MPN-780

Safety and Efficacy of Bromodomain and Extra-Terminal Inhibitor INCB057643 in Patients With Relapsed or Refractory Myelofibrosis and Other Advanced Myeloid Neoplasms: A Phase 1 Study

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Introduction

- Bromodomain and extra-terminal (BET) proteins are epigenetic readers that regulate expression of critical oncoproteins involved in the pathophysiology of hematologic malignancies, including myelofibrosis (MF)[1,2]
- INCB057643 is an oral, small-molecule BET inhibitor[3]
- In a previous phase 1/2 basket study, INCB057643 demonstrated favorable tolerability and encouraging clinical activity as monotherapy or in combination with the Janus kinase (JAK)1/JAK2 inhibitor ruxolitinib in patients with advanced MF[3]

Objective

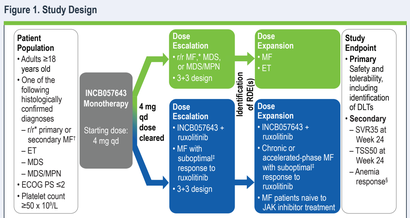
- To evaluate the safety and tolerability of INCB057643
  - As monotherapy in patients with relapsed/refractory MF, essential thrombocythemia (ET), myelodysplastic syndromes (MDS), or MDS/myeloproliferative neoplasm (MPN) overlap syndromes
  - In combination with ruxolitinib in patients with advanced chronic or accelerated-phase MF who have suboptimal response to ruxolitinib or JAK inhibitor treatment–naive MF

Methods

Study Design and Patients

- This is an ongoing phase 1, open-label, 3+3 dose-escalation/expansion study (NCT04279847) evaluating the safety and tolerability of INCB057643 in adults **(Figure 1)**
  - Key exclusion criteria included Eastern Cooperative Oncology Group performance status >2, prior BET inhibitor treatment within 5 half-lives, platelet count <50×10⁹/L for monotherapy or <75×10⁹/L for combination therapy, absolute neutrophil count <0.75×10⁹/L, and allogeneic transplant ≤6 months before enrollment
- The initial INCB057643 dose was 4 mg once daily (qd) with dose escalation up to 12 mg qd
  - All doses were administered continuously in 28-day cycles

Figure 1. Study Design



CT, computed tomography; DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, essential thrombocythemia; JAK, Janus kinase; MDS, myelodysplastic syndromes; MF, myelofibrosis; MPN, myeloproliferative neoplasm; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form total symptom score; MRI, magnetic resonance imaging; qd, once daily; RDE, recommended doses for expansion; r/r, relapsed/refractory; SVR35, ≥35% reduction from baseline in spleen volume per MRI/CT; TSS50, ≥50% reduction from baseline in MPN-SAF TSS.
* Patients who have received ≥1 line of prior therapy and experienced a recurrence of their disease or failed to respond to the last treatment, and for whom no additional known therapy is available to offer clinical benefits.
† Patients with MF must have received ≥1 JAK inhibitor, such as ruxolitinib.
‡ Patients who have been receiving a stable dose of ruxolitinib 5–25 mg twice daily for ≥8 weeks before the first dose of study treatment but are not experiencing an optimal response to ruxolitinib monotherapy; ‡ dose reduction due to toxicities within 8 weeks before Study Day 1 was permitted.
§ Hemoglobin increase of ≥1.5 g/dL from baseline lasting ≥12 weeks during the treatment period if transfusion-independent at baseline or achieving transfusion independence for ≥12 weeks if transfusion-dependent at baseline. "Transfusion dependent at baseline" was defined as patients requiring ≥4 units of packed red blood cells in the 56 days before enrollment, with ≥1 transfusion occurring during the 28 days before enrollment; patients not meeting criteria for transfusion dependent at baseline were considered transfusion independent.

