Abstract 7065

PACRITINIB (PAC) VS BEST AVAILABLE THERAPY (BAT) IN MYELOFIBROSIS (MF): 72 WEEK FOLLOW-UP OF THE PHASE III PERSIST-1 TRIAL

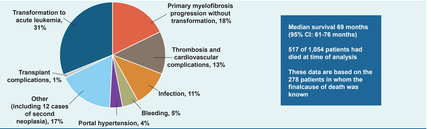
Ruben A Mesa[1], Miklos Egyed[2], Anita Szoke[3], Aleksandr Suvorov[4], Andrew Perkins[5], Jiri Mayer[6], Peter Ganly[7], Harry C Schouten[8], Patrizia Tosi[9], Charles Michael Farber[10], Pierre Zachee[11], Christof Scheid[12], James P Dean[13], Tanya Granston[13], Jean-Jacques Kiladjian[14], Alessandro M Vannucchi[15], Jyoti Nangalia[16], Adam Mead[17], Claire N. Harrison[18]

[1]Mayo Clinic, Scottsdale, AZ, USA; [2]Kaposi Mor Teaching Hospital, Kaposvar, Hungary; [3]Albert Szent-Györgyi Clinical Center, University of Szeged, Szeged, Hungary; [4]First Republican Clinical Hospital of Ministry of Health of the Udmurt Republic, Izhevsk, Russia; [5]ICON Cancer Care, Brisbane, Australia; [6]University Hospital Brno, Brno, Czech Republic; [7]Christchurch Hospital, Christchurch, New Zealand; [8]University Hospital Maastricht, Maastricht, Netherlands; [9]Ospendale, Rimini, Italy; [10]Morristown Memorial Hospital, Carol G. Simon Cancer Center, Morristown, NJ; [11]ZNA Stuivenberg, Antwerp, Belgium; [12]University of Cologne, Cologne, Germany; [13]CTI BioPharma Corp., Seattle, WA, USA; [14]Hôpital Saint Louis, Paris, France; [15]University of Florence, Florence, Italy; [16]University of Cambridge, Cambridge, UK; [17]Oxford University, Oxford, UK; [18]Guy's and St Thomas' NHS Foundation Trust, London, UK

INTRODUCTION

- MF is a myeloproliferative neoplasm characterized by clonal myeloproliferation, dysregulated kinase signaling, and release of abnormal cytokines[1]
- Frequent causes of death among pts with MF include leukemic transformation (31%), disease progression (18%), and thrombosis and cardiovascular complications (13%; **Figure 1**)[2]
- As early as 1 year from the time of diagnosis, the incidence of disease-related thrombocytopenia, anemia, and red blood cell (RBC) transfusion requirements increase dramatically[3]
- Current treatments may exacerbate disease-related thrombocytopenia and anemia
- Pacritinib is an oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1, and CSF1R[4,5]
- The phase 3 PERSIST-1 trial (**Figure 2**) met its primary objective of spleen volume reduction (SVR) ≥35% and a significant proportion of pacritinib-treated patients achieved total symptom score (TSS) reduction ≥50% vs BAT[6]
- This analysis examines outcomes at 72 weeks among pts in the PERSIST-1 trial treated with pacritinib vs BAT, and pts crossing over from BAT to pacritinib
- On February 8, 2016, the U.S. Food and Drug Administration notified the sponsor that the IND for pacritinib has been placed on full clinical hold due to concerns over interim survival results, bleeding and cardiovascular events and all therapy was discontinued

Figure 1. Causes of Mortality in Pts with MF[2]



Median survival 69 months (95% CI: 61-76 months)

617 of 1,054 patients had died at time of analysis

These data are based on the 278 patients in whom the finalcause of death was known

MF, myelofibrosis

METHODS

Figure 2. PERSIST-1 Study Design

Key Eligibility Criteria

PMF, PET-MF, or PPV-MF
Intermediate- or high-risk disease
Palpable spleen ≥5 cm
No exclusion for baseline platelet levels; stratified for platelet counts ≥100,000/μL, ≥50,000 to <100,000/μL, and <50,000/μL
No exclusion for baseline Hgb levels
No prior treatment with JAK2 inhibitors

R (2:1) N=327

Pacritinib 400 mg qd

Best Available Therapy (BAT)[a] excluding ruxolitinib

[a]Crossover from BAT allowed after progression or after Week 24 assessment

Hgb, hemoglobin; JAK, Janus kinase; PET-MF, post-essential thrombocythemia myelofibrosis; PMF, primary myelofibrosis; PPV-MF, post-polycythemia vera myelofibrosis; R, randomized.

