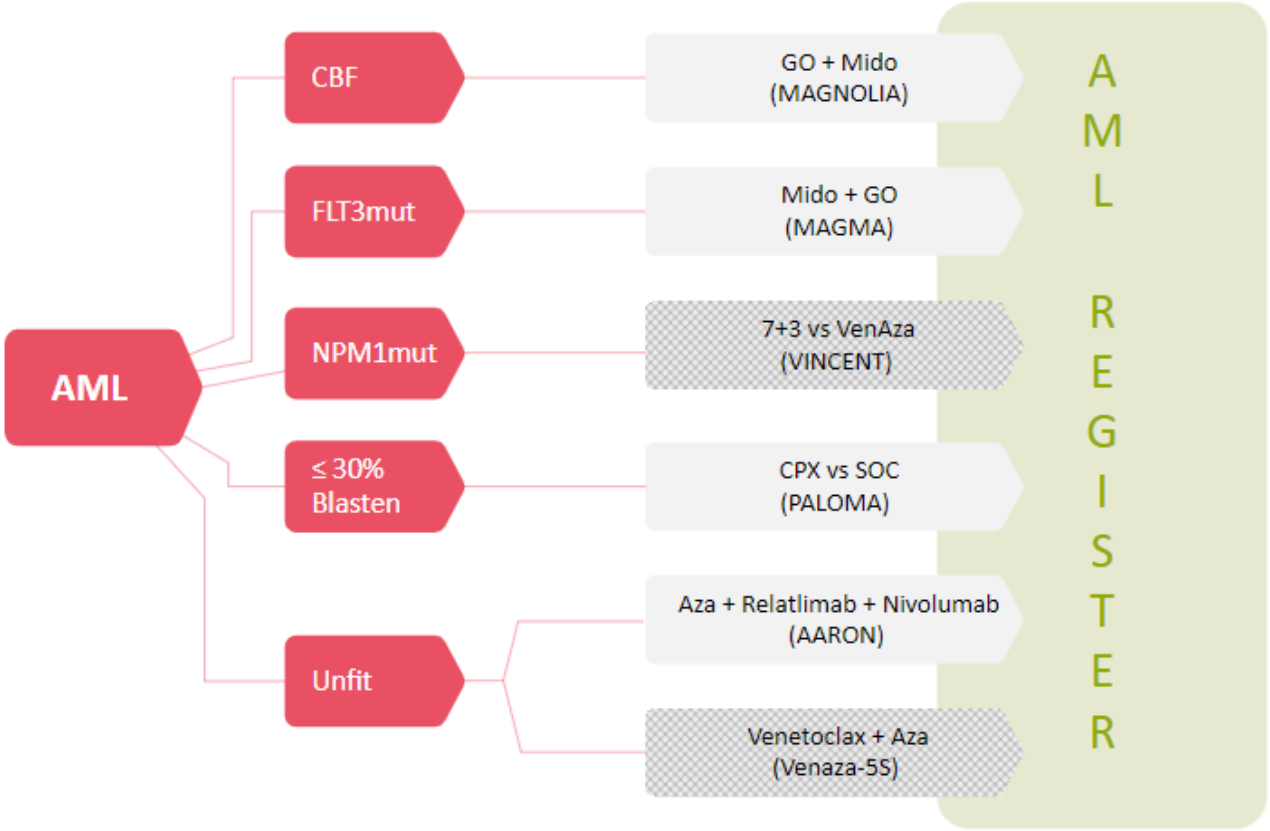




Röllig C, et al. *Blood* 2020

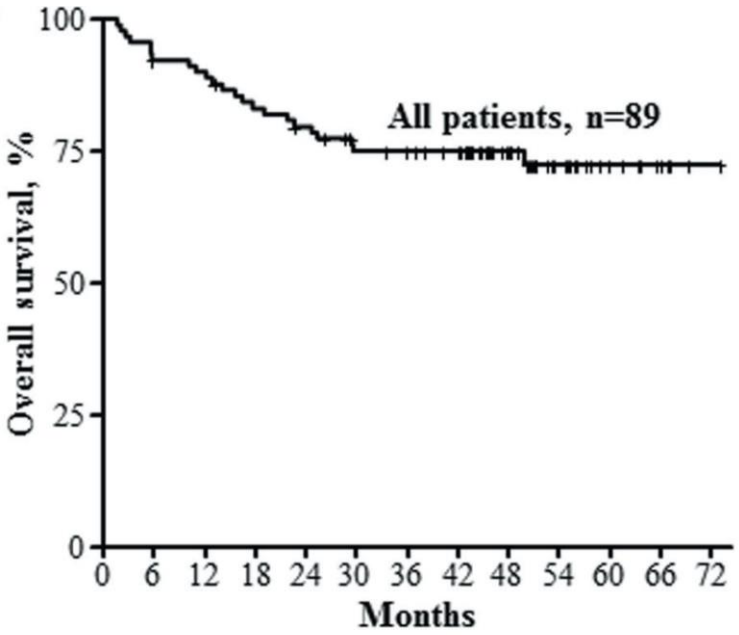
Trial Portfolio First-line Treatment

Studienportfolio Erstdiagnose



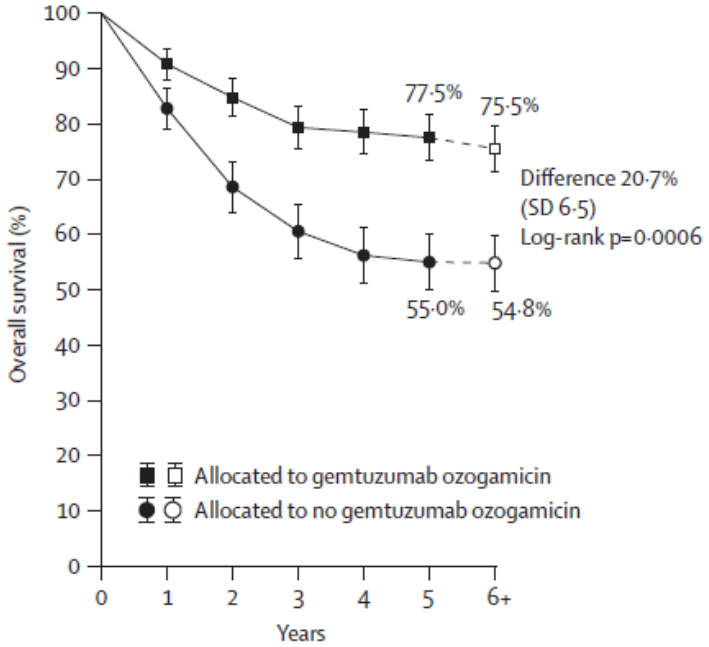
Targeting KIT and CD33 in CBF AML

Dasatinib



Paschka et al., Leukemia 2018

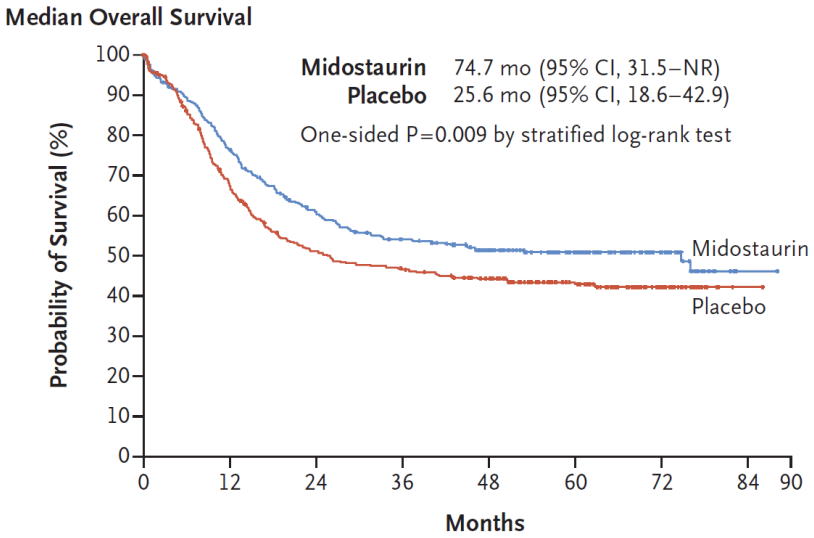
Gemtuzumab Ozogamicin



Burnett et al., J Clin Oncol 2011

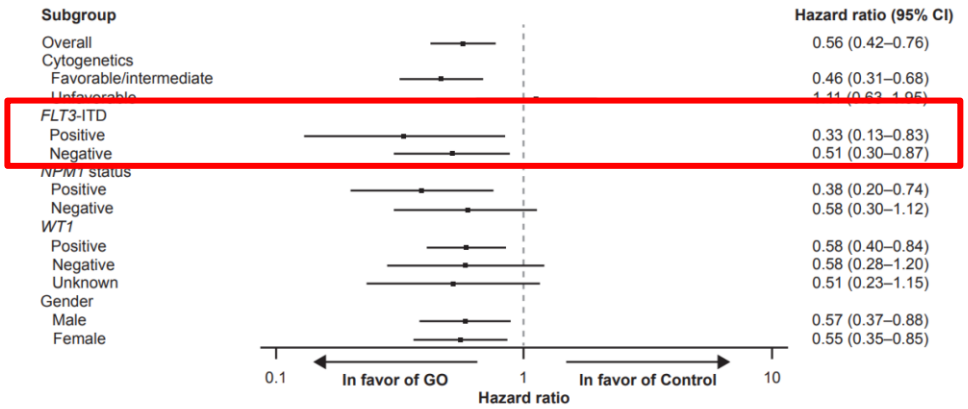
Midostaurin and GO in $FLT3_{mut}$ AML

Midostaurin



Stone et al., NEJM 2017

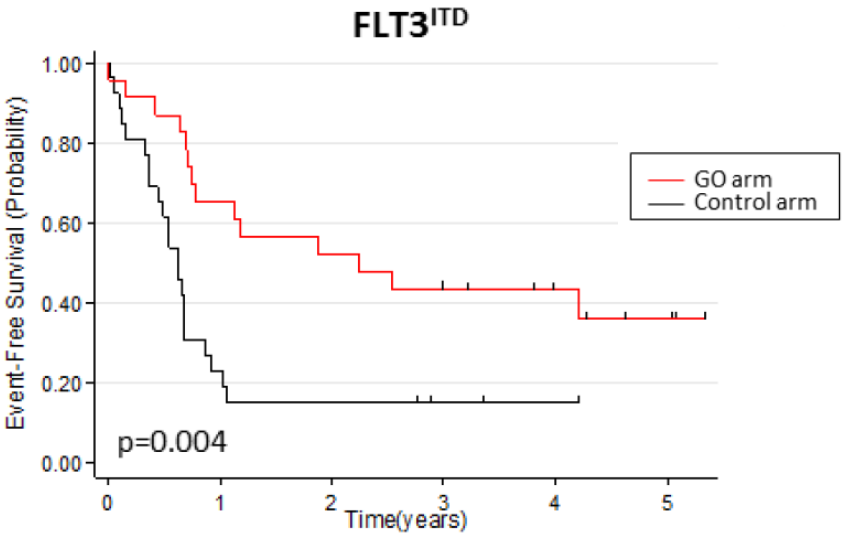
Gemtuzumab Ozogamicin

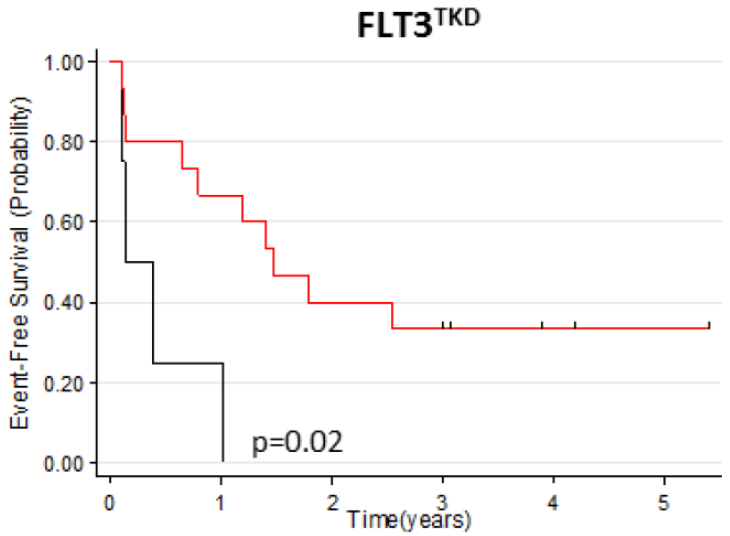


Lambert et al., Haematologica 2018

GO may be beneficial for FLT3-mut AML

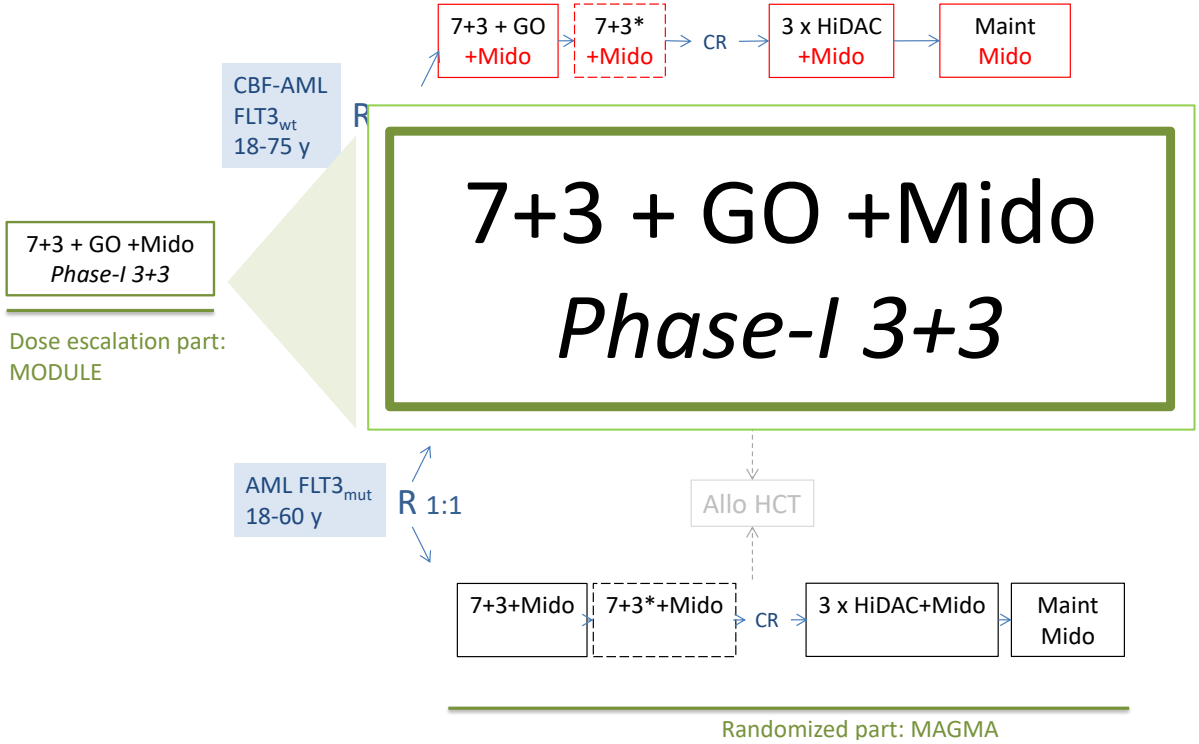
(ALFA-0701 trial)





Fournier et al., Blood 2020

Combining Midostaurin and GO in CBF AML and $FLT3_{mut}$ AML: SAL MOSAIC Trial



Combination intensive induction plus midostaurin plus GO

It is feasible… :

- Russell et al., EHA 2022 #S126
- Borate et al., ASH 2021 #1296
- Röllig et al., ASH 2021 #2324

GEMTUZUMAB OZOGAMICIN PLUS MIDOSTAURIN IN COMBINATION WITH STANDARD INTENSIVE INDUCTION THERAPY WITH NEWLY DIAGNOSED AML: RESULTS FROM A PHASE-I STUDY

C. RÖLLIG[1], C. SCHLIEMANN[2], L. FRANSECKY[3], C.D. BALDUS[3], B.-N. HEYDRICH[3], M. HANOUN[4], R. NOPPENEY[4], S. SCHOLL[5], U. SCHNETZKE[5], K. SCHÄFER-ECKART[5], K. WENDELIN[6], M. WERMKE[1], M. REIMANN[1], F. FIEBIG[1], T. KRETSCHMANN[1], F. STÖLZEL[1], N. ALAKEL[1], and M. BORNHÄUSER[1]

