

# Safety and Efficacy of the Mutant Calreticulin–Specific Monoclonal Antibody INCA033989 as Monotherapy or in Combination With Ruxolitinib in Patients With Myelofibrosis: Preliminary Results From Dose Escalation of Two Global Phase 1 Studies

**John Mascarenhas**,<sup>1</sup> Haifa Kathrin Al-Ali,<sup>2</sup> Vikas Gupta,<sup>3</sup> Haris Ali,<sup>4</sup> Francesca Palandri,<sup>5</sup> Francesco Passamonti,<sup>6</sup> Raajit Rampal,<sup>7</sup> Aaron Gerds,<sup>8</sup> Tania Jain,<sup>9</sup> Sanjay Mohan,<sup>10</sup> Steffen Koschmieder,<sup>11</sup> Caroline McNamara,<sup>12</sup> Andrew Perkins,<sup>13</sup> Bethan Psaila,<sup>14</sup> Vincent Ribrag,<sup>15</sup> William Shomali,<sup>16</sup> Rosa Ayala Diaz,<sup>17</sup> Mikkel Helleberg Dorff,<sup>18</sup> Claire Harrison,<sup>19</sup> Stephen Oh,<sup>20</sup> Frank Stegelmann,<sup>21</sup> Alessandro Maria Vannucchi,<sup>22</sup> Abdulraheem Yacoub,<sup>23</sup> Jason Gotlib,<sup>16</sup> Jyoti Nangalia,<sup>24</sup> Chenwei Tian,<sup>25</sup> Betty Lamothe,<sup>25</sup> Erin Crowgey,<sup>25</sup> Tatiana Zinger,<sup>25</sup> Evan Braunstein,<sup>25</sup> David M. Ross<sup>26</sup>

<sup>1</sup>Icahn School of Medicine at Mount Sinai, New York, NY, USA; <sup>2</sup>University Medicine Halle, Saale, Germany; <sup>3</sup>Princess Margaret Cancer Centre, Toronto, ON, Canada; <sup>4</sup>City of Hope Medical Center, Duarte, CA, USA; <sup>5</sup>IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy; <sup>6</sup>Fondazione IRCCS Ca Ganda Ospedale Maggiore, