ELSEVIER

Blood 142 (2023) 5173–5175

The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

906.OUTCOMES RESEARCH-MYELOID MALIGNANCIES

Comparative Analysis of Clinical Outcomes and Healthcare Resource Utilization (HRU) in Patients (Pts) with Newly Diagnosed (ND) Acute Myeloid Leukemia (AML) Unfit for High-Intensity Chemotherapy Treated with Venetoclax (VEN) Vs Other Therapies: Results from the AML Real World Evidence (ARC) Initiative

Pinkal Desai, MD MPH[1], Jacqueline S. Garcia, MD[2], Joshua F. Zeidner, MD[3], Sameem Abedin, MD[4], Ofir Wolach[5], Pankit Vachhani, MD[6], Yakir Moshe, MDPhD[7], Daniel A. Pollyea, MD[8], Catherine Lai, MD MPH[9], Thomas W LeBlanc, MD[10], Marin Xavier, MD[11], Boaz Nachmias, MD[12], Evan C. Chen, MD[13], Srilakshmi Bathini[6], Inderpreet Bhatti[14], Cat N. Bui, PharmD, PhD[15], Annie Guérin, MS[16], Rebecca Burne[17], Esprit Ma, MPH[18], Moshe Grunspan[19], Neta Frankel[19], Aaron D. Goldberg, MDPhD[20]

[1] Weill Cornell Medicine, The New York Presbyterian Hospital, New York, NY
[2] Department of Medical Oncology, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA
[3] University of North Carolina, Lineberger Comprehensive Cancer Center, Chapel Hill, NC
[4] Medical College of Wisconsin, Milwaukee, WI
[5] Rabin Medical Center, Petah Tikva, Israel
[6] O'Neal Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, AL
[7] Division of Hematology, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel
[8] University of Colorado School of Medicine, Aurora, CO
[9] Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA
[10] Division of Hematologic Malignancies and Cellular Therapy, Duke University School of Medicine, Durham, NC
[11] Scripps Health, San Diego, CA
[12] Hebrew University, Jerusalem, Israel
[13] Dana Farber Cancer Institute, Boston, MA
[14] Scripps MD Anderson, San Diego, CA
[15] AbbVie Inc, North Chicago, IL
[16] Analysis Group, Inc, Montreal, Canada
[17] Analysis Group Inc, Montreal, Canada
[18] Genentech, Inc., South San Francisco, CA
[19] AbbVie Inc, Hod Hasharon, Israel
[20] Memorial Sloan Kettering Cancer Center, New York City, NY

Introduction: The BCL-2 inhibitor VEN is approved in combination with hypomethylating agents or low-dose cytarabine for adults with ND AML. The ARC Initiative is a multicenter chart review study of adult pts with AML. This abstract presents real-world clinical outcomes and hospitalizations among ND AML VEN treated pts ineligible for intensive chemotherapy (IC) and their matched controls.

Methods: This multicenter chart review study included adult pts (≥18 years) with ND AML who received VEN in combination with HMA on or after April 2016, or non-VEN regimens on or after May 2015, from 15 international academic sites (US: 11; Israel: 4). Pts ineligible for IC (i.e., ≥75 years or ≥1 comorbidity based on the Ferrara criteria) and treated with VEN (VEN cohort) were matched 1:1 to control pts who received non-VEN-based regimens (CON cohort). Pts were matched based on age (<60, 60-74, ≥75 years) and European LeukemiaNet (ELN 2017) risk. All analyses are based on the May 2023 data cutoff; data collection is ongoing. Clinical outcomes include composite complete remission (CRc; i.e., CR, CR with partial hematologic recovery [CRh], or CR with incomplete marrow recovery [CRi]) and overall survival (OS; assessed using Kaplan-Meier analysis). Hospitalizations were assessed overall and among pts who achieved CRc. Results were separately reported overall and among the respective subsets of VEN pts matched to CON pts treated with high-intensity regimens (CON-H) or low-intensity regimens (CON-L).

Results: A total of 142 IC-ineligible VEN pts and 142 matched CON pts were included in the analysis, including 80 VEN pts matched to CON-H pts (56.3%) and 62 VEN pts matched to CON-L pts (43.7%) (**Table 1**). Overall, VEN pts received VEN-

azacitidine (75.4%) or VEN-decitabine (24.6%). A total of 68.3% of all pts were classified as ELN adverse risk, and 24.6% of VEN pts and 20.4% of CON pts were classified as Eastern Cooperative Oncology Group (ECOG) Grade ³2. Among pts with genetic mutations tested (96.5% of VEN pts and 94.4% of CON pts), 22.6% of VEN pts and 14.2% of CON pts had *TP53* mutations and 21.9% and 19.4%, respectively, had *IDH1/2* mutations.