Statistical Analyses

- The full analysis set included all patients who received ≥1 dose of INCB057643 and was used for patient demographics, safety, and efficacy analyses

Results

Patient Characteristics

- As of March 17, 2025, 18 patients were treated in the INCB057643 monotherapy dose-escalation group and 34 in the monotherapy dose-expansion group, 23 received INCB057643 in combination with ruxolitinib therapy dose escalation, and 13 were in the combination therapy dose expansion group **(Table 1)**

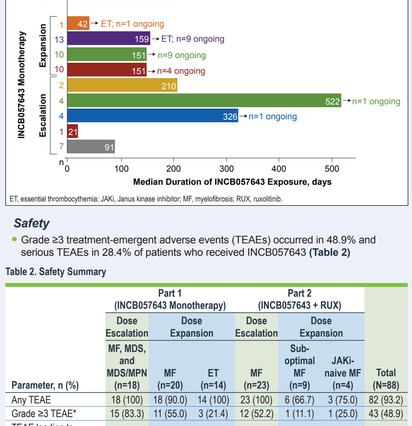
Table 1. Patient Demographics and Baseline Disease Characteristics

	Part 1 (INCB057643 Monotherapy)				Part 2 (INCB057643 + RUX)			
	Dose Escalation		Dose Expansion		Dose Escalation	Dose Expansion		
Parameter	MF (n=13)	MDS and MDS/MPN (n=5)	MF (n=20)	ET (n=14)	MF (n=23)	Sub-optimal MF (n=9)	JAKi-naive MF (n=4)	
Age, median (range), y	71 (50–79)		71 (55–80)	61 (24–71)	70 (50–77)	69 (40–80)	66 (57–74)	
Male, n (%)	11 (61.1)		14 (70.0)	5 (35.7)	14 (60.9)	6 (66.7)	3 (75.0)	
Race, n (%)								
White	14 (77.8)		14 (70.0)	8 (57.1)	19 (82.6)	8 (88.9)	3 (75.0)	
Black	0		1 (5.0)	6 (42.9)	0	0	0	
Asian	1 (5.6)		5 (25.0)	0	4 (17.4)	1 (11.1)	1 (25.0)	
Other	3 (16.7)		0	0	0	0	0	
ECOG PS, n (%)								
0	2 (11.1)		11 (55.0)	6 (42.9)	14 (60.9)	7 (77.8)	1 (25.0)	
1	16 (88.9)		9 (45.0)	8 (57.1)	8 (34.8)	2 (22.2)	3 (75.0)	
2	0		0	0	1 (4.3)	0	0	
Time since initial diagnosis, median (range), y	4.7 (1.8–13.4)	2.0 (0.8–8.2)	5.1 (0–17.6)	3.0 (0.8–16.2)	3.6 (0–12.9)	3.1 (0.8–12.1)	0.2 (0–1.3)	
RBC transfusion dependent, n (%)	2 (15.4)	1 (20.0)	3 (15.0)	0	2 (8.7)	0	1 (25.0)	
MF type, n (%)								
Primary MF	5 (38.5)	—	12 (60.0)	—	13 (56.5)	2 (22.2)	3 (75.0)	
Post-PV	4 (30.8)	—	6 (30.0)	—	6 (26.1)	3 (33.3)	1 (25.0)	
Post-ET	4 (30.8)	—	2 (10.0)	—	4 (17.4)	4 (44.4)	0	
MDS/MPN type, n (%)								
MDS	—	1 (20.0)	—	—	—	—	—	
CMML	—	2 (40.0)	—	—	—	—	—	
Unclassified MDS/MPN overlap syndrome	—	1 (20.0)	—	—	—	—	—	
MDS/MPN-RS-T	—	1 (20.0)	—	—	—	—	—	
IWG risk level, n (%)								
High	2 (15.4)	—	8 (40.0)	—	2 (8.7)	0	1 (25.0)	
Int-2	11 (84.6)	—	12 (60.0)	—	18 (78.3)	4 (44.4)	2 (50.0)	
Int-1	0	—	0	—	3 (13.0)	5 (55.6)	1 (25.0)	
JAK2-positive, n (%)	8 (61.5)	—	12 (60.0)	—	17 (73.9)	6 (66.7)	3 (75.0)	
CALR exon 9 mutation-positive, n (%)	—	—	—	4 (28.6)	—	—	—	
Spleen volume, median (range), cm³	2028 (618–4766)	—	2742 (18–6612)	—	1902 (634–4381)	2661 (691–5104)	—	
Spleen length, median (range), cm	11.0 (3–24)	—	17.0 (3–31)	—	12.0 (6–25)	14.0 (10–17)	7.0 (6–10)	
MPN-SAF TSS at baseline, mean (range)	35.5 (0–78.0)	—	31.6 (0–77.0)	17.2 (0–67.0)	20.3 (0–57.0)	22.9 (1.0–44.0)	—	

CMML, chronic myelomonocytic leukemia; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, essential thrombocythemia; Int, intermediate; IWG, International Working Group; JAK, Janus kinase; JAKi, Janus kinase inhibitor; MDS, myelodysplastic syndromes; MF, myelofibrosis; MPN, myeloproliferative neoplasm; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form total symptom score; PV, polycythemia vera; RBC, red blood cell; RS-T, ring sideroblasts and thrombocytosis; RUX, ruxolitinib.

- Median (range) duration of INCB057643 exposure **(Figure 2)**:
  - Dose-escalation monotherapy (MF): 195.5 (15–1001) days
  - Dose-expansion monotherapy (MF): 151.0 (14–530) days
  - Dose-expansion monotherapy (ET): 153.5 (29–336) days
  - Dose-escalation combination therapy (MF): 334.0 (85–749) days
  - Dose-expansion combination therapy (suboptimal MF): 112 (12–172) days
  - Dose-expansion combination therapy (JAK inhibitor–naive): 26.5 (19–34) days

Figure 2. Treatment Duration



ET, essential thrombocythemia; JAKi, Janus kinase inhibitor; MF, myelofibrosis; RUX, ruxolitinib.

Safety

- Grade ≥3 treatment-emergent adverse events (TEAEs) occurred in 48.9% and serious TEAEs in 28.4% of patients who received INCB057643 **(Table 2)**

Table 2. Safety Summary

	Part 1 (INCB057643 Monotherapy)			Part 2 (INCB057643 + RUX)			
	Dose Escalation	Dose Expansion		Dose Escalation	Dose Expansion		
Parameter, n (%)	MF, MDS, and MDS/MPN (n=18)	MF (n=20)	ET (n=14)	MF (n=23)	Sub-optimal MF (n=9)	JAKi-naive MF (n=4)	Total (N=88)
Any TEAE	18 (100)	18 (90.0)	14 (100)	23 (100)	6 (66.7)	3 (75.0)	82 (93.2)
Grade ≥3 TEAE*	15 (83.3)	11 (55.0)	3 (21.4)	12 (52.2)	1 (11.1)	1 (25.0)	43 (48.9)
TEAE leading to discontinuation†	5 (27.8)	3 (15.0)	0	3 (13.0)	0	0	11 (12.5)
Serious TEAE	9 (50.0)	4 (20.0)	3 (21.4)	7 (30.4)	2 (22.2)	0	25 (28.4)
Fatal TEAE‡	1 (5.6)	0	0	2 (8.7)	0	0	3 (3.4)
Treatment-related TEAE	17 (94.4)	16 (80.0)	13 (92.9)	19 (82.6)	2 (22.2)	2 (50.0)	69 (78.4)
Treatment-related serious TEAE§	1 (5.6)	0	1 (7.1)	2 (8.7)	0	0	4 (4.5)
Treatment-related fatal TEAE	0	0	0	0	0	0	0
Most common TEAEs¶							
Thrombocytopenia#	11 (61.1)	6 (30.0)	0	15 (65.2)	2 (22.2)	1 (25.0)	35 (39.8)
Anemia	6 (33.3)	3 (15.0)	1 (7.1)	7 (30.4)	2 (22.2)	1 (25.0)	20 (22.7)
Nausea	9 (50.0)	3 (15.0)	5 (35.7)	2 (8.7)	0	0	19 (21.6)
Blood bilirubin increased	7 (38.9)	2 (10.0)	0	2 (8.7)	0	0	11 (12.5)
Dysgeusia	5 (27.8)	5 (25.0)	0	2 (8.7)	0	0	12 (13.6)
Pruritus	6 (33.3)	1 (5.0)	3 (21.4)	3 (13.0)	0	0	13 (14.8)

