Updated Safety & Antileukemic Activity Data of Sonrotoclax (BGB-11417), a Potent and Selective BCL2 Inhibitor, in Treatment-Naive Patients With Acute Myeloid Leukemia Unfit for Intensive Chemotherapy

PF477

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CONCLUSIONS

- Sonrotoclax + azacitidine combination treatment was generally well tolerated and demonstrated antileukemic activity in patients with TN unfit AML across all dose cohorts
  - DLTs occurred in four patients (grade 4 neutropenia, n=1; grade 4 thrombocytopenia, n=4)
  - The ORR was 74.7%; CR was achieved by 50.6% and CR/CRh by 59.5%
- The safety stopping criteria have not been met in any of the dose cohorts
  - Shorter sonrotoclax + azacitidine treatment schedules (<21 d) were well tolerated with a median RDI of >80%
- Exploratory exposure-response analysis in 14-d cohorts showed that antileukemic activity at exposures associated with an 80-mg dose was ≈2-fold lower than exposures associated with 160-mg or 320-mg dose
- Follow-up evaluation of 14-d dosing cohorts is ongoing in 80-mg, 160-mg, and 320-mg cohorts to determine the recommended phase 2 dose
- Data for patients with relapsed/refractory AML in this study are presented in poster PF491

INTRODUCTION

- Acute myeloid leukemia (AML), the most common acute form of leukemia in adults, has an aggressive disease course[1,2]
- Combination treatment with venetoclax, a B-cell lymphoma 2 (BCL2) inhibitor, and azacitidine has improved outcomes in treatment-naive patients with AML unfit for intensive chemotherapy (TN AML)[3]; however, relapse is common, and prognosis is suboptimal[4,5]
- Sonrotoclax (BGB-11417), a next-generation BCL2 inhibitor, is a more selective and pharmacologically potent inhibitor of BCL2 than venetoclax, with a shorter half-life and no drug accumulation[6]
- Updated safety and antileukemic activity data of sonrotoclax + azacitidine in TN AML from the phase 1b part of the BGB-11417-103 study are presented

METHODS

- BGB-11417-103 (NCT04771130) is an ongoing, phase 1b/2, global, dose-finding and -expansion study evaluating the safety and antileukemic activity of sonrotoclax + azacitidine in patients with AML, myelodysplastic syndromes (MDS), or MDS/myeloproliferative neoplasms (**Figure 1**)

Figure 1. BGB-11417-103 Study Design

Eligibility criteria
- AML (non-APL):
  - TN unfit for intensive chemotherapy
  - No prior BCL2 inhibitor
- ECOG PS 0-2
- Not receiving warfarin or moderate or strong CYP3A4 inhibitor or inducer within 5 half-lives

Sonro (orally once daily for 10, 14, 21, or 28 d in 28-d cycle with 4-d ramp-up in cycle 1 starting at one-eighth the target dose[a])
+
Aza (75 mg/m² for 7 d/cycle SC or IV)

Part 1 Dose escalation	Part 2 Safety expansion	Part 3 Efficacy expansion
n≈3-6	n≈10	n≈20

DLT observation window
Hematologic DLT
Nonhematologic DLT
First dose — D28 — D42[b]

Sonrotoclax dosage: TN AML[c]

40 mg x 10 d | 80 mg x 10 d, 80 mg x 14 d | 160 mg x 10 d, 160 mg x 14 d, 160 mg x 28 d | 320 mg x 14 d, 320 mg x 21 d

Primary and key secondary endpoints
- Safety per CTCAE v5.0
- RP2D
- CR/CRh rate[d] per ELN 2017 criteria and partial hematology recovery criteria for AML[7,8]

Exploratory analyses
- MRD-negative[d,e] status assessed by multiparameter flow cytometry
- Exposure response relationship

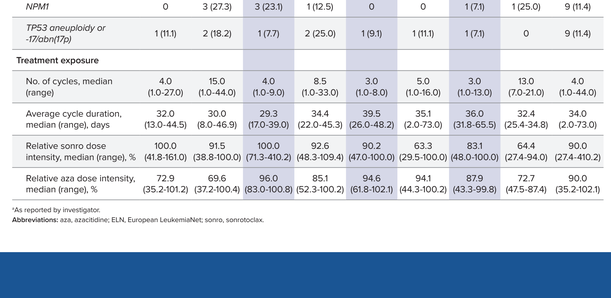
[a]Initial 4-d ramp-up to mitigate potential risk of TLS. As a precautionary measure for TLS monitoring, patients were hospitalized during the ramp-up period. [b]Or C2 initiation. [c]Dose reductions were done first by reducing the number of dosing days/cycles of sonro. Once 10-d dosing was reached, aza dosing was reduced and then sonro daily dose. [d]Response and MRD status were assessed at end of C1 (C2 if remission not yet achieved) and then every three cycles until C13, then every six cycles. [e]MRD negative was defined as ≤1 residual leukemic blasts per 1,000 leukocytes or 10⁻³ at any time on the study.