- Stratification at randomization: platelet count category, risk category, and region (North America, Europe, Russia, Oceania)
- Study endpoints
  - **Primary**: proportion of pts achieving a ≥35% reduction in spleen volume (by MRI/CT) from baseline to Week 24
  - **Secondary**: proportion of pts with ≥50% reduction in total symptom score (TSS) from baseline to Week 24 on the Myeloproliferative Neoplasm Symptom Assessment Form v 2.0

RESULTS

Baseline Characteristics

- Most pts had poor-risk features including MF stage 2-3 disease and baseline thrombocytopenia and/or anemia (**Table 1**)

Table 1. Baseline Characteristics

Characteristic	PAC (n=220)		BAT (n=107)	
Median age, years (range)	67	(23-87)	65	(37-84)
≥65 years, n (%)	135	(61)	55	(51)
Male, n (%)	125	(57)	60	(56)
ECOG PS, n (%)				
0-1	192	(87)	96	(90)
2-3	28	(13)	11	(10)
MF diagnosis, n (%)				
Primary MF	144	(65)	59	(55)
Post-polycythemia vera MF	48	(22)	33	(31)
Post-essential thrombocythemia MF	27	(12)	15	(14)
IPSS score, n (%)[a]				
Int-1	30	(14)	18	(17)
Int-2	76	(35)	35	(33)
High	106	(48)	51	(48)
Median spleen length by physical exam, cm (range)[b]	12	(4-33)	12	(4-30)
Median spleen volume by MRI/CT, cm^3 (range)[c]	2006	(472-7948)	2153	(436-5404)
JAK2^{V617F} positive, n (%)	154	(70)	92	(86)

[a]Derived from central laboratory data. [b]n=219 for PAC; n=106 for BAT. [c]n=218 for PAC; n=107 for BAT.
BAT, best available therapy; CT, computed tomography; ECOG, Eastern Cooperative Oncology Group; MF, myelofibrosis; MRI, magnetic resonance imaging; PAC, pacritinib; PS, performance status.

Table 1. Baseline Characteristics (cont.)

Characteristic	PAC (n=220)		BAT (n=107)	
BM biopsy completed, n (%)	219	(100)	107	(100)
Reticulin and collagen fibrosis staging				
MF 0-1	32	(15)	18	(17)
MF 2-3	**180**	**(82)**	**83**	**(78)**
Missing	7	(3)	6	(6)
Peripheral blasts, n (%)				
<1%	78	(35)	44	(41)
≥1%	94	(43)	38	(36)
<5%	159	(72)	74	(69)
≥5%	13	(6)	8	(7)
Missing	48	(22)	25	(23)
White blood cell count, n (%)				
≤25 ×10^9/L	177	(80)	80	(75)
>25 ×10^9/L	43	(20)	26	(24)
Hemoglobin, n (%)				
<10 g/dL	**84**	**(38)**	**47**	**(44)**
≥10 g/dL	136	(62)	59	(55)
Platelet count, n (%)				
<50,000/μL	**35**	**(16)**	**16**	**(15)**
≥50,000 to <100,000/μL	**37**	**(17)**	**18**	**(17)**
≥100,000/μL	148	(67)	73	(68)

Apparent Risk Factor Imbalances by Platelet Strata

- There was an apparent significant imbalance in Dynamic International Prognostic Scoring System risk factors between pacritinib and BAT arms in the predefined <100,000/μL strata and most apparent in patients with baseline platelets 50,000-100,000/μL (Table 2)

Table 2. Apparent Risk Factor Imbalances by Platelet Strata

	<50,000 plt/μL		50,000-100,000 plt/μL[a]		<100,000 plt/μL		ITT	
	PAC n=35	BAT n=16	PAC n=37	BAT n=18	PAC n=72	BAT n=34	PAC n=220	BAT n=107
Age >65 y (%)	74	50	62	33	68	41	57	47
p-value[b]	0.1150		0.0828		0.0112		0.0773	
Baseline WBC >25K (%)	14	25	35	11	25	18	20	24
Baseline Hgb<10 g/dL (%)	66	63	49	67	57	65	38	44
Baseline blasts ≥1% (%)	46	44	57	33	51	38	43	36

[a]Non-prespecified baseline platelet count subgroup. [b]Using Fisher's exact test.
BAT, best available therapy; Hgb, hemoglobin; ITT, intent to treat; PAC, pacritinib; plt, platelets; WBC, white blood cell.