1. Medizinische Klinik und Poliklinik I, Medizinische Fakultät Carl Gustav Carus, Dresden, Germany; 2. Medizinische Klinik A, Universitätsklinikum Münster, Münster, Germany; 3. Klinik für Innere Medizin, Universitätsklinikum Schleswig-Holstein, Kiel, Germany; 4. Klinik für Hämatologie, Universitätsklinikum Essen, Essen, Germany; 5. Klinik für Innere Medizin II, Universitätsklinikum Jena, Jena, Germany

SAL Study Alliance Leukemia

INTRODUCTION

In newly diagnosed acute myeloid leukemia (AML) with FLT3 mutations (FLT3-mut), the tyrosine kinase inhibitor midostaurin (MIDO) in combination with intensive chemotherapy (IC) is considered standard of care (SoC) (1). Subgroup analyses from the ALFA 0701 trial indicate that the addition of the conjugated CD33 antibody gemtuzumab ozogamicin (GO) to IC increases efficacy in the FLT3-ITD subgroup of patients (pts) (2), providing a rationale for the combined use of MIDO plus GO with IC in newly diagnosed FLT3-mut AML. On the other hand, there is evidence that the subgroup of core-binding factor (CBF) AML benefits from the inhibition of the tyrosine kinase KIT with respect to survival end points (3,4). In this respect, MIDO is a more powerful KIT inhibitor as compared to dasatinib which has been applied in previous studies (3). While the combination of IC plus GO in induction treatment is considered SoC in patients with CBF AML (1) the addition of MIDO to SoC seems promising to further improve treatment outcomes in the CBF subgroup.