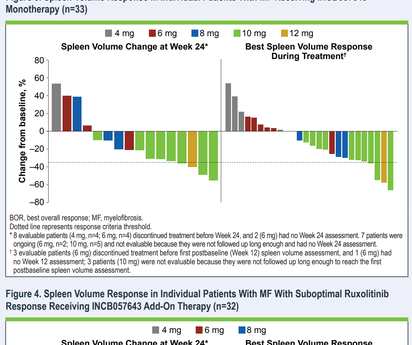
ET, essential thrombocythemia; JAKi, Janus kinase inhibitor; MDS, myelodysplastic syndromes; MF, myelofibrosis; MPN, myeloproliferative neoplasm; RUX, ruxolitinib; TEAE, treatment-emergent adverse event.
* Grade ≥3 TEAEs occurring in >4 patients: thrombocytopenia or platelet count decreased (n=19) and anemia (n=14).
† TEAEs leading to discontinuation of INCB057643: thrombocytopenia or platelet count decreased (n=6), acute myeloid leukemia (n=1), anemia (n=1), bacteremia (n=1), ejection fraction decreased (n=1), hemolysis (n=1), and skin lesion (n=1). One patient was discontinued for both thrombocytopenia and anemia.
‡ Fatal TEAE: acute myeloid leukemia (n=2), and cardiac arrest (n=1).
§ Treatment-related serious TEAEs: pneumonia (n=1), herpes zoster (n=1), pyrexia (n=1), and hematoma (n=1).
¶ TEAEs occurring in ≥20% of patients in the total population.
# Includes thrombocytopenia and platelet count decreased.

- There were 2 dose-limiting toxicities (DLTs) observed with monotherapy, including hyperbilirubinemia in a patient with MF and thrombocytopenia in a patient with MDS/MPN, both in the 12-mg cohort
- One DLT of thrombocytopenia was observed in a patient with MF in the 6-mg combination therapy cohort
- Transformation to acute myeloid leukemia was detected in 1 patient with MDS/MPN (4-mg monotherapy), 1 patient with MDS (10-mg monotherapy), and 2 patients with MF (4-mg combination therapy [n=1] and 8-mg combination therapy [n=1])

Efficacy

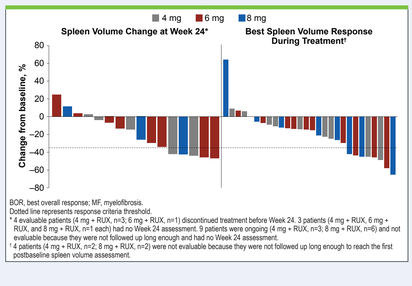
- Of those receiving INCB057643 monotherapy, a spleen volume response of ≥35% reduction from baseline (SVR35) at Week 24 was achieved by 4/26 evaluable patients and by 4/9 patients receiving a ≥10-mg dose
  - Best overall response (BOR) SVR35 was achieved by 4/30 patients **(Figure 3)**
- Among patients receiving combination therapy, 5/23 evaluable patients achieved an SVR35 at Week 24, and 8/28 experienced a BOR of SVR35 **(Figure 4)**
- Among patients receiving INCB057643 monotherapy, 8/23 evaluable patients achieved a ≥50% reduction from baseline in Myeloproliferative Neoplasm Symptom Assessment Form total symptom score (TSS50) at Week 24 (5/9 patients receiving a ≥10-mg dose), and 14/28 patients had a BOR of TSS50 **(Figure 5)**
- Among patients receiving combination therapy, 11/21 evaluable patients experienced a TSS50 at Week 24, and 20/29 patients achieved a BOR of TSS50 **(Figure 6)**
- Durable anemia responses of ≥1.5 g/dL increase in hemoglobin from baseline for ≥12 weeks were achieved by 9/31 evaluable patients with MF, MDS/MPN, and MDS receiving monotherapy; 4/13 evaluable patients with ET receiving monotherapy; and 7/28 evaluable patients with MF receiving combination therapy, regardless of transfusion status at baseline **(Figure 7)**
  - 2/4 monotherapy patients who were transfusion-dependent at baseline achieved transfusion independence