VEN pts had a mean of 11.6 months of follow-up, and CON pts had a mean of 15.0 months of follow-up. VEN pts were significantly more likely to achieve CRc than CON pts (64.7% vs 44.3%, p=0.001). This difference was more pronounced for VEN pts matched to CON-L pts (62.1% vs 18.0%, p<0.001). The 6-month OS rates were not statistically different between VEN pts and matched CON pts (74.7% vs 67.6%; p=0.20), despite the majority of CON pts receiving high-intensity regimens, but improved among VEN pts matched to CON-L pts (73.5% vs 55.3%; p<0.05).

VEN pts had fewer days of hospitalization per pt per month (PPPM; mean 6.3 days vs 8.9 days, p=0.045) and shorter mean duration of hospitalization (13.7 days vs 18.2 days, p<0.001) compared with CON pts. A larger difference was seen in the amount of time (days) (6.5 vs 10.5 PPPM, p=0.006) and mean length of hospital stay (13.9 vs 22.4 days, p<0.001) for VEN pts matched to CON-H pts. Among pts with ≥1 all-cause hospitalization, 69.2% of VEN pts and 74.8% of CON pts were hospitalized for treatment administration (p=0.42).

Among pts who achieved CRc, VEN pts had fewer days of hospitalization PPPM than CON pts (mean 4.3 days vs 6.8 days, p=0.002). This difference was more pronounced for VEN pts compared to CON-H pts (4.3 days vs 7.7 days, p=0.001). Mean duration of hospitalization was also shorter for VEN vs CON pts (13.6 days vs 20.4 days, p<0.001). Both VEN and CON pts experienced more hospitalizations before CRc was achieved, with statistically fewer hospitalizations for VEN pts compared with CON pts (days of hospitalization PPPM: 10.1 vs 17.4, p=0.001; duration of hospitalization: 16.4 vs 28.2, p<0.001). In the 60 days after CRc was achieved, VEN pts still had fewer days of hospitalization PPPM than CON pts (1.4 vs 5.2, p<0.001).

Conclusions: Pts with ND AML who were ineligible for IC and received VEN had significantly higher rates of CRc than matched pts who received non-VEN-based regimens. Although pts treated with VEN-based regimens achieved similar rates of CRc compared to matched control pts treated with high-intensity therapy, pts treated with VEN-based regimens required a significantly lower burden of hospitalizations compared with matched pts on non-VEN-based regimens.