AIM

We therefore set up the clinical trial MOSAIC composed of a phase-I part to prospectively assess the feasibility of combining MIDO plus GO with IC (MODULE), followed by a randomized phase-II part evaluating the benefit of adding GO to SoC in FLT3-mut AML (MAGMA) and of adding MIDO to SoC in CBF AML (MAGNOLIA). Here, we report the results of the phase-I part (MODULE).

METHODS

MODULE is a dose escalation phase-I trial following a 3+3 design. Eligibility criteria include newly diagnosed AML harboring either FLT3 or CBF mutations, and fitness for IC. Standard 7+3 IC using cytarabine 200 mg/m^2 continuous infusion over 7 days plus daunorubicin 60 mg/m^2 on 3 days was combined with increasing doses of MIDO and GO in three dose levels (plus a fall-back cohort) (Table 1). Based on the 3+3 design, each dose cohort consisted of three but maximal six patients. The protocol predefined the maximal tolerable dose (MTD) as reached if ≤2 dose-limiting toxicity events (DLTs) would occur in maximum six evaluable patients who received ≥80% of the planned study therapy. A DLT was defined as any non-hematologic grade 3-5 toxicity with reasonable causal relationship to MIDO or GO during days 8-28 or hematologic grade 4 toxicity on or beyond day 42 of start of study therapy in presence of < 5 % bone marrow blasts.

Study Design of MOSAIC Trial

RESULTS

From September 2020 to July 2021, 11 patients were enrolled (Table 2). In the 1st dose level, three patients completed the regular study period without DLT, whereas treatment had to be discontinued in one patient on day 6 before commencement of MIDO due to infusion related reaction CTC grade 4. This patient was subsequently replaced. In the 2nd dose level, one of three enrolled patients experienced neutropenic colitis CTC grade 3 on day 14 of treatment, which was classified as DLT. The colitis fully recovered by day 27 after commencement of treatment. As a result of the DLT, the dose cohort was subsequently extended by three additional patients. Of those, one patient developed signs of sinusoidal obstruction syndrome (SOS) CTC grade 3 starting on day 13 of treatment. SOS was classified as DLT. The patient was treated with defibrotide and supportive care until recovery on day 28. Another patient had to discontinue treatment on day 14 due to inability of swallowing MIDO. This patient was replaced as the target dose of MIDO was not reached. As predefined in the study protocol, the occurrence of 2 DLTs in six evaluable patients precluded further dose escalation to the 3rd dose level and defined the 2nd dose level as safe and feasible.

A total number of 5 serious adverse events (SAEs) were observed among all 11 patients who completed the DLT evaluation period: infusion related reaction, colitis, parvo-B19 infection, prolonged neutropenia CTC grade 4, and SOS. An unexpected increase in frequency of common AML adverse events was not observed. The 30-day mortality among all enrolled patients was 0%.

After blood count recovery, remission assessment showed complete remission (CR) in 7 pts, CR with incomplete hematologic/platelet recovery (CRi/CRp) in 3 pts and primary refractory disease in one patient.

Table 2. Patient characteristics and outcome according to dose level

Dose Level	Pat	Age/Gender	Genetics	SAE term (CTC grade, onset,outcome)	DLT	Remission	Survival
1	1	58 years / female	CBF / FLT3-Co-mutated AML	none	none	CRp	alive
	2	*58 years / female*	*CBF AML*	*infusion related reaction (grade 4, on day 1, resolved)*	*none*	*CRp*	*alive*
	3	31 years / female	CBF AML	none	none	CR	alive
	4	54 years / male	FLT3-mut AML	none	none	Refractory disease	alive
2	1	20 years / male	FLT3-mut AML	**colitis** (grade 3, on day 14, resolved) **parvo-B19 infection** (grade 3, on day 30, resolved)	**colitis**	CR	alive
	2	40 years / male	FLT3-mut AML	**neutropenia** (grade 4, beyond day 42, resolved on day 46)	none	CRi	alive
	3	54 years / male	FLT3-mut AML	none	none	CR	alive
	4	47 years / female	FLT3-mut AML	none	none	CR	alive
	5	*44 years / female*	*FLT3-mut AML*	*none*	*none*	*CR*	*alive*
	6	55 years / female	CBF AML	**sinusoidal obstruction syndrome** (SOS) (grade 3, on day 13, resolved)	**SOS**	CR	alive
	7	60 years / female	FLT3-mut AML	none	none	CR	alive

Patient 2 in dose level 1 and patient 5 in dose level 2 had to be replaced

Table 1. Dose levels

Dose level	GO in Induction	Midostaurin days 8-21
-1 (fall-back)	3 mg/m^2 on d1	50 mg (25 mg BID)
1	3 mg/m^2 on d1, 4	50 mg (25 mg BID)
2	3 mg/m^2 on d1, 4	100 mg (50 mg BID)
3	3 mg/m^2 on d1, 4, 7	100 mg (50 mg BID)

CONCLUSIONS

GO standard dose on days 1 + 4 and MIDO standard dose on days 8-21 of induction treatment is defined as MTD which can be safely combined with standard IC in newly diagnosed AML. In the phase-I cohort of the MOSAIC trial, CR/CRi/CRp rates of 91% were reached. Based on the results of this dose finding trial the MTD of combined MIDO and GO will be defined as phase-II dose for the randomized phase-II studies in CBF and FLT-mut AML.

REFERENCES

1 **Heuser M et al.** Acute myeloid leukemia in adult patients: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol* 2020; 31: 697-712.

2 **Castaigne S et al.** Effect of gemtuzumab ozogamicin on survival of adult patients with de-novo acute myeloid leukaemia (ALFA-0701): a randomised, open-label, phase 3 study. *Lancet* 2012; 379: 1508-16.

3 **Paschka P et al.** Adding dasatinib to intensive treatment in core-binding factor acute myeloid leukemia-results of the AMLSG 11-08 trial. *Leukemia 2018*; 32: 1621-30.

4 **Paschka P et al Döhner. K.** Core-binding factor acute myeloid leukaemia: can we improve on HIDAC consolidation? *Hematology Am Soc Hematol Educ Program 2013*; 2013:209-19.