Abbreviations: APL, acute promyelocytic leukemia; aza, azacitidine; BCL2, B-cell lymphoma 2; C, cycle, CYP3A4, cytochrome P450 3A4; D, day; DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; ELN, European LeukemiaNet; IV, intravenous; MRD, minimal residual disease; RP2D, recommended phase 2 dose; SC, subcutaneous; sonro, sonrotoclax; TLS, tumor lysis syndrome.

RESULTS

- As of January 10, 2025, 79 patients with TN AML were enrolled and treated with sonrotoclax + azacitidine; 19 (24.1%) remained on treatment (**Figure 2**)
- The median study follow-up was 7.7 months (m; range, 0.3-34.0 m); median age was 74 years (**Table 1**)
- The median number of study treatment cycles was four, and the median average cycle length was 34.0 days (d)
- The median relative dose intensity of sonrotoclax was >80%, except in the 160-mg × 28-d and 320-mg × 21-d cohorts

Figure 2. Patient Disposition



Data cutoff: January 10, 2025. [a]Patients who (1) completed ≥1 treatment cycle (initiated the second cycle) or 42 days, whichever is earlier, or discontinued treatment during the first cycle or (2) had ≥1 response assessment. [b]Hematologic relapse (after CR/CRi) defined as bone marrow blasts ≥5%, reappearance of blasts in the blood, or development of extramedullary disease. [c]Defined as evidence of an increase in bone marrow blast percentage and/or in absolute blast counts in the blood, both per ELN 2017 response criteria. [d]Defined as no CR or CRi after six cycles of sonro + aza according to ELN 2017.
Abbreviations: CRi, CR with incomplete hematologic recovery; ELN, European LeukemiaNet.