Figure 3. Spleen Volume Response in Individual Patients With MF Receiving INCB057643 Monotherapy (n=33)



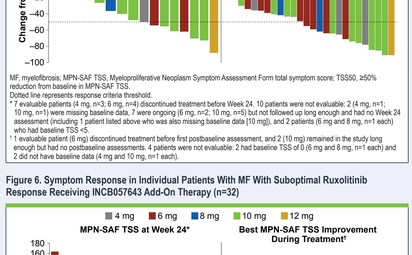
BOR, best overall response; MF, myelofibrosis.
Dotted line represents response criteria threshold.
* 8 evaluable patients (4 mg, n=4; 6 mg, n=4) discontinued treatment before Week 24, and 2 (6 mg) had no Week 24 assessment. 7 patients were ongoing (6 mg, n=2; 10 mg, n=5) and not evaluable because they were not followed up long enough and had no Week 24 assessment.
† 3 evaluable patients (6 mg) discontinued treatment before first postbaseline (Week 12) spleen volume assessment, and 1 (6 mg) had no Week 12 assessment. 3 patients (10 mg) were not evaluable because they were not followed up long enough to reach the first postbaseline spleen volume assessment.

Figure 4. Spleen Volume Response in Individual Patients With MF With Suboptimal Ruxolitinib Response Receiving INCB057643 Add-On Therapy (n=32)



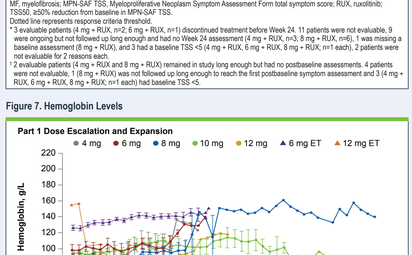
BOR, best overall response; MF, myelofibrosis.
Dotted line represents response criteria threshold.
* 4 evaluable patients (4 mg + RUX, n=3; 6 mg + RUX, n=1) discontinued treatment before Week 24. 3 patients (4 mg + RUX, 6 mg + RUX, and 8 mg + RUX, n=1 each) had no Week 24 assessment. 9 patients were ongoing (4 mg + RUX, n=3; 8 mg + RUX, n=6) and not evaluable because they were not followed up long enough and had no Week 24 assessment.
† 4 patients (4 mg + RUX, n=2; 8 mg + RUX, n=2) were not evaluable because they were not followed up long enough to reach the first postbaseline spleen volume assessment.

Figure 5. Symptom Response in Individual Patients With MF Receiving INCB057643 Monotherapy (n=33)



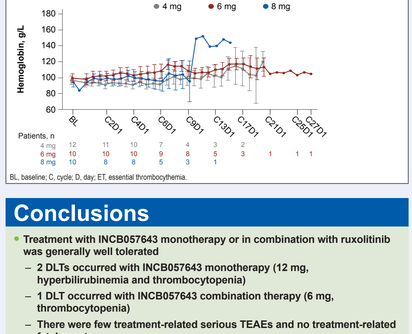
MF, myelofibrosis; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form total symptom score; TSS50, ≥50% reduction from baseline in MPN-SAF TSS.
Dotted line represents response criteria threshold.
* 7 evaluable patients (4 mg, n=3; 6 mg, n=4) discontinued treatment before Week 24. 10 patients were not evaluable: 2 (4 mg, n=1; 10 mg, n=1) were missing baseline data, 7 were ongoing (6 mg, n=2; 10 mg, n=5) but not followed up long enough and had no Week 24 assessment (including 1 patient listed above who was also missing baseline data [10 mg]), and 2 patients (6 mg and 8 mg, n=1 each) who had baseline TSS <5.
† 1 evaluable patient (6 mg) discontinued treatment before first postbaseline assessment, and 2 (10 mg) remained in the study long enough but had no postbaseline assessments. 4 patients were not evaluable: 2 had baseline TSS of 0 (8 mg and 8 mg, n=1 each) and 2 did not have baseline data (4 mg and 10 mg, n=1 each).