Disclosures Desai: *Janssen Pharmaceuticals:* Current Employment; *BMS:* Consultancy, Other: Advisory role; *Servier:* Consultancy, Other: Advisory role; *Abbvie:* Consultancy, Other: Advisory role; *Janssen Research & Development:* Research Funding. **Garcia:** *AbbVie:* Consultancy, Research Funding; *AstraZeneca:* Research Funding; *Pfizer:* Research Funding; *Prelude:* Research Funding; *New Wave:* Research Funding; *Servier:* Consultancy; *Gilead:* Consultancy; *Genentech:* Consultancy, Research Funding; *Bristol Myers Squibb:* Consultancy; *Astellas:* Consultancy. **Zeidner:** *Arog:* Research Funding; *Daiichi Sankyo:* Honoraria; *Sumitomo Dainippon Pharma:* Research Funding; *Stemline:* Research Funding; *Shattuck Labs:* Honoraria, Research Funding; *Servier:* Consultancy, Honoraria; *Astex:* Research Funding; *AbbVie:* Consultancy, Honoraria, Research Funding; *Takeda:* Research Funding; *Sellas:* Consultancy; *Foghorn:* Consultancy; *Novartis:* Consultancy; *Merck:* Research Funding; *Jazz:* Research Funding; *Immunogen:* Honoraria; *Gilead:* Consultancy, Honoraria, Research Funding. **Abedin:** *Incyte:* Research Funding; *AltruBio:* Research Funding; *AbbVie:* Consultancy, Honoraria; *Actinium Pharmaceutical:* Research Funding; *Daichii Sankyo:* Consultancy, Honoraria; *Servier:* Consultancy, Honoraria. **Wolach:** *AbbVie, Astellas, Novartis:* Speakers Bureau; *AbbVie, Astellas, Novartis, Pfizer, Medison, Teva:* Consultancy. **Vachhani:** *Cogent Biosciences:* Consultancy; *Incyte:* Consultancy, Speakers Bureau; *CTI BioPharma Corp:* Consultancy, Speakers Bureau; *Daiichi Sankyo:* Consultancy; *GlaxoSmith Kline:* Consultancy; *Karyopharm:* Consultancy; *Novartis:* Consultancy; *Pfizer:* Consultancy; *Genentech:* Consultancy; *Servier:* Consultancy; *Stemline:* Consultancy; *MorphoSys:* Consultancy; *LAVA therapeutics:* Consultancy; *Blueprint Medicines:* Consultancy, Speakers Bureau; *Amgen:* Consultancy; *AbbVie:* Consultancy. **Moshe:** *Abbvie:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Astellas:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Novartis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Pfizer:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Stemline:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees. **Pollyea:** *Teva, Karyopharm, Bristol Myers Squibb, and AbbVie.:* Research Funding; *AbbVie, Bristol Myers Squibb, Syros, Novartis, Beigene, Bergen Bio, Arcellx, Jazz, Genentech, Immunogen, AstraZeneca, Kura, Ryvu, Magenta, Qihan, Zentalis, Medivir, Hibercell, LINK, Daiichi Sankyo, Aptevo, Rigel, Sumitomo, Adicet, Seres, Gilead, OncoVerit:* Consultancy. **Lai:** *Pfizer:* Consultancy; *Jazz:* Consultancy, Research Funding, Speakers Bureau; *Daiichi:* Consultancy; *Novartis:* Consultancy; *Genentech:* Consultancy; *BMS:* Consultancy; *Rigel:* Consultancy; *Taiho:* Consultancy; *Astellas:* Consultancy, Speakers Bureau; *AbbVie:* Consultancy. **LeBlanc:** *Astellas:* Consultancy, Honoraria, Speakers Bureau; *Agios:* Consultancy, Honoraria, Speakers Bureau; *Agilix:* Consultancy, Honoraria; *Deverra Therapeutics:* Research Funding; *Duke University:* Research Funding; *AstraZeneca:* Consultancy, Honoraria, Research Funding; *Incyte:* Honoraria, Speakers Bureau; *Dosentrx:* Current equity holder in private company; *UpToDate:* Patents & Royalties; *American Cancer Society:* Research Funding; *Novartis:* Consultancy, Honoraria; *BlueNote:* Consultancy, Honoraria; *Pfizer:* Consultancy, Honoraria; *BeiGene:* Consultancy, Honoraria; *Jazz Pharmaceuticals:* Research Funding; *Meter Health:* Consultancy, Honoraria; *BMS/Celgene:* Consultancy, Honoraria, Research Funding, Speakers Bureau; *CareVive:* Consultancy, Honoraria; *Lilly:* Consultancy, Honoraria; *Genentech:* Consultancy, Honoraria; *GSK:* Consultancy, Honoraria, Research Funding; *Flatiron:* Consultancy, Honoraria; *AbbVie:* Consultancy, Honoraria, Research Funding, Speakers Bureau; *Leukemia and Lymphoma Society:* Research Funding; *National Institute of Nursing Research/National Institutes of Health:* Research Funding; *Seattle Genetics:* Research Funding; *Servier:* Consultancy, Honoraria. **Xavier:** *Biegene, Morphosys/Incyte, AbbVie, AstraZeneca, Celgene/BMS, ADC Therapeutics, Blueprint Medicines, Lily/Loxo, Pharmacyclics:* Speakers Bureau; *Janssen/Pharmacyclics*

Kite/Gilead, Genentech, AstraZeneca: Honoraria; *AbbVie, Acrotec, Blueprint Medicines, Loxo, CTI BioPharma:* Consultancy. **Nachmias:** *AbbVie, Medison, Astellas:* Consultancy, Membership on an entity's Board of Directors or advisory committees. **Chen:** *Rigel:* Consultancy; *Abbvie:* Consultancy. **Bui:** *AbbVie Inc:* Current Employment, Current holder of *stock options* in a privately-held company. **Guérin:** *Analysis Group:* Current Employment, Other: I am an employee of Analysis Group, Inc. a consulting company which received funding from Novartis.; *Novartis Pharmaceuticals Corporation:* Consultancy, Other: I am an employee of Analysis Group, Inc. a consulting company which received funding from Novartis.; *AbbVie:* Consultancy. **Burne:** *Analysis Group:* Current Employment. **Ma:** *Genentech, Inc.:* Current Employment, Current equity holder in private company. **Grunspan:** *AbbVie:* Current Employment, Current equity holder in publicly-traded company. **Frankel:** *AbbVie:* Current Employment, Current equity holder in publicly-traded company. **Goldberg:** *Abbvie:* Consultancy, Research Funding; *Aprea:* Research Funding; *Trillium:* Research Funding; *Prelude:* Research Funding; *AROG:* Research Funding; *Pfizer:* Research Funding; *ADC Therapeutics:* Research Funding; *Genentech:* Consultancy; *Daiichi Sankyo:* Consultancy, Research Funding; *Astellas Pharma:* Consultancy; *Aptose:* Research Funding; *DAVA Oncology:* Honoraria; *Celularity:* Research Funding.