Table 1. Baseline Patient Characteristics and Treatment Exposure in TN AML

	Sonro dose + aza								
	40 mg × 10 d (n=9)	80 mg × 10 d (n=11)	80 mg × 14 d (n=13)	160 mg × 10 d (n=8)	160 mg × 14 d (n=11)	160 mg × 28 d (n=9)	320 mg × 14 d (n=14)	320 mg × 21 d (n=4)	Total (N=79)
Follow-up, median (range), months	9.5 (0.5-38.8)	20.6 (0.3-43.4)	5.5 (0.6-10.4)	14.1 (1.4-35.1)	6.4 (1.1-8.6)	13.6 (5.1-26.9)	5.3 (3.5-15.1)	16.4 (8.8-22.0)	7.7 (0.3-43.4)
Age, median (range), years	72.0 (64-91)	77.0 (67-85)	74.0 (68-83)	78.0 (70-87)	71.0 (65-79)	70.0 (65-80)	73.0 (66-89)	76.0 (72-81)	74.0 (64-91)
Male, n (%)	6 (66.7)	5 (45.5)	7 (53.8)	6 (75.0)	6 (54.5)	7 (77.8)	12 (85.7)	3 (75.0)	52 (65.8)
AML type, n (%)									
De novo	5 (55.6)	11 (100)	12 (92.3)	6 (75.0)	8 (72.7)	6 (66.7)	11 (78.6)	3 (75.0)	62 (78.5)
Secondary	4 (44.4)	0	1 (7.7)	2 (25.0)	3 (27.3)	3 (33.3)	3 (21.4)	1 (25.0)	17 (21.5)
ELN 2017 AML risk stratification,[a] n (%)									
Favorable	0	2 (18.2)	4 (30.8)	1 (12.5)	2 (18.2)	1 (11.1)	1 (7.1)	1 (25.0)	12 (15.2)
Intermediate	4 (44.4)	4 (36.4)	6 (46.2)	2 (25.0)	3 (27.3)	3 (33.3)	6 (42.9)	3 (75.0)	31 (39.2)
Adverse	5 (55.6)	5 (45.5)	3 (23.1)	4 (50.0)	6 (54.5)	4 (44.4)	7 (50.0)	0	34 (43.0)
Positive genetic abnormality, n (%)[a]									
IDH1/ IDH2	1 (11.1)	1 (9.1)	2 (15.4)	1 (12.5)	2 (18.2)	0	1 (7.1)	0	8 (10.1)
FLT3	1 (11.1)	2 (18.2)	2 (15.4)	1 (12.5)	1 (9.1)	0	2 (14.3)	1 (25.0)	10 (12.7)
NPM1	0	3 (27.3)	3 (23.1)	1 (12.5)	0	0	1 (7.1)	1 (25.0)	9 (11.4)
TP53 aneuploidy or -17/abn(17p)	1 (11.1)	2 (18.2)	1 (7.7)	2 (25.0)	1 (9.1)	1 (11.1)	1 (7.1)	0	9 (11.4)
Treatment exposure									
No. of cycles, median (range)	4.0 (1.0-27.0)	15.0 (1.0-44.0)	4.0 (1.0-9.0)	8.5 (1.0-33.0)	3.0 (1.0-8.0)	5.0 (1.0-16.0)	3.0 (1.0-13.0)	13.0 (7.0-21.0)	4.0 (1.0-44.0)
Average cycle duration, median (range), days	32.0 (13.0-44.5)	30.0 (8.0-46.9)	29.3 (17.0-39.0)	34.4 (22.0-45.3)	39.5 (26.0-48.2)	35.1 (2.0-73.0)	36.0 (31.8-65.5)	32.4 (25.4-34.8)	34.0 (2.0-73.0)
Relative sonro dose intensity, median (range), %	100.0 (41.8-161.0)	91.5 (38.8-100.0)	100.0 (71.3-410.2)	92.6 (48.3-109.4)	90.2 (47.0-100.0)	63.3 (29.5-100.0)	83.1 (48.0-100.0)	64.4 (27.4-94.0)	90.0 (27.4-410.2)
Relative aza dose intensity, median (range), %	72.9 (35.2-101.2)	69.6 (37.2-100.4)	96.0 (83.0-100.8)	85.1 (52.3-100.2)	94.6 (61.8-102.1)	94.1 (44.3-100.2)	87.9 (43.3-99.8)	72.7 (47.5-87.4)	90.0 (35.2-102.1)

[a]As reported by investigator.
Abbreviations: aza, azacitidine; ELN, European LeukemiaNet; sonro, sonrotoclax.

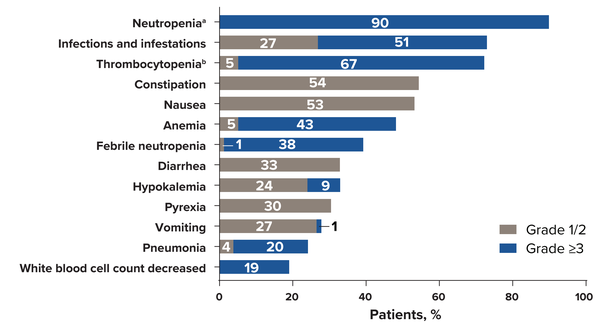
- Treatment-emergent adverse event (TEAE) frequency and severity were similar across doses (**Table 2**)
- The most common any-grade and grade ≥3 TEAEs were neutropenia, infections and infestations, and thrombocytopenia (**Figure 3**)
- Tumor lysis syndrome (TLS) occurred in four patients (laboratory, n=2; clinical, n=2); all resolved in ≤4 d without sequelae (**Table 2**)
- Dose-limiting toxicities (DLTs) occurred in four patients; all were hematologic
- Twelve patients (15.2%) had a TEAE leading to death; two were treatment related (80 mg × 14 d, anemia; 160 mg × 14 d, neutropenic sepsis); the 30-d mortality rate was 3.8%
- Treatment discontinuation due to TEAEs occurred in 11 patients (13.9%)
  - The most common TEAE class leading to discontinuation of sonrotoclax (n=7, 8.9%) or azacitidine (n=7, 8.9%) was infections and infestations
- TEAEs leading to dose reduction occurred in 22 patients (27.8%) and 14 patients (17.7%) with sonrotoclax and azacitidine, respectively
  - The most common TEAE class leading to sonrotoclax (n=18, 22.8%) and azacitidine (n=12, 15.2%) dose reduction was neutropenia
- Shorter treatment schedules (<21 d) were better tolerated with relative dose intensities (RDIs) of >80%, and <30% of patients required sonrotoclax dose reduction (**Table 1**)