Figure 6. Symptom Response in Individual Patients With MF With Suboptimal Ruxolitinib Response Receiving INCB057643 Add-On Therapy (n=32)



MF, myelofibrosis; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form total symptom score; RUX, ruxolitinib; TSS50, ≥50% reduction from baseline in MPN-SAF TSS.
Dotted line represents response criteria threshold.
* 3 evaluable patients (4 mg + RUX, n=2; 6 mg + RUX, n=1) discontinued treatment before Week 24. 11 patients were not evaluable, 9 were ongoing but not followed up long enough and had no Week 24 assessment (4 mg + RUX, n=3; 8 mg + RUX, n=6), 1 was missing a baseline assessment (8 mg + RUX), and 3 had a baseline TSS <5 (4 mg + RUX, 6 mg + RUX, 8 mg + RUX; n=1 each), 2 patients were not evaluable for 2 reasons each.
† 2 evaluable patients (4 mg + RUX and 8 mg + RUX) remained in study long enough but had no postbaseline assessments. 4 patients were not evaluable, 1 (8 mg + RUX) was not followed up long enough to reach the first postbaseline symptom assessment and 3 (4 mg + RUX, 6 mg + RUX, 8 mg + RUX; n=1 each) had baseline TSS <5.

Figure 7. Hemoglobin Levels



BL, baseline; C, cycle; D, day; ET, essential thrombocythemia.

Conclusions

- **Treatment with INCB057643 monotherapy or in combination with ruxolitinib was generally well tolerated**
  - **2 DLTs occurred with INCB057643 monotherapy (12 mg, hyperbilirubinemia and thrombocytopenia)**
  - **1 DLT occurred with INCB057643 combination therapy (6 mg, thrombocytopenia)**
  - **There were few treatment-related serious TEAEs and no treatment-related fatal events**
  - **The most common TEAEs were thrombocytopenia, anemia, nausea, blood bilirubin increased, dysgeusia, and pruritus**
- **Improvements in anemia, spleen size, and symptom burden were observed in patients receiving INCB057643 monotherapy and in combination with ruxolitinib**
- **Dose expansion is ongoing for 6-mg and 10-mg INCB057643 monotherapy in patients with MF and 6-mg and 12-mg INCB057643 monotherapy in patients with ET**
- **Dose expansion is ongoing for the 4-mg and 8-mg combination ("add-on") therapy groups**
- **Enrollment is ongoing for the JAK inhibitor–naive combination therapy group**