ACKNOWLEDGEMENTS

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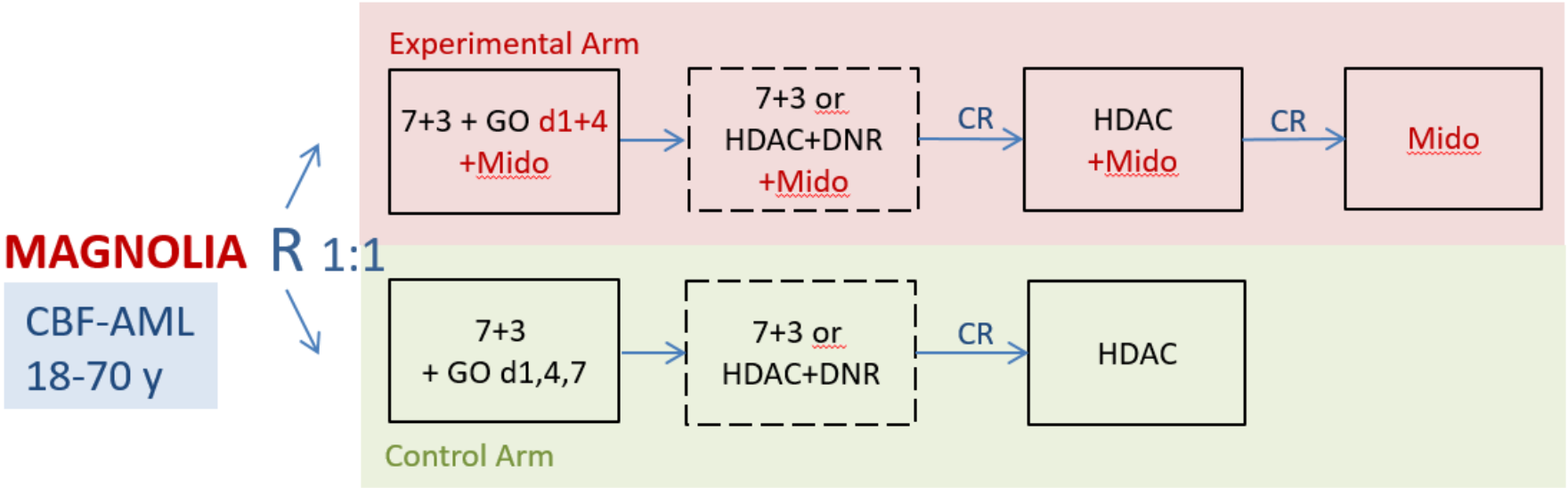
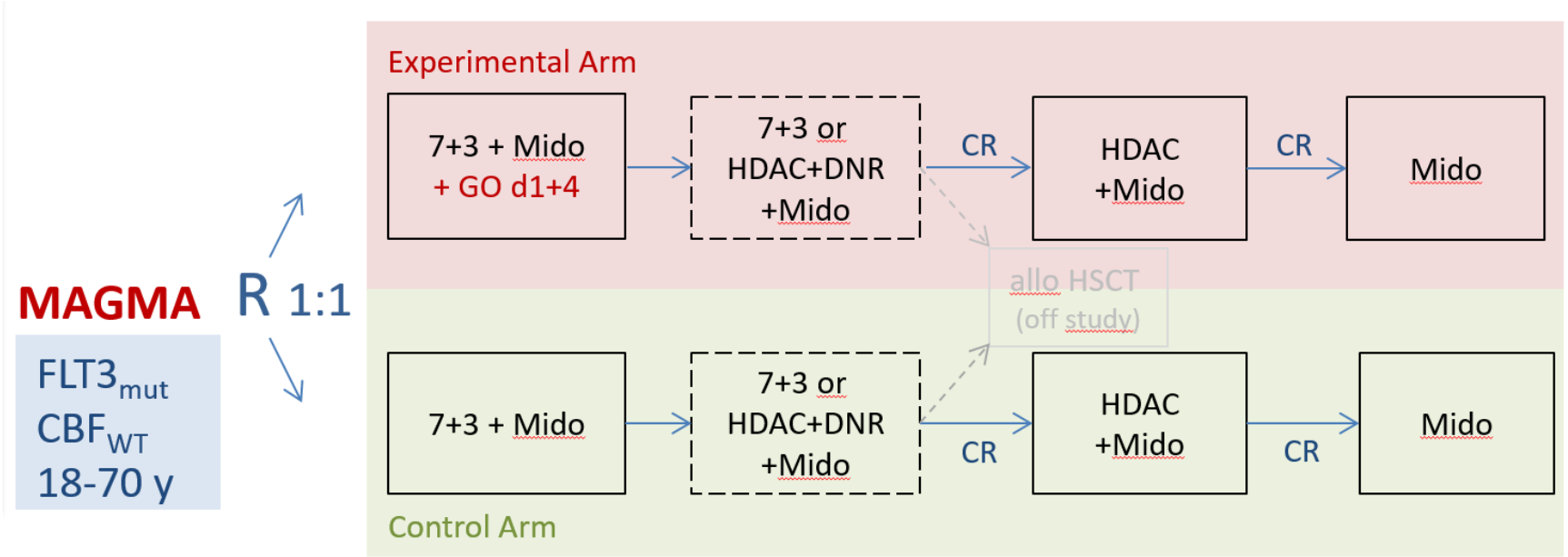
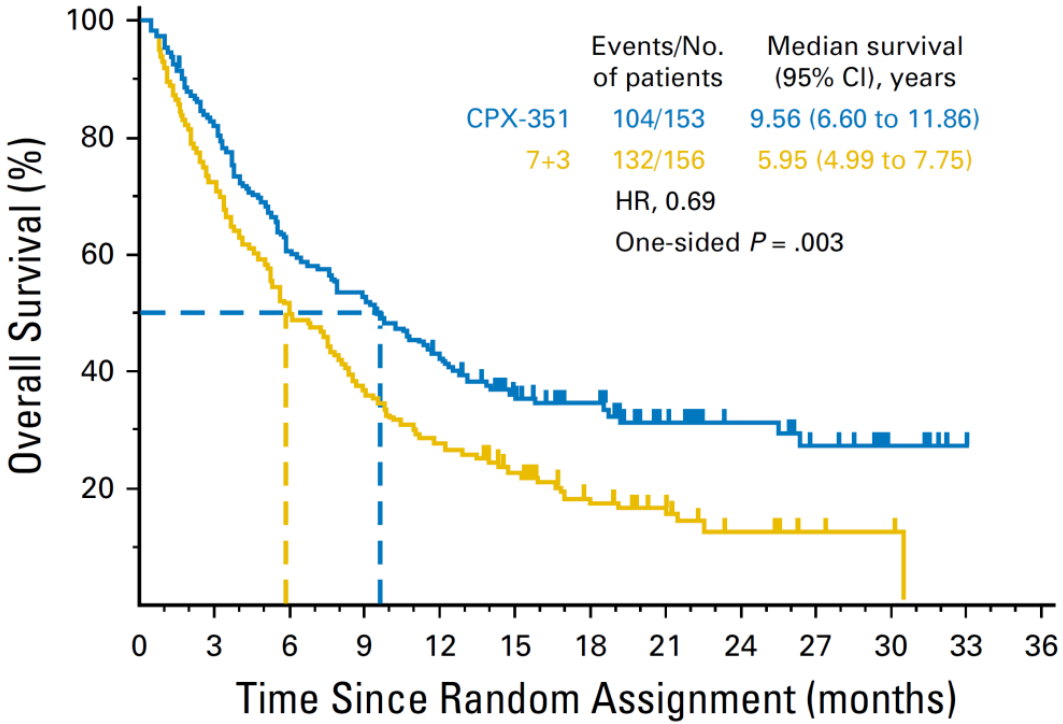
Combining Midostaurin and GO in CBF AML



Combining Midostaurin and GO in $FLT3_{mut}$ AML

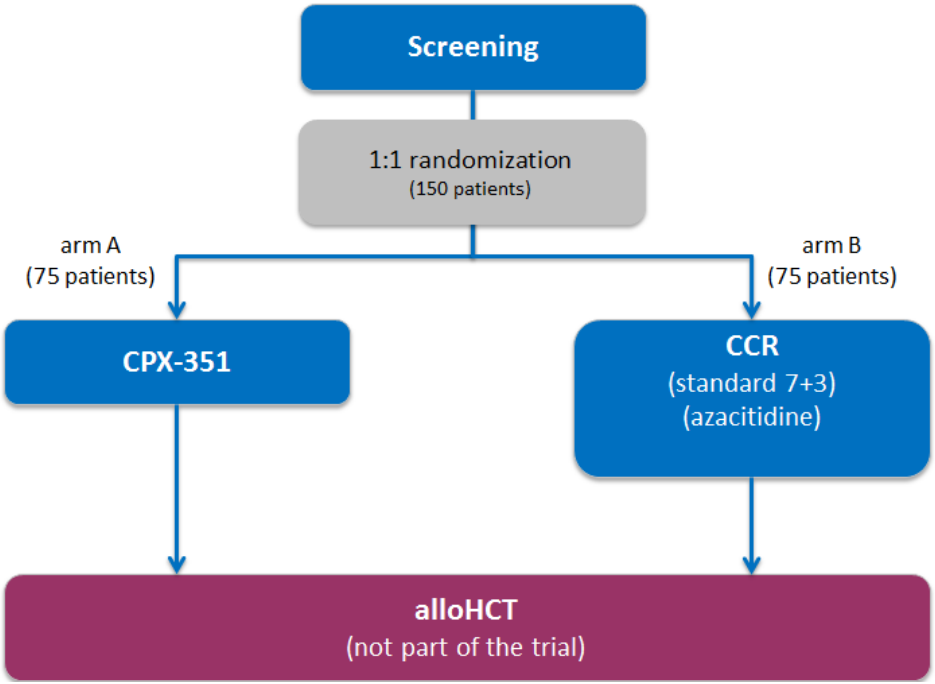


CPX-351 versus 7+3: Significantly prolonged survival in tAML, sAML, AML-MDS >60 J



Lancet et al., J Clin Oncol 2018

CPX-351 versus SOC (7+3 or aza) before allo HCT in High-risk MDS/oligoproliferative AML: PALOMA Trial