BAT Treatment

- The majority of lower risk pts randomized to BAT were treated with hydroxyurea (n=59 [56%]), whereas higher risk pts received no active treatment (n=27 [26%]); or other therapies 38 (36%)

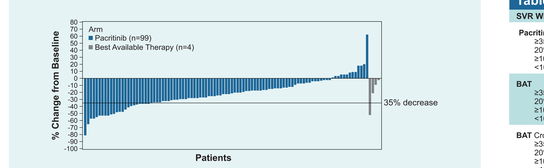
Patient Disposition

- Median follow-up: 22 mo (range, 0.6-36.4)
- 90 (84%) pts randomized to BAT crossed over to receive pacritinib at a median of 27.2 weeks (range, 14.1-99.0)
- Median duration of pacritinib treatment was 15.64 mo and median duration of BAT treatment was 5.91 mo
  - Following crossover from BAT to pacritinib, median duration of pacritinib therapy post-crossover was 13.85 mo

Spleen Volume Reduction

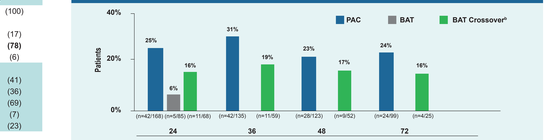
- Reductions in spleen volume ≥35% at Week 72 were observed in 24% (24/99) of pts treated with pacritinib (**Figure 3**)
- At Week 72, there were similar proportions of evaluable pacritinib-treated pts who achieved SVR ≥35% by MRI/CT (**Figure 4**) as were observed at Week 24 (24% vs 25%)
  - In patients crossing over from BAT to pacritinib SVR ≥35% was achieved by 16% of pts at both Weeks 24 and 72
- Median duration of SVR ≥35% was 80.9 wks for pacritinib and not applicable for BAT
- Pacritinib-treated pts consistently maintained a mean % change in spleen volume of approximately –20% through Week 72
  - Pts crossing over from BAT to pacritinib had substantial decreases in spleen volume observed as early as Week 12 post-crossover and a mean % change in spleen volume of ~15% through Week 48 post crossover
  - Pts treated with BAT achieved only a mean 1% decrease in spleen volume through Week 24

Figure 3. Spleen Volume Reduction At Week 72[a,b]



[a]As of data transfer date: April 25, 2016. [b]As assessed by MRI or CT; n=99 for PAC and n=4 for BAT.
CT, computed tomography; ITT, intent to treat; MRI, magnetic resonance imaging.

Figure 4. Evaluable[a] Patients Achieving Spleen Volume Reduction ≥35% Over Time

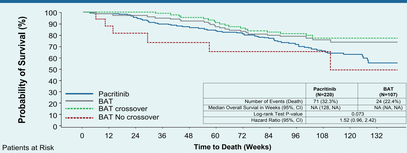


[a]Baseline and timepoint assessments by MRI or CT. [b]From the time of crossover. [c]Numbers for evaluable BAT-treated patients too small for meaningful analysis beyond Week 24 (≤11 patients at any point).
BAT, best available therapy; PAC, pacritinib.

Overall Survival

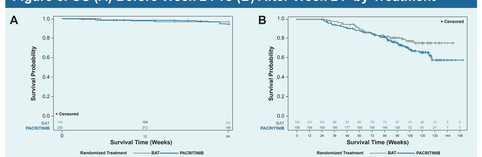
- Prior to Week 24, OS was similar between pacritinib and BAT arms (**Figure 5, 6A**); after Week 24, there was a trend toward improved survival for the BAT arm, but 90 (84%) pts had crossed over to receive pacritinib (**Figure 6B**); moreover an imbalance in risk factors, especially in pts with baseline platelets <100,000/μL appears to be a factor
- SVR ≥20% within 24 weeks in the pacritinib arm correlated with improved OS relative to pts achieving SVR <10% (**Table 3**)
  - There was a trend for improved OS for patients treated with pacritinib with SVR ≥10% to <20%
- There was no correlation between SVR and OS for BAT-treated patients with SVR ≥20%

Figure 5. Overall Survival by Treatment



[a]72 week data for the primary population and 48 weeks for the crossover population as of data transfer date: April 25, 2016. [b]Patients had both baseline and each timepoint spleen assessment by MRI or CT.

