

Low-dose azacitidine, pioglitazone and all-*trans* retinoic acid is safe in patients aged ≥ 60 years with acute myeloid leukemia refractory to standard induction chemotherapy (AMLSG 26-16/AML-ViVA): results of the safety run-in phase

Daniel Heudobler,^{1,2} Florian Lüke,^{1,3} Joachim Hahn,¹ Matthias Grube,¹ Pavla Schlosser,¹ Stephan Kremers,⁴ Thomas Südhoff,⁵ Jörg Westermann,⁶ Marie Luise Hütter-Krönke,^{6,7} Richard F. Schlenk,^{8,9} Daniela Weber,⁷ Peter Paschka,⁷ Florian Zeman,¹⁰ Hartmut Döhner,⁷ Wolfgang Herr,¹ Albrecht Reichle^{1#} and Simone Thomas^{1,11#}

¹University Hospital Regensburg, Department of Internal Medicine III, Hematology and Oncology, Regensburg; ²Bavarian Center for Cancer Research, University Hospital Regensburg, Regensburg;

³Division of Personalized Tumor Therapy, Fraunhofer Institute for Toxicology and Experimental Medicine, Regensburg;

⁴Caritaskrankenhaus Lebach, Department of Hematology/Oncology, Lebach; ⁵Klinikum Passau, Department Hematology and Oncology, Passau; ⁶Charité - University Medical Center Berlin - Department of Hematology, Oncology and Tumor Immunology, Campus

Virchow-Klinikum, Berlin; ⁷University Hospital Ulm, Department of Internal Medicine III, Ulm; ⁸National Center of Tumor Diseases Trial Center, German Cancer Research Center and Heidelberg University Hospital, Heidelberg; ⁹Heidelberg University Hospital, Department of Internal Medicine V, Heidelberg; ¹⁰Center for Clinical Studies, University Hospital Regensburg, Regensburg and ¹¹Leibniz Institute for Immunotherapy, Division of Genetic Immunotherapy, Regensburg, Germany

#AR and ST contributed equally as senior authors.

Correspondence:

D. HEUDOBLER - daniel.heudobler@ukr.de

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Supplementary Data

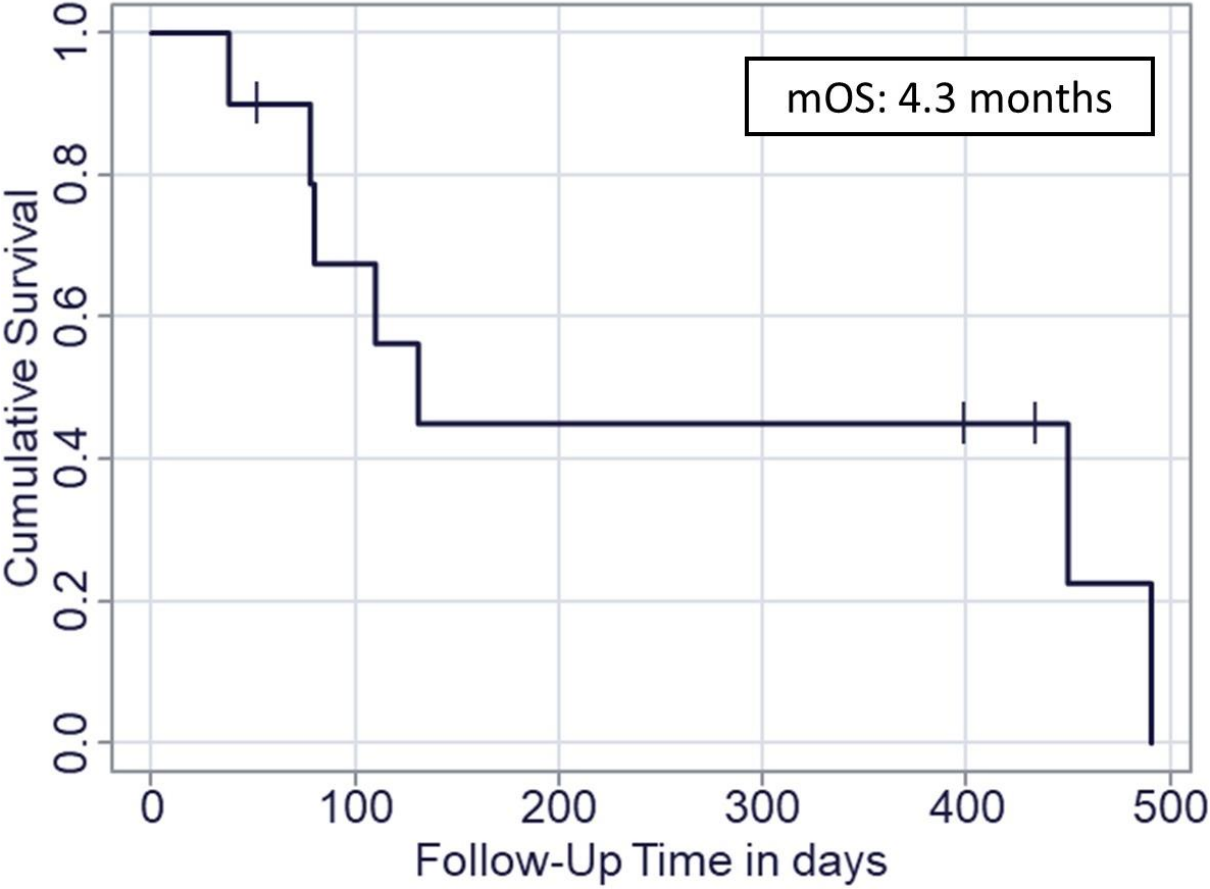
Supplementary Table 1: Adverse events on patient basis (n=10)