CPX-351 vs. SOC followed by alloSCT

Compare EFS after 2 years

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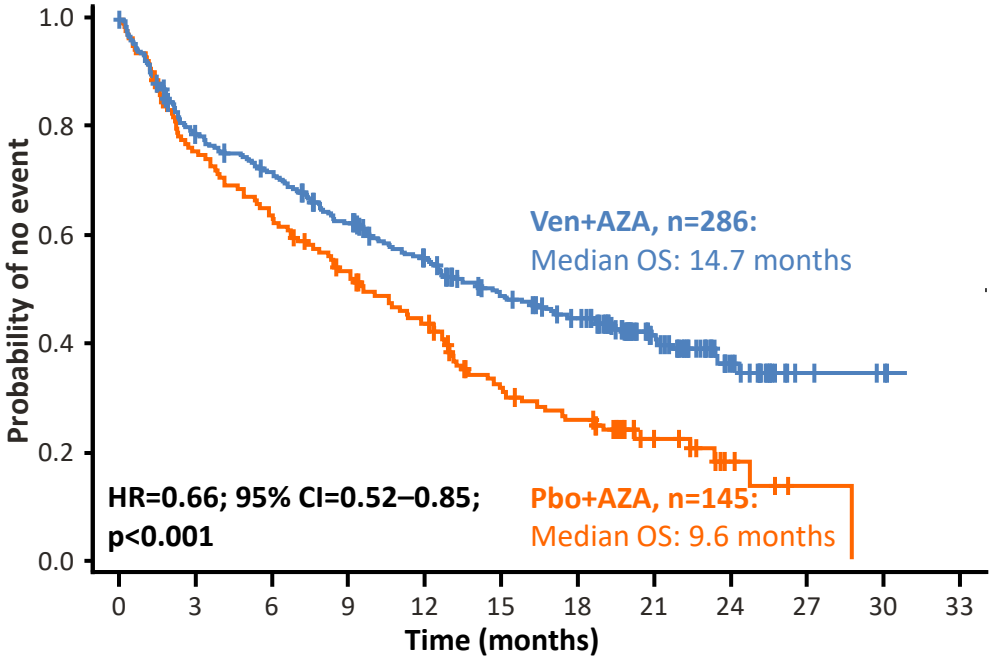
Venetoclax plus Azacitidine versus Placebo plus Azacitidine: Higher response rate and prolonged survival (VIALE A)



Endpoint	Ven+AZA n=286	Pbo+AZA n=145
CR+CRi rate	**66.4%**	**28.3%**
CR rate	36.7%	17.9%
CR+CRi by initiation of cycle 2	43.4%	7.6%

Ähnliche Wirksamkeit für die Venetoclax-Kombi mit Aza oder Deci

Cohort	N	Composite response rate (CR + CRi) [n], n (%)
All patients	145	[54 + 43], 97 (67)
VEN 400 mg + HMA	60	44 (73)
VEN 400 mg + AZA	29	22 (76)
VEN 400 mg + DEC	31	22 (71)

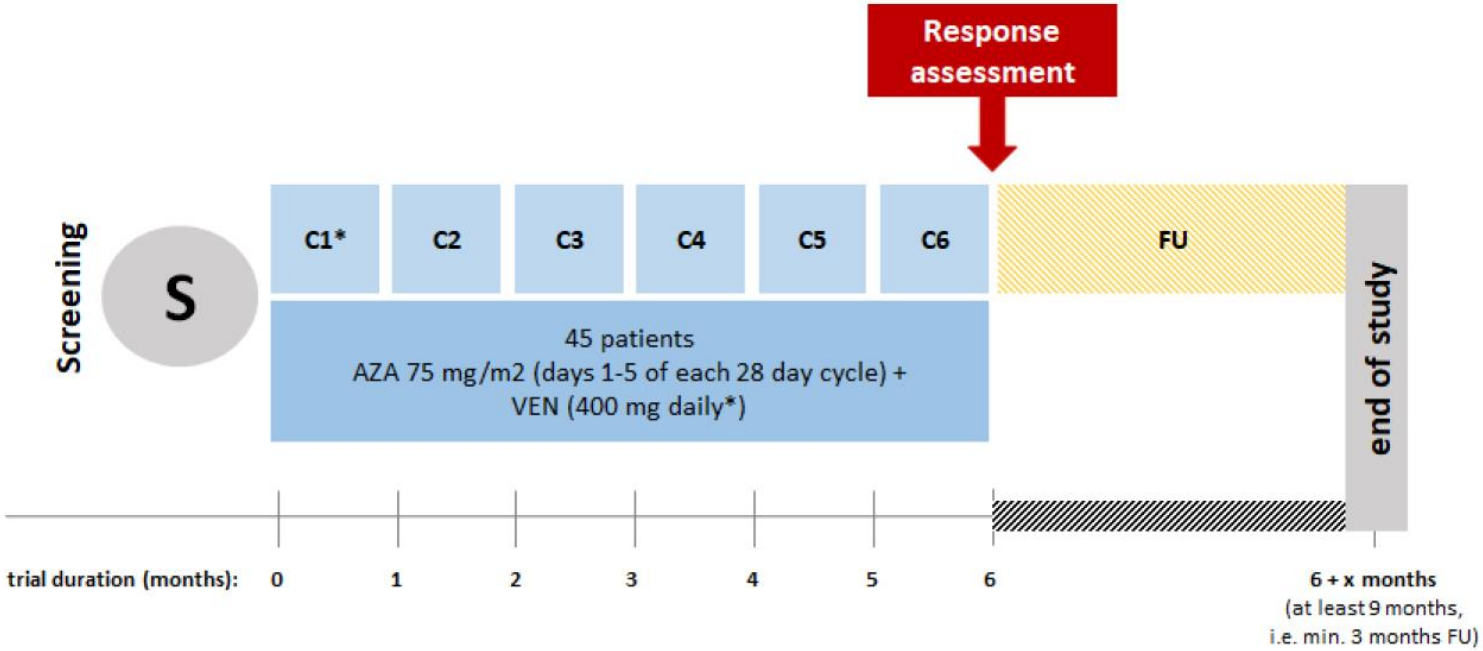
DiNardo et al. N Engl J Med 2020, DiNardo et al., Blood 2019

VIALE-A

Grade ≥3 AEs in >2 patients in the Ven arm, n (%)	Ven+Aza n=283	Pbo+Aza n=144
Hematologic AEs		
Thrombocytopenia	126 (45)	55 (38)
Neutropenia	119 (42)	41 (28)
Febrile neutropenia	118 (42)	27 (19)
Anemia	74 (26)	29 (20)
Leukopenia	58 (21)	17 (12)
Non-hematologic AEs		
Pneumonia	56 (20)	36 (25)
Nausea	5 (2)	1 (1)
Diarrhea	13 (5)	4 (3)
Vomiting	6 (2)	1 (1)
Hypokalemia	30 (11)	15 (10)
Pyrexia	5 (2)	2 (1)
Fatigue	8 (3)	2 (1)
Decreased appetite	12 (4)	1 (1)

Other safety events, n (%)	Ven+Aza n=283	Pbo+Aza n=144
30-day mortality	21 (7)	9 (6)
Discontinuations due to AEs	(24)	(20)

