LETTER TO THE EDITOR

A phase I/II multicenter, open-label, dose escalation and randomized trial of BI 836858 in patients with low- or intermediate-1-risk myelodysplastic syndrome

Rami S. Komrokji,[1] Hetty E. Carraway,[2] Ulrich Germing,[3] Martin Wermke,[4] Amer M. Zeidan,[5] Eric Fu,[6] Björn Rüter,[7] Ute Burkard,[7] Annika Osswald[7] and James M. Foran[8]

[1]Malignant Hematology Department, H Lee Moffitt Cancer Center and Research Institute, Tampa, FL, USA; [2]Leukemia Program, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH, USA; [3]Department of Hematology, Oncology, and Clinical Immunology, Heinrich-Heine University Dusseldorf, Universitätsklinikum, Dusseldorf, Germany; [4]NCT/UCC-ECTU, Medical Faculty Carl Gustav Carus, Technical University, Dresden, Germany; [5]Department of Internal Medicine, Section of Hematology, Yale University School of Medicine, New Haven, CT, USA; [6]Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; [7]Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach/Riss, Germany and [8]Department of Hematology and Medical Oncology, Mayo Clinic, Jacksonville, FL, USA

Correspondence:
RAMI S. KOMROKJI - Rami.Komrokji@moffitt.org

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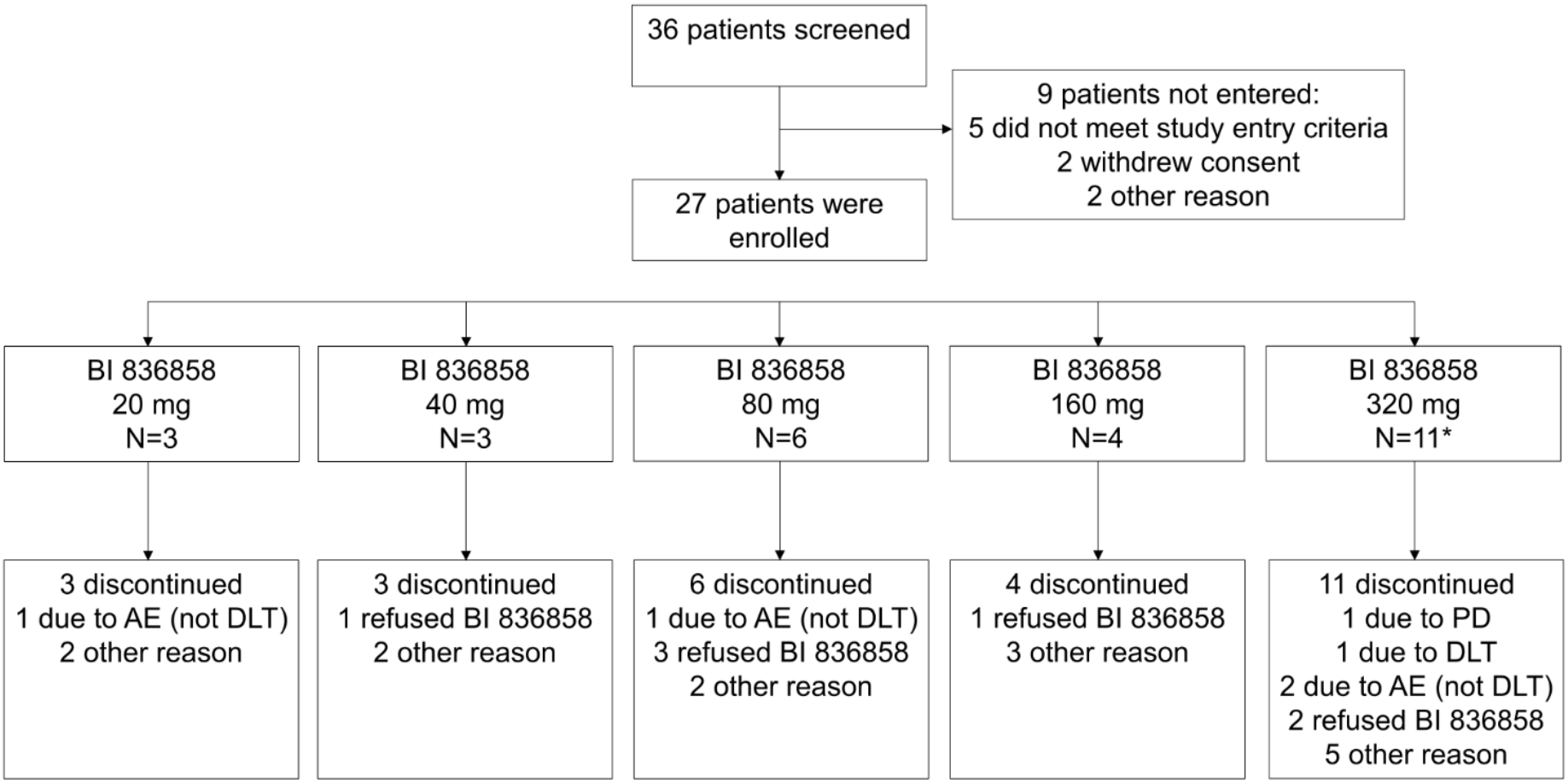
Supplementary material