	Safety population (N=10)	
	Any Grade	Grade 3 or 4
	<i>Number of patients with event (percent)</i>	
Anemia	8 (80%)	6 (60%)
Platelet count decreased	6 (60%)	4 (40%)
White blood cell decreased	6 (60%)	5 (50%)
Neutrophil count decreased	5 (50%)	5 (50%)
Fever	2 (20%)	2 (20%)
Chills	1 (10%)	
Lung infection	4 (40%)	4 (40%)
Urinary tract infection	3 (30%)	2 (20%)
Sepsis	1 (10%)	1 (10%)
Nail infection	1 (10%)	
Infections and infestations - Other	3 (30%)	1 (10%)
Epistaxis	2 (20%)	
Urinary urgency	1 (10%)	1 (10%)
Renal and urinary disorders – Other (Urinary tract bleeding)	1 (10%)	1 (10%)
Gastric hemorrhage	1 (10%)	1 (10%)
Eye disorders – Others (retinal bleeding)	1 (10%)	
Cough	4 (40%)	
Dyspnea	3 (30%)	
Hypokalemia	4 (40%)	1 (10%)
Fibrinogen decreased	1 (10%)	
Investigations - Other (CRP increase): 12.38.1	1 (10%)	
Iron overload	1 (10%)	1 (10%)
Hyperthyroidism	1 (10%)	
Pain	7 (70%)	2 (20%)
Bone pain	1 (10%)	
Arthralgia	1 (10%)	
Headache	1 (10%)	
Hypotension	1 (10%)	
Atrial flutter	1 (10%)	
Thromboembolic event	2 (20%)	2 (20%)
Edema limbs	3 (30%)	
Edema trunk	1 (10%)	
Diarrhea	2 (20%)	
Constipation	2 (20%)	1 (10%)
Gastrointestinal pain	1 (10%)	
Gastrointestinal disorders – Other (decrease of appetite)	2 (20%)	
Nausea	1 (10%)	
Vomiting	1 (10%)	
Weight loss	1 (10%)	
Fatigue	1 (10%)	
General disorders and administration site conditions - Other	2 (20%)	
Insomnia	2 (20%)	1 (10%)
Skin and subcutaneous tissue disorders	3 (30%)	
Skin ulceration	1 (10%)	
Wound complication	1 (10%)	1 (10%)
Allergic reaction	1 (10%)	

Injection site reaction	1 (10%)	
Dizziness	2 (20%)	
Nervous system disorders - Other	1 (10%)	1 (10%)
Depression	1 (10%)	
Psychiatric disorders – Others (panic attack)	1 (10%)	

Supplementary Figure 1: Kaplan-Meier plot for overall survival (n=9)

Overall Survival



Supplementary Figure 2: Resolution of fungal pneumonia in patient 4. CT scan of the thorax shows pulmonary infiltrates in the right lung at baseline. During/after cycle 2 of AML-ViVA treatment CT scan demonstrates resolution of infiltrates.