VenAza with 5 instead of 7 days Azacitidine: VENAZA-5S



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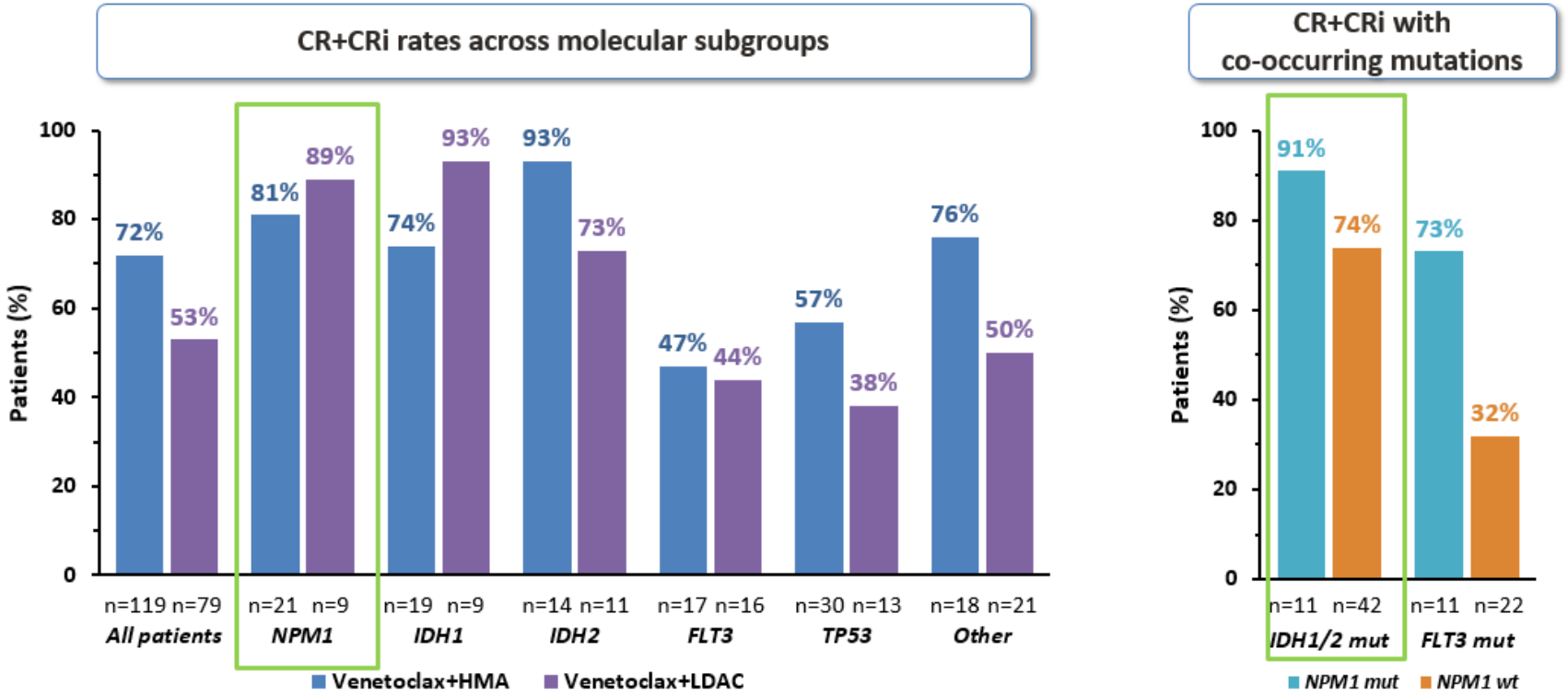
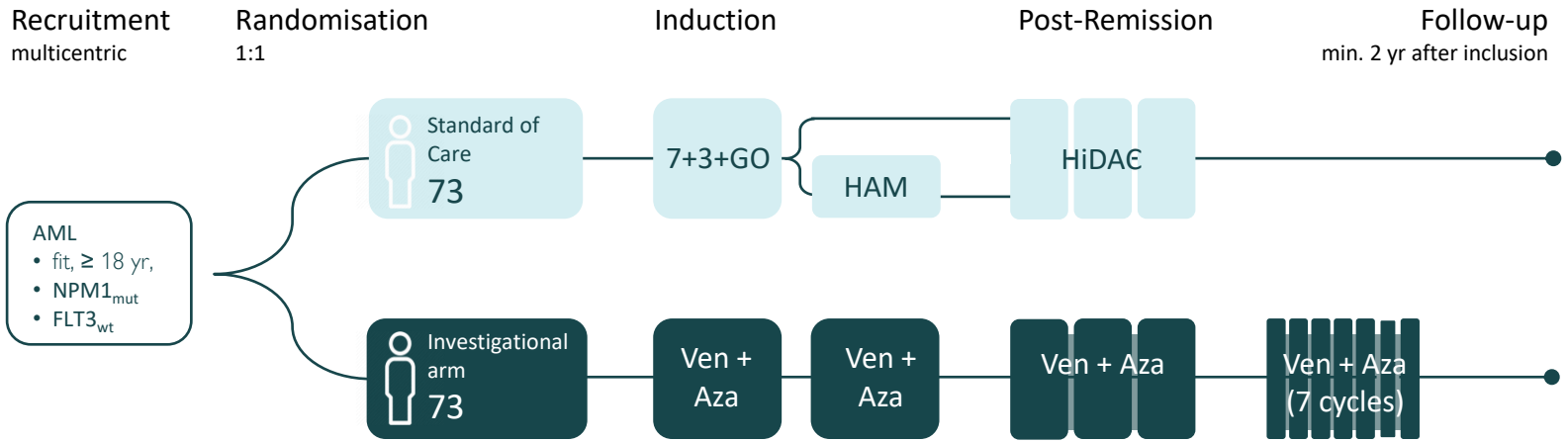
High response rates for Venetoclax + HMA in $NPM1_{mut}$ AML



Chyla B, *et al.* ASH 2019; oral presentation 546.

Ven+Aza versus Intensive Chemotherapy in NPM1^{mut} AML: VINCENT



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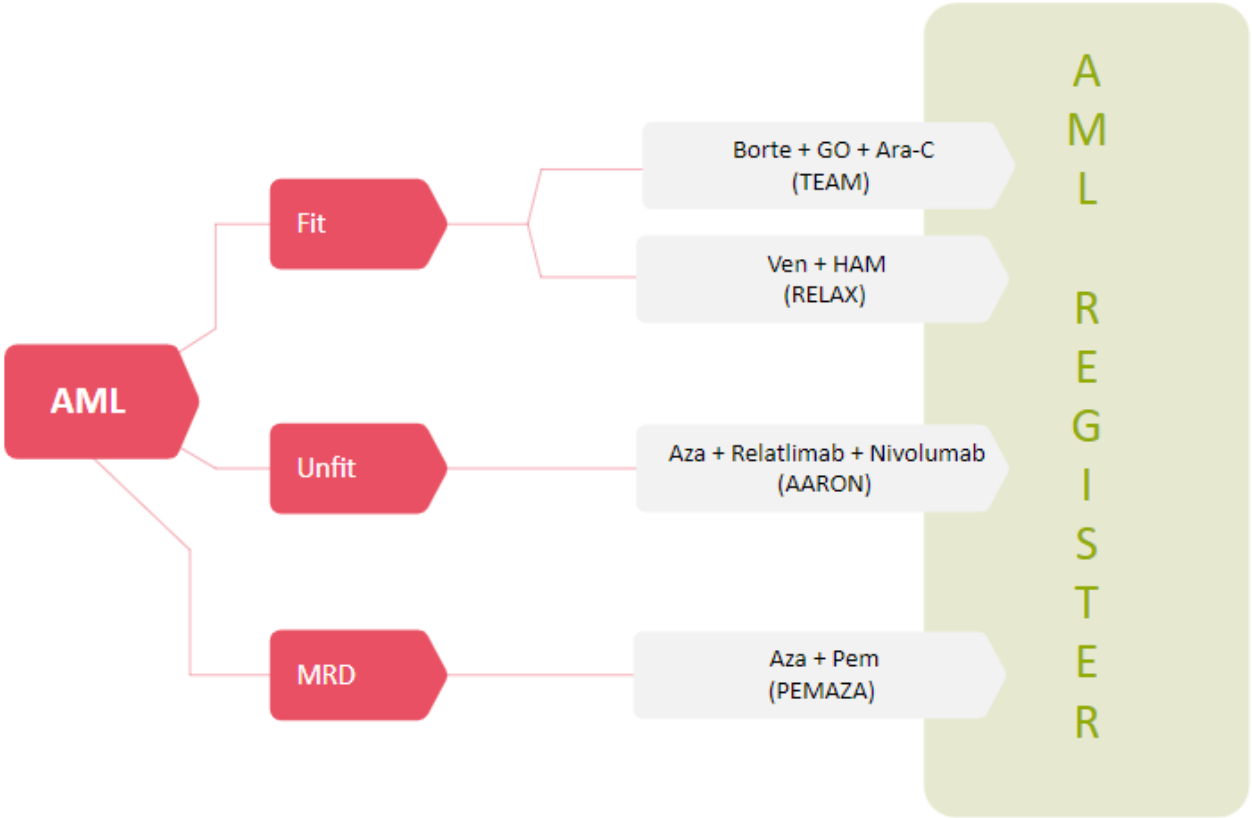
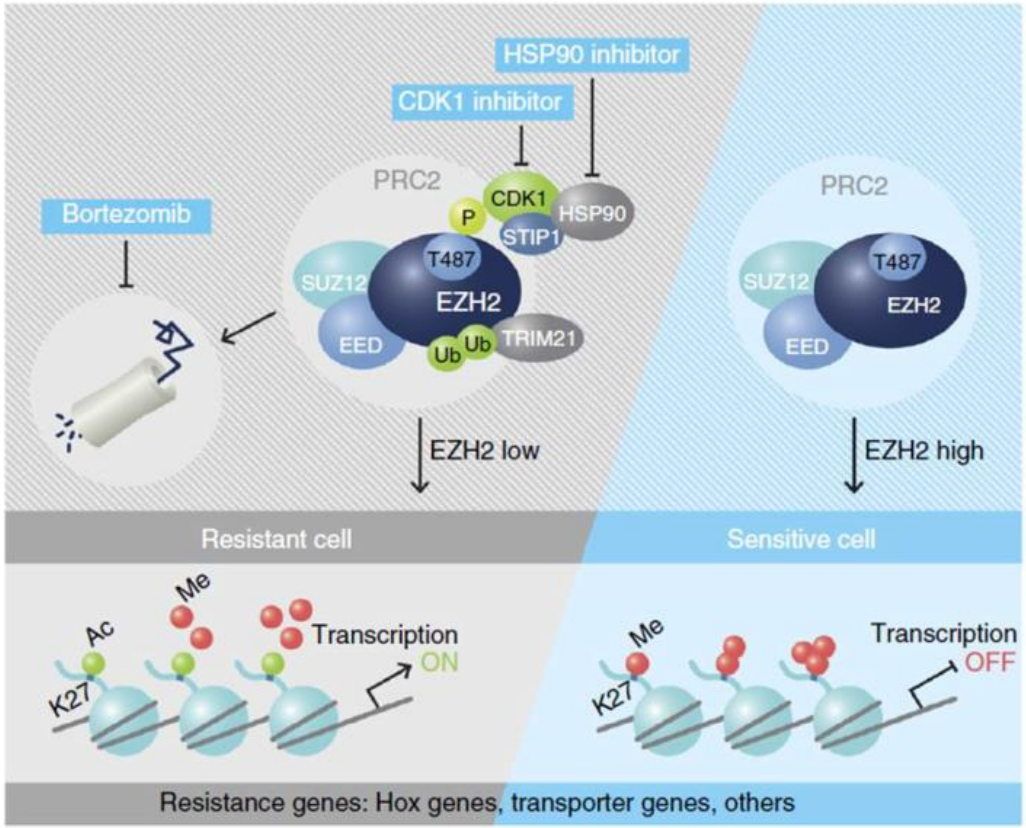
Trial Portfolio Relapse Treatment