Table 2. TEAE Summary in TN AML

	Sonro dose + aza								
Patients, n (%)	40 mg × 10 d (n=9)	80 mg × 10 d (n=11)	80 mg × 14 d (n=13)	160 mg × 10 d (n=8)	160 mg × 14 d (n=11)	160 mg × 28 d (n=9)	320 mg × 14 d (n=14)	320 mg × 21 d (n=4)	Total (N=79)
Any TEAEs	9 (100)	11 (100)	13 (100)	8 (100)	11 (100)	9 (100)	14 (100)	4 (100)	79 (100)
Grade ≥3	9 (100)	10 (90.9)	13 (100)	8 (100)	11 (100)	9 (100)	13 (92.9)	4 (100)	77 (97.5)
Neutropenia[a]	9 (100)	9 (81.8)	12 (92.3)	8 (100)	9 (81.8)	8 (88.9)	12 (85.7)	4 (100)	71 (89.9)
Thrombocytopenia[b]	7 (77.8)	9 (81.8)	9 (69.2)	4 (50.0)	7 (63.6)	7 (77.8)	9 (64.3)	1 (25.0)	53 (67.1)
Infections and infestations	5 (55.6)	7 (63.6)	6 (46.2)	4 (50.0)	4 (36.4)	6 (66.7)	7 (50.0)	1 (25.0)	40 (50.6)
Serious TEAEs	8 (88.9)	10 (90.9)	10 (76.9)	7 (87.5)	7 (63.6)	8 (88.9)	9 (64.3)	2 (50.0)	61 (77.2)
Laboratory TLS	0	0	0	1 (12.5)	0	0	1 (7.1)	0	2 (2.5)
Clinical TLS	0	0	0	0	1 (9.1)	0	1 (7.1)	0	2 (2.5)
DLT, n/N (%)	0	2/10 (20.0)[c]	0	0	1/11 (9.1)[d]	0	1/13 (7.7)[e]	0	4/69 (5.8)
Led to death[a]	1 (11.1)	3 (27.3)	5 (38.5)	1 (12.5)	2 (18.2)	0	0	0	12 (15.2)
Led to discontinuation									
Aza	1 (11.1)	3 (27.3)	0	3 (37.5)	4 (36.4)	1 (11.1)	0	0	12 (15.2)
Sonro	2 (22.2)	3 (27.3)	0	2 (25.0)	4 (36.4)	1 (11.1)	0	0	12 (15.2)
Led to reduction									
Aza	3 (33.3)	6 (54.5)	0	1 (12.5)	0	2 (22.2)	1 (7.1)	1 (25.0)	14 (17.7)
Sonro	2 (22.2)	3 (27.3)	3 (23.1)	0	3 (27.3)	4 (44.4)	4 (28.6)	3 (75.0)	22 (27.8)
Led to interruption									
Aza	2 (22.2)	5 (45.5)	2 (15.4)	1 (12.5)	2 (18.2)	1 (11.1)	2 (14.3)	0	15 (19.0)
Sonro	1 (11.1)	5 (45.5)	6 (46.2)	2 (25.0)	2 (18.2)	6 (66.7)	4 (28.6)	0	26 (32.9)

[a]Neutropenia includes the terms *neutropenia, febrile neutropenia, neutrophil count decreased,* and *neutropenic sepsis*. [b]Thrombocytopenia includes the terms *thrombocytopenia* and *platelet count decreased*. [c]Grade 4 neutropenia, n=1; grade 4 thrombocytopenia, n=2. [d]Grade 4 thrombocytopenia. [e]Hospital-acquired pneumonia (80 mg × 10 d), neutropenic sepsis (160 mg × 10 d; related to disease), bronchopulmonary aspergillosis (80 mg × 10 d; related to disease), pulmonary sepsis without preceding confirmed pneumonia (40 mg × 10 d), metastatic squamous cell carcinoma (80 mg × 10 d), anemia (80 mg × 14 d; related to sonro, aza, and disease), coronary artery thrombosis (160 mg × 14 d), general physical health deterioration (80 mg × 14 d; related to disease), death from unknown cause (80 mg × 14 d; related to disease), neutropenic sepsis (160 mg × 14 d; related to sonro and aza), pneumonia (80 mg × 14 d; related to disease), and respiratory failure (80 mg × 14 d; related to disease).
Abbreviations: aza, azacitidine; DLT, dose-limiting toxicity; sonro, sonrotoclax; TEAE, treatment-emergent adverse event; TLS, tumor lysis syndrome.