Disclosures

JW reports consultancy or advisory boards from Rigel, Servier, Daiichi Sankyo, Aptose, BMS, Incyte, and Rgenta; research funding from Immune System Key Ltd and Rigel. **AMV** reports advisory role for Novartis, AOP Orphans Pharmaceuticals, Incyte Corporation, AbbVie, Blueprint Medicines, GSK, and Roche; lectures for Novartis, BMS, Incyte, Blueprint, AbbVie, and AOP Orphans Pharmaceuticals. **AMH** reports advisory boards for Sierra Oncology; consulting/honoraria from GSK, PharmaEssentia, Blueprint Medicines, Sobi (formerly CTI Biopharma), and Incyte; research funding from Incyte, Cogent Biosciences, Ascentage Pharma, Blueprint Medicines, Syntrix Biosystems, Novartis, and PharmaEssentia. **VG** reports consultancy for Novartis, Constellation Biopharma, and Sumitomo Pharm; consultancy and participation on a data safety monitoring board or advisory board for BMS Celgene, Sierra Oncology, Pfizer, and CTI Biopharma; consultancy, participation on a data safety monitoring board or advisory board, and honoraria for AbbVie; consultancy, honoraria, support for attending meetings and/or travel for GSK Pharma; participation on a data safety monitoring board or advisory board for Roche. **SKT** reports research funding from Karyopharm Therapeutics; and consultancy and honoraria received from Karyopharm Therapeutics Inc, Novartis, GSK, MorphoSys, AbbVie, CTI BioPharma, Genentech, and Partnership for Health Analytic Research LLC. **JY** reports research funding from AbbVie, Amgen, AstraZeneca, BMS, Brightpath Bio, Celeid Therapeutics, Chugai, Daiichi Sankyo, Genmab, Incyte, Janssen, Mitsubishi Tanabe, MSD, Novartis, Sanofi, Sumitomo, and Takeda. **AI** reports speaker honoraria and consultancy from AOP, BMS, GSK, Incyte, Novartis, and Pfizer. **PB** reports research support from Incyte, BMS, CTI, MorphoSys, Kartos, Blueprint, Cogent, Astellas, Pfizer, NS Pharma, Promedior, Disc Medicine, Ionis, and Telios; honoraria from Incyte, BMS, CTI, Sierra (now GSK), Blueprint, Cogent, Novartis, Karyopharm, AbbVie, PharmaEssentia, MorphoSys, and Kartos. **BX** and **MTG-C** have no conflicts of interest to report. **BM** reports consultancy work for GSK and PharmaEssentia. **FP** reports honoraria and consultancy from Novartis, Celgene, AOP, Sierra Oncology, and CTI. **ES** reports advisory services for BMS, DarkBlue Therapeutics, Sanofi, and Shattuck Labs; speakers honoraria for Janssen, Pfizer, and AbbVie. **AS** reports advisory services for Sobi. **ABH** reports consultancy for AbbVie, Notable Labs, and Agios; research funding from Imago Biosciences, Bayer, Gilead, Jazz, Incyte, Karyopharm Therapeutics, and Disc Medicine. **RAD** reports consultancy for Novartis and Incyte; speakers bureau for Astellas, BMS, and Novartis. **JMHR** reports serving as a consultant for GlaxoSmithKline; receiving honoraria from Amgen, Bristol Myers Squibb, GlaxoSmithKline, and Pfizer; membership on an entity's board of directors or advisory committees for Amgen, Bristol Myers Squibb, and Pfizer; serving on a speakers bureau for Amgen and Bristol Myers Squibb; and received research funding from Bristol Myers Squibb. **AT** reports research funding from Chugai Pharmaceutical, Astellas Pharma, Eisai, Otsuka Pharmaceutical, Ono Pharmaceutical, Kyowa Kirin, Shionogi, Sumitomo Dainippon Pharma, Taiho Pharmaceutical, Takeda Pharmaceutical, Teijin, Nippon Shinyaku, Nihon Pharmaceutical, Pfizer Japan, Mochida Pharmaceutical, Yakult Honsha, and Perseus Proteomics; lecture fee from AstraZeneca, Chugai Pharmaceutical, AbbVie GK, Genmab, Kyowa Kirin, Eisai, Takeda Pharmaceutical, Astellas Pharma, Nippon Shinyaku, Janssen Pharmaceutical, Zenyaku Kogyo, Bristol Myers Squibb, and SymBio Pharmaceutical. **LB**, **FZhou**, and **FZheng** are employees and stakeholders in Incyte. **PV** reported consultancy, speakers bureau, and board of directors or advisory committee membership for Incyte; consultancy and/or advisory role for Blueprint Medicines, AbbVie, CTI BioPharma Corp, Novartis, Amgen, Pfizer, Genentech, Stemline, and MorphoSys; research funding from Seattle Genetics, Amgen, Astex Pharmaceuticals, Incyte, Blueprint Medicines, Kartos Therapeutics, Gilead/Forty Seven, Constellation Pharmaceuticals, AbbVie, CTI BioPharma Corp, and Takeda.

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