Studienportfolio Rezidiv

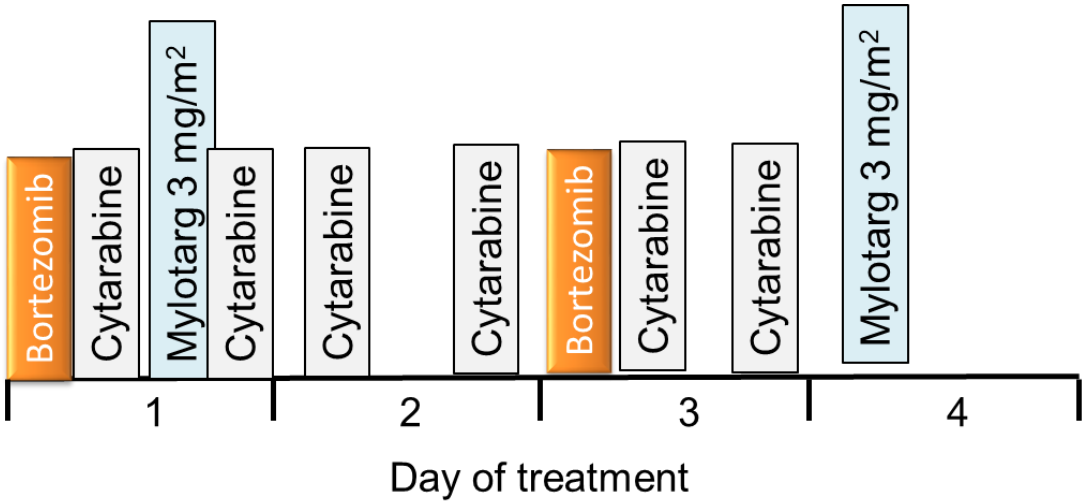


Treatment resistance by EZH2 degradation through proteasome



Göllner et al, Nature Medicine 2017

TEAM Trial: EZH2 Inhibition with Bortezomib plus GO and HiDAC in fit r/r AML



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PI: C. Müller-Tidow

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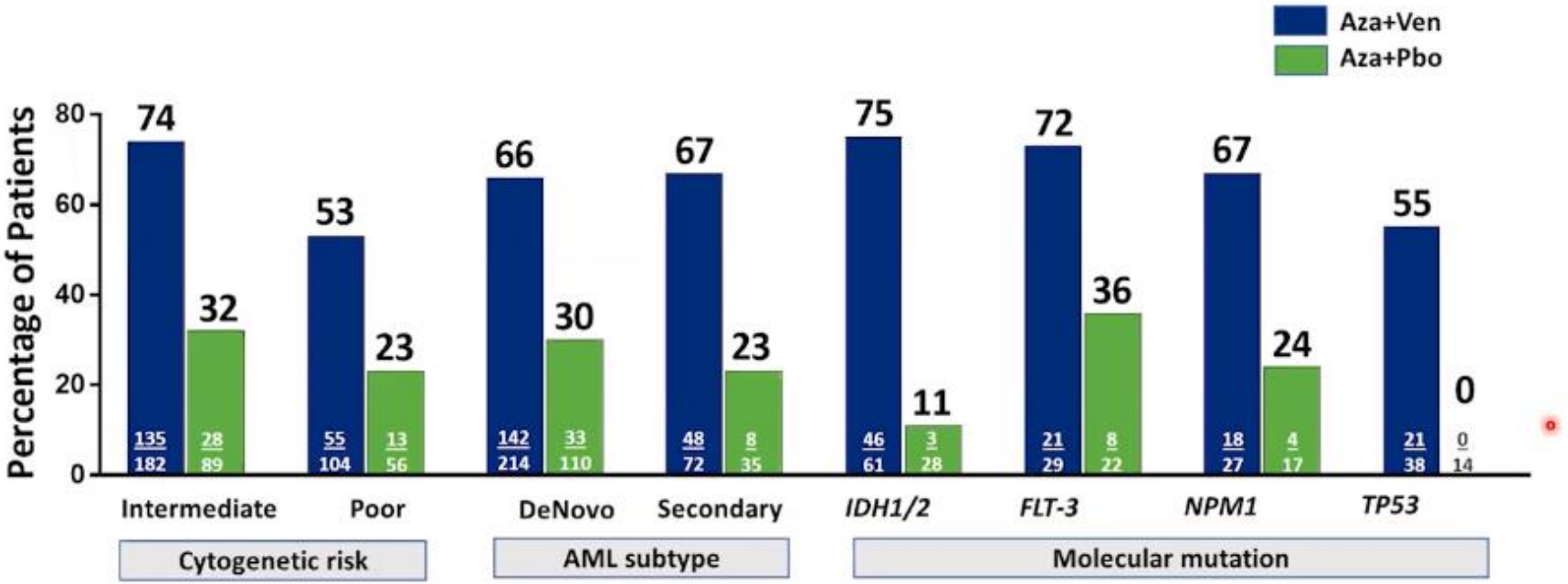
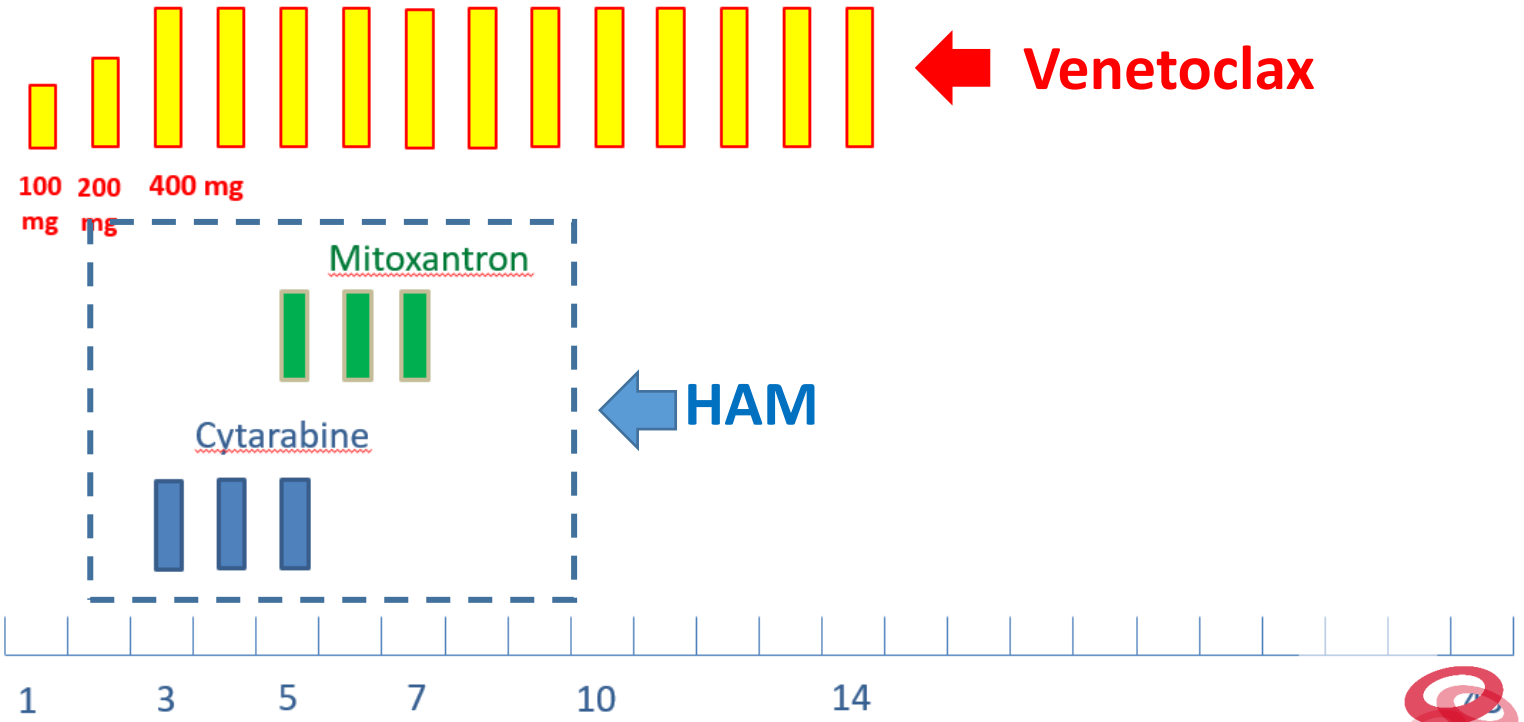
Aza+Ven versus Aza+Plac: CR/CRi