Supplementary Table S1. Treatment-related AEs by MedDRA preferred terms and highest CTCAE grade in patients with low or intermediate risk-1 MDS (n=27). On treatment period.

AE, n (%)	All grades	Grade 1/2	Grade 3	Grade 4
Total with AEs	24 (88.9)	17 (62.9)	4 (14.8)	3 (11.1)
Infusion-related reaction	21 (77.8)	20 (74.0)	1 (3.7)	0
Neutrophil count decreased	6 (22.2)	0	4 (14.8)	2 (7.4)
Nausea	3 (11.1)	3 (11.1)	0	0
WBC count decreased	3 (11.1)	2 (7.4)	1 (3.7)	0
Anemia	1 (3.7)	0	1 (3.7)	0
Platelet count decreased	1 (3.7)	0	1 (3.7)	0
Sepsis	1 (3.7)	0	0	1 (3.7)

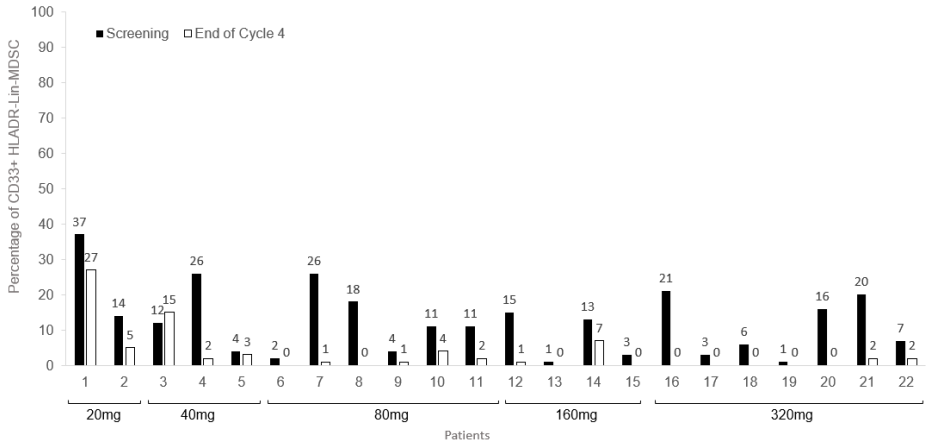
AEs shown are those occurring in >10% of patients for all grades and all grades 3 and 4.
CTCAE: Common Terminology Criteria for Adverse Events; MDS: myelodysplastic syndromes; MedDRA: Medical Dictionary for Regulatory Activities; WBC: white blood cell.

Supplementary Figure S1: Study profile. *Six patients were treated in the expansion cohort. AE: adverse event; DLT: dose-limiting toxicity; PD: progressive disease.



Supplementary Figure S2. A) Percentages of CD33+ HLADR-Lin-MDSC in the FACs analysis set at screening and the end of Cycle 4. Data for patients with a percentage above zero at screening. B) Percentages of CD3-CD16+CD69+ NK cells in the FACs analysis set (filled symbol indicates that the value is predose)

A)



B)