Figure 6. OS (A) Before Week 24 vs (B) After Week 24[a] by Treatment



[a]Pts who are alive at Week 24
BAT, best available therapy; OS, overall survival; PAC, pacritinib.

Table 3. Overall Survival by Spleen Volume Response

SVR Within 24 Weeks	Hazard Ratio (95% CI)[a]	p-value
Pacritinib		
≥35% (n=42)	0.294 (0.137, 0.633)	0.0017
20% to <35% (n=60)	0.256 (0.129, 0.511)	0.0001
≥10% to <20% (n=38)	0.439 (0.222, 0.871)	0.0185
<10% (n=59)	1.000 (1.000, 1.000)	NA
BAT		
≥35% (n=5)	0.000 (0.000, NA)	0.9930
20% to <35% (n=6)	2.633 (0.754, 9.189)	0.1291
≥10% to <20% (n=15)	1.429 (0.470, 4.342)	0.5290
<10% (n=75)	1.000 (1.000, 1.000)	NA
BAT Crossover (from start of crossover)		
≥35% (n=11)	0.928 (0.187, 4.598)	0.9267
20% to <35% (n=23)	0.707 (0.177, 2.827)	0.6237
≥10% to <20% (n=15)	1.091 (0.272, 4.369)	0.9020
<10% (n=34)	1.000 (1.000, 1.000)	NA

[a]Compared with SVR <10%.
BAT, best available therapy; SVR, spleen volume reduction; PAC, pacritinib

Safety

- There were a total of 71 (32%) deaths in the pacritinib arm and 24 (22%) in the BAT arm (**Table 4**)
  - On study deaths were 12% vs 3% in the pacritinib and BAT arms and there were similar proportions of deaths attributed to cardiac and bleeding adverse events (AEs) between arms within 24 weeks (last timepoint before crossover)
  - Among all deaths, those occurring due to AEs represented 39.4% and 58.3% of deaths in the pacritinib and BAT arms, respectively
- The most frequent AEs occurring within 72 weeks (assessed by investigator) were primarily gastrointestinal (GI) disorders (**Table 5**)
- Grade 3/4 anemia, thrombocytopenia, and neutropenia were reported in 26% vs 16%, 16% vs 11%, and 4% vs. 2% of pacritinib- vs. BAT-treated pts, respectively
- 15% of pts in the pacritinib arm had dose reductions due to AEs (5% diarrhea; 4% anemia)
- Peripheral neuropathy occurred in 1% of pts treated with pacritinib vs 4% of BAT-treated pts
- Leukemic transformation occurred in 11 (5%) pts randomized to pacritinib vs. 2 (2%) randomized to BAT

Table 4. Summary of Mortality

	PAC (n=220)	BAT (n=107)	BAT Crossover (n=90)	BAT No Crossover (n=17)
All Deaths (any causes)	71 (32%)	24 (22%)	18 (20%)	6 (35%)
On study death[a]	27 (12%)	3 (3%)	9 (10%)	3 (18%)
Deaths of any cause Within 24 Weeks	11 (5%)	3 (3%)	4 (4%)[a]	3 (18%)
Due to Cardiac AEs	1 (<1%)	1 (<1%)	0	1 (6%)
Due to Bleeding AEs	1 (<1%)	0	1 (1%)	0

[a]During the treatment or <30 days off treatment; [b]24 weeks after crossover
AE, adverse event; BAT, best available therapy; PAC, pacritinib.