Modifiziert nach DiNardo J *et al. EHA* 2020; Abstr. LB2601

RELAX Trial: Venetoclax plus HAM in fit r/r AML



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1442 Venetoclax Plus High-Dose Cytarabine and Mitoxantrone As Feasible and Effective Novel Treatment for Relapsed AML: Results of the Phase-I SAL Relax Trial

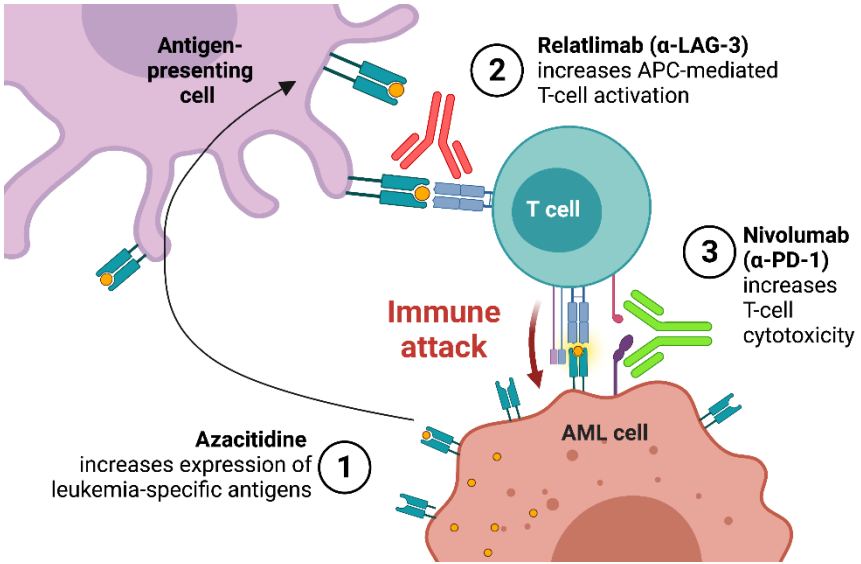
Program: Oral and Poster Abstracts
Session: 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster I
Hematology Disease Topics & Pathways:
Research, clinical trials, adult, Clinical Research, Combination therapy, Therapies, Study Population, Human, Minimal Residual Disease

Saturday, December 10, 2022, 5:30 PM-7:30 PM

Christoph Röllig, MD, MSC[1*], *Lars Fransecky, MD*[2*], *Maher Hanoun, MD, PhD*[3*], *Björn Steffen, MD*[4*], *Sabrina Kraus, MD*[5*], *Christoph Schliemann, MD*[6*], *Annett Haake*[7*], *Frank Fiebig*[7*], *Sven Zukunft*[8*], *Nael Alakel, MD*[9*], *Jan Moritz Middeke, MD*[10*], *Martin Bornhaeuser, MD*[11], *Friedrich Stoelzel, MD*[10], *Johannes Schetelig, MD, MSc*[12], *Leo Ruhnke*[8*], *Michael Kramer, MSc*[8*], *Malte Von Bonin, MD*[13*], *Maximilian Alexander Röhnert*[14*], *Uta Oelschlägel, PhD*[15*], *Claudia D. Baldus, MD*[16*], *Hubert Serve, MD*[4] *and Martin Wermke, MD*[17*]

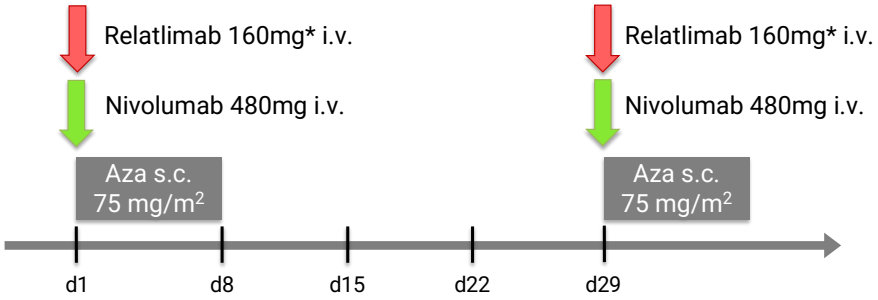
AARON (NCT04913922)

Relatlimab (α-LAG-3) + Nivolumab (α-PD1) in Combination with 5-Azacytidine in r/r AML



r/r AML (including HMA-pretreated patients)

- Lead-in phase currently ongoing (4/6 recruited)
- Preparations for multi-center recruitment ongoing (after completion of lead-in phase)



- **Primary objective: ORR**
- Secondary objectives: HI, PFS, OS

* dose de-escalation in case of DLTs during lead-in phase

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1399 Trial in Progress: An Open-Label Phase II Study of Relatlimab with Nivolumab in Combination with 5-Azacytidine for the Treatment of Patients with Relapsed/Refractory and Elderly Patients with Newly Diagnosed Acute Myeloid Leukemia (AARON)

Program: Oral and Poster Abstracts
Session: 613. Acute Myeloid Leukemias: Clinical and Epidemiological: Poster I
Hematology Disease Topics & Pathways:
Research, clinical trials, Acute Myeloid Malignancies, AML, Biological therapies, Antibody Therapy, Clinical Research, Checkpoint Inhibitor, Diseases, Therapies, Immunotherapy, Myeloid Malignancies

Saturday, December 10, 2022, 5:30 PM-7:30 PM

Veit L Buecklein, MD[1,2*], *Maximilian Warm*[2*], *Karsten Spiekermann*[2,3], *Christian Schmidt, MD*[2*], *Michael Unterhalt, MD, PhD*[2*], *Naval Daver, MD*[4] *and Marion Subklewe, MD*[1,5,6]

[1]*Translational Cancer Immunology, Gene Center, LMU Munich, Munich, Germany*
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[3]*Experimental Leukemia and Lymphoma Research (ELLF), University Hospital, LMU Munich, Munich, Germany*
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[6]*Department of Medicine III (Hematology/Oncology), LMU University Hospital Munich, Muenchen, Germany*

Immunogenicity of mutated NPM1 protein

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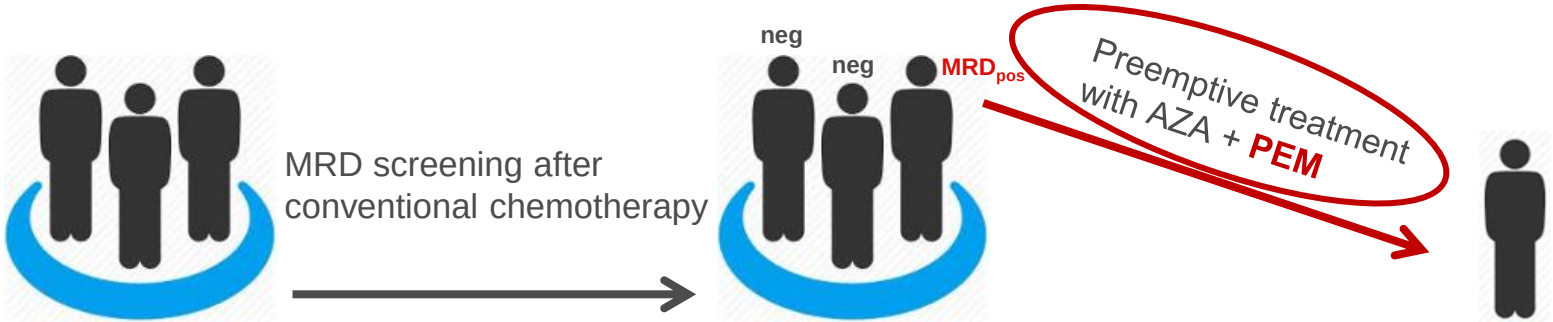
CORRESPONDENCE | AUGUST 8, 2013

Immune responses against the mutated region of cytoplasmatic NPM1 might contribute to the favorable clinical outcome of AML patients with *NPM1* mutations (*NPM1*^{mut})

Jochen Greiner, Vanessa Schneider, Michael Schmitt, Marlies Götz, Konstanze Döhner, Markus Wiesneth, Hartmut Döhner, Susanne Hofmann

PemAza Trial: Pembrolizumab plus Azacitidine as Preemptive MRD based Relapse Treatment in NPM1-mut AML



Primary EP:

- **Proportion of relapse-free patients after 24 weeks of combination treatment** (after 6 cycles of AZA for 7 d (5+2) Q4W and 8 PEM infusions Q3W)

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