Table 1. Characteristics, clinical outcomes, and HRU of IC-ineligible pts treated with VEN vs non-VEN-based regimens

	Overall IC-ineligible VEN Pts and Matched Controls			IC-ineligible VEN Pts Matched to High-Intensity Controls			IC-ineligible VEN Pts Matched to Low-Intensity Controls		
	VEN N = 142	CON N = 142	P-value	VEN N = 80	CON-H N = 80	P-value	VEN N = 62	CON-L[1] N = 62	P-value
Pts characteristics									
Age (years), mean [median] (range)	73.0 [74.5] (33.5, 89.3)	71.7 [73.2] (40.5, 90.4)	0.129	69.0 [69.9] (33.5, 87.7)	66.2 [66.9] (40.5, 78.6)	0.020	78.2 [79.1] (60.2, 89.3)	78.7 [78.6] (62.7, 90.4)	0.799
≥75, N (%)	67 (47.2)	67 (47.2)	1.000	16 (20.0)	16 (20.0)	1.000	51 (82.3)	51 (82.3)	1.000
Female, N (%)	53 (37.3)	53 (37.3)	1.000	30 (37.5)	28 (35.0)	0.869	23 (37.1)	25 (40.3)	0.854
ELN adverse risk, N (%)	97 (68.3)	97 (68.3)	1.000	48 (60.0)	48 (60.0)	1.000	49 (79.0)	49 (79.0)	1.000
Pts with ≥1 comorbidity of interest, N (%)	101 (71.1)	59 (41.5)	<0.001	68 (85.0)	22 (27.5)	<0.001	33 (53.2)	37 (59.7)	0.587
Months of follow-up, mean [median] (IQR)	11.6 [10.0] (3.8, 15.7)	15.0 [10.1] (3.4, 19.4)	0.558	11.1 [8.1] (4.0, 14.8)	17.7 [13.0] (4.8, 21.1)	0.036	12.2 [12.0] (3.7, 16.0)	11.7 [6.7] (2.2, 16.9)	0.177
Months of first-line treatment, mean [median] (IQR)	7.4 [4.1] (2.1, 11.2)	3.6 [2.1] (0.4, 4.1)	0.003	7.4 [4.1] (2.4, 10.6)	2.8 [1.9] (0.3, 3.6)	<0.001	7.5 [4.2] (1.7, 12.4)	4.5 [2.2] (1.0, 6.0)	0.010
Outcomes[2]									
CR, N (%)	50/136 (36.8)	50/140 (35.7)	0.955	31/78 (39.7)	43/79 (54.4)	0.092	19/58 (32.8)	7/61 (11.5)	0.010
CR or CRi, N (%)	77/136 (56.6)	58/140 (41.4)	0.016	47/78 (60.3)	48/79 (60.8)	1.000	30/58 (51.7)	10/61 (16.4)	<0.001
CRc (CR, CRh or CRi), N (%)	88/136 (64.7)	62/140 (44.3)	0.001	52/78 (66.7)	51/79 (64.6)	0.912	36/58 (62.1)	11/61 (18.0)	<0.001
Months to CRc, mean [median] (IQR)	2.6 [1.7] (1.0, 3.1)	1.8 [1.3] (1.0, 2.0)	0.180	2.6 [2.0] (1.0, 2.9)	1.6 [1.2] (1.0, 1.8)	0.031	2.7 [1.2] (1.0, 3.7)	2.8 [1.9] (1.7, 3.8)	0.191
Duration of CRc (months), median (95% CI)	12.2 (8.6, 15.2)	11.7 (6.5, 17.1)	0.800	15.7 (12.3, -)	11.7 (5.7, -)	0.600	10.4 (7.8, 14.4)	9.7 (6.3, -)	0.800
Received HSCT in first-line, N (%)	11 (7.7)	17 (12.0)	0.320	7 (8.8)	17 (21.3)	0.046	4 (6.5)	0 (0.0)	0.119
6 month Kaplan-Meier OS rate	74.7%	67.6%	0.200	75.5%	77.3%	0.800	73.5%	55.3%	<0.050
Pts with HRU data[3], N (%)	133 (93.7)	133 (93.7)	1.000	78 (97.5)	78 (97.5)	1.000	55 (88.7)	55 (88.7)	1.000
Hospitalization during first line									
Days of hospitalization PPPM, mean [median] (IQR)	6.3 [4.0] (0.8, 8.7)	8.9 [5.2] (1.7, 13.6)	0.045	6.5 [4.0] (0.8, 8.5)	10.5 [7.9] (2.6, 17.1)	0.006	6.1 [4.6] (0.8, 10.0)	6.6 [2.7] (0.4, 11.9)	0.852