Figure 3. TEAEs in ≥20% (All Grades) or ≥10% (Grade ≥3) of Patients With TN AML



[a]Neutropenia includes the terms *neutropenia, febrile neutropenia, neutrophil count decreased,* and *neutropenic sepsis*. [b]Thrombocytopenia includes the terms *thrombocytopenia* and *platelet count decreased*.
Abbreviation: TEAE, treatment-emergent adverse event.

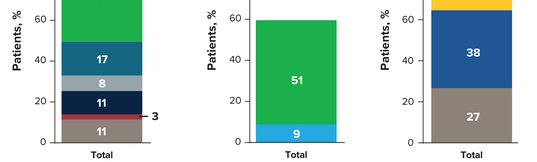
- With a median follow-up of 7.7 m, the overall response rate (ORR) in all patients was 74.7% (**Figure 4A**)
  - Complete response (CR)/CR with partial hematologic recovery (CRh) was achieved in 59.5% (95% CI, 47.9%-70.4%) by a median of 1.3 m; CR was achieved in 50.6% (95% CI, 39.1%-62.1%) of patients by a median of 1.7 m (**Table 3** and **Figure 4B**)
  - In cohorts with the longest follow-up (40, 80, and 160 mg × 10 d), 75% of patients who achieved CR/CRh remained alive and progression free at 12 m since the first determination of response
- Minimal residual disease–negative status was achieved by 35.4% of patients (**Figure 4C**)

Table 3. Summary of Disease Responses in TN AML[a]

	Sonro dose + aza								
	40 mg × 10 d (n=9)	80 mg × 10 d (n=11)	80 mg × 14 d (n=13)	160 mg × 10 d (n=8)	160 mg × 14 d (n=11)	160 mg × 28 d (n=9)	320 mg × 14 d (n=14)	320 mg × 21 d (n=4)	Total (N=79)
CR, n (%)	4 (44.4)	8 (72.7)	5 (38.5)	4 (50.0)	5 (45.5)	4 (44.4)	6 (42.9)	4 (100)	40 (50.6)
Time to CR, median (range), months	1.3 (1.3-1.8)	1.8 (0.9-6.5)	1.7 (1.0-2.8)	2.6 (1.0-21.1)	1.2 (0.8-2.7)	3.0 (1.1-7.9)	1.3 (0.9-2.1)	7.6 (2.1-21.7)	1.7 (0.8-21.7)
By end of cycle 2, n (%)	4 (44.4)	6 (54.5)	4 (30.8)	2 (25.0)	5 (45.5)	2 (22.2)	6 (42.9)	1 (25.0)	30 (38.0)
CR/CRh, n (%)	5 (55.6)	8 (72.7)	7 (53.8)	5 (62.5)	6 (54.5)	5 (55.6)	7 (50.0)	4 (100)	47 (59.5)
Time to CR/CRh, median (range), months	1.3 (1.3-5.6)	1.4 (0.9-4.4)	1.7 (1.0-2.8)	1.2 (1.0-4.0)	1.0 (0.8-2.5)	1.2 (1.1-4.9)	1.2 (0.9-2.1)	4.1 (2.1-9.7)	1.3 (0.8-9.7)
CR/CRi, n (%)	6 (66.7)	8 (72.7)	7 (53.8)	6 (75.0)	6 (54.5)	6 (66.7)	10 (71.4)	4 (100)	53 (67.1)
Time to CR/CRi, median (range), months	1.3 (1.1-5.6)	1.4 (0.9-4.4)	1.7 (1.0-2.8)	1.1 (1.0-4.0)	1.0 (0.8-2.5)	1.5 (1.1-4.9)	1.5 (0.8-2.1)	1.8 (1.7-2.1)	1.3 (0.8-5.6)
MRD negative, n (%)	4 (44.4)	4 (36.4)	4 (30.8)	2 (25.0)	3 (27.3)	5 (55.6)	4 (28.6)	2 (50.0)	28 (35.4)
MRD NE/ND, n (%)	3 (33.3)	3 (27.3)	3 (23.1)	3 (37.5)	5 (45.5)	2 (22.2)	2 (14.3)	0	21 (26.6)

[a]Responses were determined using the ELN 2017 criteria and partial hematology recovery criteria for AML.
Abbreviations: aza, azacitidine; CR, complete response; CRh, CR with partial hematologic recovery; CRi, CR with incomplete hematologic recovery; MRD, minimal residual disease; ND, not done; NE, not estimable; sonro, sonrotoclax.