Table 5. Most Frequent Adverse Events

	All Grades		Grade 3/4	
Adverse Event, n (%)	PAC (n=220)	BAT (n=106)	PAC (n=220)	BAT (n=106)
Non-hematologic (>10%)				
Diarrhea	142 (65)	15 (14)	16 (7)	1 (1)
Nausea	70 (32)	7 (7)	3 (1)	0
Vomiting	47 (21)	7 (7)	6 (3)	0
Abdominal pain	30 (14)	11 (10)	6 (3)	0
Fatigue	32 (15)	9 (9)	5 (2)	1 (1)
Peripheral edema	25 (11)	16 (15)	1 (1)	1 (1)
Pneumonia	25 (11)	1 (1)	15 (7)	1 (1)
Hematologic (>5%)				
Anemia	68 (31)	23 (22)	57 (26)	17 (16)
Thrombocytopenia	50 (23)	15 (14)	36 (16)	12 (11)
Neutropenia	12 (6)	2 (2)	9 (4)	2 (2)

BAT, best available therapy; PAC, pacritinib.

- Incidence of all grade diarrhea among pacritinib-treated pts was highest between Weeks 1-8 (51%) and decreased to 12% between Weeks 8-16, and was ≤9% thereafter (**Table 6**)
- Incidence of grade 3/4 treatment-emergent diarrhea with initial pacritinib treatment was highest in Weeks 1-8 (3%), and decreased to 1.4% in Weeks 8-16, 1.5% in Weeks 16-24, and 0.9% between Weeks 64-72
  - Incidence of all grade diarrhea decreased to 7.0% between Weeks 64 and 72
- A similar trend was observed among pts who crossed over from BAT to pacritinib

Table 6. Incidence of Diarrhea Over Time (All Grades)

Time Interval	Pacritinib (N=220) n/n at risk (%)	BAT Initial Treatment (N=106) n/n at risk (%)	BAT Crossover[a] (N=90) n/n at risk (%)
Week 1 – Week 8	113/220 (51)	6/106 (6)	42/90 (47)
Week 8 – Week 16	26/210 (12)	4/103 (4)	13/83 (16)
Week 16 – Week 24	17/195 (9)	5/100 (5)	7/75 (9)
Week 24 – Week 32	11/177 (6)	1/89 (1)	1/72 (1)
Week 32 – Week 40	12/157 (8)	1/33 (3)	3/65 (5)
Week 40 – Week 48	4/140 (3)	1/13 (8)	2/61 (3)
Week 48 – Week 56	5/131 (4)	1/7 (14)	1/55 (2)
Week 56 – Week 64	4/121 (3)	1/6 (17)	3/48 (6)
Week 64 – Week 72	8/114 (7)	1/6 (17)	0

[a]From the time of crossover
BAT, best available therapy

- Incidence of bleeding events was highest between Weeks 1-24 for pacritinib (≤9%) and BAT-treated (≤15%) pts and decreased to ≤3% between Weeks 48-72 for pacritinib-treated pts (**Table 7**)
- Similar results were observed among pts crossing over to pacritinib from BAT with the greatest incidence (11%) occurring in Weeks 1-8 post crossover

Table 7. Incidence of Bleeding AEs By SMQ Over Time (All Grades)

Time Interval	Pacritinib (N=220) n/n at risk (%)	BAT Initial Treatment (N=106) n/n at risk (%)	BAT Crossover[a] (N=90) n/n at risk (%)
Week 1 – Week 8	17/220 (8)	16/106 (15)	10/90 (11)
Week 8 – Week 16	18/210 (9)	6/103 (6)	5/83 (6)
Week 16 – Week 24	15/195 (8)	3/100 (3)	6/75 (8)
Week 24 – Week 32	9/177 (5)	2/89 (2)	2/72 (3)
Week 32 – Week 40	9/157 (6)	1/33 (3)	3/65 (5)
Week 40 – Week 48	6/140 (4)	0/13	2/61 (3)
Week 48 – Week 56	4/131 (3)	0/7	3/55 (6)
Week 56 – Week 64	1/121 (1)	0/6	0/48
Week 64 – Week 72	2/114 (2)	0/6	0/38

[a]From the time of crossover
BAT, best available therapy

- Among all patients, incidence of grade 3/4 bleeding events was ≤3% during any 8-week time interval (**Table 8**)

Table 8. Incidence of Bleeding AEs By SMQ Over Time (Grade 3/4)