Duration of a hospitalization (days), mean [median] (IQR)	13.7 [10.3] (7.0, 17.0)	18.2 [14.3] (10.0, 25.0)	<0.001	13.9 [11.7] (8.0, 16.0)	22.4 [21.0] (13.1, 28.3)	<0.001	13.4 [9.0] (6.5, 18.0)	11.8 [10.0] (6.0, 13.5)	0.949
Pts with HRU data who achieved CRc	**N = 80**	**N = 61**		**N = 80**	**N = 50**		**N = 80**	**N = 11**	
Hospitalization during first line									
Days of hospitalization PPPM, mean [median] (IQR)	4.3 [2.3] (0.4, 6.5)	6.8 [4.5] (2.1, 9.6)	0.002	4.3 [2.3] (0.4, 6.5)	7.7 [5.4] (2.7, 10.5)	0.001	4.3 [2.3] (0.4, 6.5)	2.7 [2.3] (0.3, 3.0)	0.531
Duration of a hospitalization (days), mean [median] (IQR)	13.6 [9.7] (7.0, 17.0)	20.4 [18.5] (11.0, 26.0)	<0.001	13.6 [9.7] (7.0, 17.0)	22.0 [18.5] (13.0, 28.0)	<0.001	13.6 [9.7] (7.0, 17.0)	12.3 [8.8] (5.5, 18.5)	0.816
Hospitalizations before CRc									
Days of hospitalization PPPM, mean [median] (IQR)	10.1 [7.0] (0.5, 16.5)	17.4 [20.6] (8.3, 27.5)	0.001	10.1 [7.0] (0.5, 16.5)	19.2 [23.4] (12.6, 28.0)	<0.001	10.1 [7.0] (0.5, 16.5)	8.9 [4.3] (0.7, 11.7)	0.776
Duration of a hospitalization (days), mean [median] (IQR)	16.4 [11.0] (7.0, 25.5)	28.2 [26.0] (18.0, 37.0)	<0.001	16.4 [11.0] (7.0, 25.5)	31.1 [28.0] (20.0, 41.0)	<0.001	16.4 [11.0] (7.0, 25.5)	14.6 [9.0] (5.3, 26.0)	0.494
Pts who have ≥ 60 days follow-up	62 (77.5%)	47 (77.0%)		62 (77.5%)	38 (76.0%)		62 (77.5%)	9 (81.8%)	
Hospitalizations from CRc to 60 days post-CRc									
Days of hospitalization PPPM, mean [median] (IQR)	1.4 [0.0] (0.0, 1.0)	5.2 [4.1] (0.0, 10.7)	<0.001	1.4 [0.0] (0.0, 1.0)	6.3 [6.1] (0.0, 11.2)	<0.001	1.4 [0.0] (0.0, 1.0)	0.4 [0.0] (0.0, 0.0)	0.574
Duration of a hospitalization (days), mean [median] (IQR)	8.2 [8.0] (5.0, 9.5)	14.3 [8.0] (6.3, 24.0)	0.155	8.2 [8.0] (5.0, 9.5)	15.1 [9.0] (6.5, 24.0)	0.077	8.2 [8.0] (5.0, 9.5)	3.5 [3.5] (2.0, 5.0)	0.159

Abbreviations: *CI: confidence interval; CON: control; CON-H: high-intensity control; CON-L: low-intensity control; CR: complete remission; CRc: composite complete remission; CRh: complete remission with partial hematologic recovery; CRi: complete remission with incomplete marrow recovery; HRU: healthcare resource utilization; HSCT: hematopoietic stem cell transplantation; IC: intensive chemotherapy; IQR: interquartile range; OS: overall survival; PPPM: per patient per month; Pts: patients;*
Note: *[1] CON-L treatments included hypomethylating agents, 59 (95.2%); low-dose cytarabine, 3 (4.8%)*
[2] Response was assessed and reported by physicians
[3] HRU was assessed from initiation of first-line therapy to earliest among the following: death date, last seen date, progression date or day prior to initiation of a 2nd line of therapy

Figure 1

https://doi.org/10.1182/blood-2023-173283