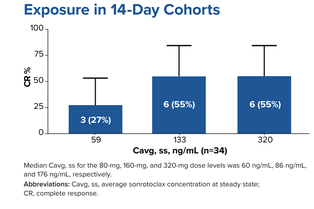
Figure 4. (A) ORR, (B) CR/CRh Rate, and (C) MRD Status in TN AML



[a]ORR included CR, CRi, MLFS, and PR.
Abbreviations: CR, complete response; CRh, CR with partial hematologic recovery; CRi, CR with incomplete hematologic recovery; MLFS, morphologic leukemia-free state; MRD, minimal residual disease; ND, not done; NE, not evaluable; ORR, overall response rate; PD, progressive disease; SD, stable disease.

- Among 14-d cohorts with comparable follow-up, exploratory exposure-response analysis showed that the CR rate for the first tertile corresponding to pharmacokinetic exposure associated with the 80-mg dose was ≈2-fold lower than the CR rate for the second and third tertiles (**Figure 5**)

Figure 5. CR Rate by Sonrotoclax Exposure in 14-Day Cohorts



Median Cavg, ss for the 80-mg, 160-mg, and 320-mg dose levels was 60 ng/mL, 86 ng/mL, and 176 ng/mL, respectively.
Abbreviations: Cavg, ss, average sonrotoclax concentration at steady state; CR, complete response.

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DISCLOSURES

JS: Consultant or advisory role: Novartis, BMS, Otsuka; Research funding: Astex/Taiho; Speakers bureau: Novartis, Mundipharma. **CYF:** Honoraria: Astellas; Consulting or advisory role: Amgen, Adaptive, Otsuka; Research funding: Jazz Pharma; Speakers bureau: Pfizer, AbbVie, Novartis, Servier. **SL:** Consulting or advisory role: BeOne Medicines Ltd; Speakers bureau: Pfizer; Travel, accommodations, expenses: BeOne Medicines Ltd, Pfizer, Janssen. **GSGM:** Honoraria: Cardinal Health, DAVA Oncology, Aptitude Health, Curio Science; Consulting or advisory board: BMS, BeOne Medicines Ltd, Pfizer, Daiichi Sankyo, Syndax, GlaxoSmithKline; Speakers bureau: Amgen, Rigel. **SYT:** Honoraria: Pfizer, Otsuka. **PM:** Consultant: Daiichi Sankyo, Jazz Pharma, AbbVie, Servier, Pfizer, Novartis, Kura Oncology, Syndax, Glycomimetics; Research funding, speakers bureau: Daiichi Sankyo, Jazz Pharma, AbbVie, Servier, Pfizer, Novartis. **LiP:** Honoraria: Novartis, BMS, Janssen, AbbVie, Curis, Geron, Jazz Pharma, Akeso, Gilead, Servier; Consulting or advisory role: AbbVie, BMS, Janssen, Novartis, GSK, Hemvant; Speakers bureau: Novartis, BMS, Janssen, Jazz Pharma, Takeda, Sobi, Blueprint, AstraZeneca; Travel, accommodations, or expenses: AbbVie, Janssen. **CD:** Consulting or advisory role: AbbVie, Astellas, AZD, BMS, Daiichi Sankyo, Gemmab, GSK, Immune Onc, Rigel, Schrodinger, Servier, Solu; Research funding: AbbVie, Astex, BMS, BeOne Medicines Ltd, Foghorn, Jazz Pharma, ImmuneOnc, Remix, Servier, Schrodinger. **SC, WM, RL, YL, OZ, AA:** Employment and may own stock: BeOne Medicines Ltd. **AHW:** Consultant: Servier, BeOne Medicines Ltd, AbbVie, Novartis; Research funding: Novartis, AbbVie, Servier, Janssen, BMS, Syndax, Astex, AstraZeneca, Amgen; Honoraria: Novartis, AstraZeneca, Astellas, Janssen, Amgen, Roche, Pfizer, AbbVie, Servier, Gilead, BMS, Shoreline, MacroGenics, Agios; Patents and royalties: Servier; Speakers bureau: AbbVie, Novartis, BMS, Servier, Astellas; Travel, accommodations, or expenses: Novartis, Servier. **XH:** No disclosures.

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