Time Interval	Pacritinib (N=220) n/n at risk (%)	BAT Initial Treatment (N=106) n/n at risk (%)	BAT Crossover[a] (N=90) n/n at risk (%)
Week 1 – Week 8	2/220 (1)	1/106 (1)	3/90 (3)
Week 8 – Week 16	3/210 (1)	1/103 (1)	2/83 (2)
Week 16 – Week 24	3/195 (2)	0/100	0/75
Week 24 – Week 32	2/177 (1)	0/89	0/72
Week 32 – Week 40	2/157 (1)	1/33 (3)	2/65 (3)
Week 40 – Week 48	1/140 (1)	0/13	1/61 (2)
Week 48 – Week 56	2/131 (2)	0/7	0/55
Week 56 – Week 64	0/121	0/6	0/48
Week 64 – Week 72	1/114 (1)	0/6	0/38

[a]From the time of crossover
AE, adverse event; BAT, best available therapy; SMQ, standardized MEDRA query.

- Incidence of all grade cardiac AEs was similar between pacritinib and BAT arms between Weeks 1-24 (**Table 9**); incidence of cardiac AEs was greater for pacritinib between Weeks 24-72 vs BAT
- Between treatment initiation and Week 24, 21 grade 3/4 cardiac AEs based on SMQ analyses were recorded among pts treated initially with pacritinib (**Table 10**)
  - 6 events occurred during the same period among BAT-treated pts; 4 grade 3/4 cardiac events occurred among pts who received pacritinib after BAT-crossover

Table 9. Incidence of Cardiac AEs Based on SMQ Analyses (All Grades)

Time Interval	Pacritinib (N=220) n/n at risk (%)	BAT Initial Treatment (N=106) n/n at risk (%)	BAT Crossover[a] (N=90) n/n at risk (%)
Week 1 – Week 8	23/220 (11)	14/106 (13)	14/90 (16)
Week 8 – Week 16	19/210 (9)	11/103 (11)	5/83 (6)
Week 16 – Week 24	11/195 (6)	3/100 (3)	4/75 (5)
Week 24 – Week 32	2/177 (1)	0/89 (0)	4/72 (6)
Week 32 – Week 40	6/157 (4)	0/33 (0)	1/65 (2)
Week 40 – Week 48	3/140 (2)	1/13 (8)	4/61 (7)
Week 48 – Week 56	4/131 (3)	0/7 (0)	2/55 (4)
Week 56 – Week 64	3/121 (3)	0/6 (0)	1/48 (2)
Week 64 – Week 72	1/114 (1)	0/6 (0)	2/38 (5)

[a]From the time of crossover
AE, adverse event; BAT, best available therapy; SMQ, standardized MEDRA query.

Table 10. Incidence of Cardiac AEs Based on SMQ Analyses (Grade 3/4)

Time Interval	Pacritinib (N=220) n/n at risk (%)	BAT Initial Treatment (N=106) n/n at risk (%)	BAT Crossover[a] (N=90) n/n at risk (%)
Week 1 – Week 8	8/220 (4)	2/106 (2)	1/90 (1)
Week 8 – Week 16	7/210 (3)	4/103 (4)	0/83
Week 16 – Week 24	6/195 (3)	0/100	3/75 (4)
Week 24 – Week 32	1/177 (1)	0/89	1/72 (1)
Week 32 – Week 40	2/157 (1)	0/33	0/65
Week 40 – Week 48	1/140 (1)	0/13	2/61 (3)
Week 48 – Week 56	2/131 (2)	0/7	1/55 (2)
Week 56 – Week 64	0/121	0/6	0/48
Week 64 – Week 72	0/114	0/6	

[a]From the time of crossover
AE, adverse event; BAT, best available therapy; SMQ, standardized MEDRA query.

CONCLUSIONS

- In pts with MF, responses to pacritinib were durable and rates of SVR ≥35% were maintained from Weeks 24-72
  - Pts who crossed over to pacritinib achieved meaningful responses following crossover
- The most frequently occurring AEs with pacritinib were GI events and incidence decreased over time
- Up to 24 weeks, there was no statistically significant difference in the incidence of cardiac and bleeding AEs between the pacritinib and BAT arms; following crossover to pacritinib, BAT patients had a similar rate of events
- OS was not significantly different between arms, and potentially confounded by a large percentage (84%) of pts crossing over at 24 weeks
- Pacritinib-treated pts who achieved SVR ≥20% had significantly longer OS vs pts who did not achieve SVR ≥20%

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Disclosures

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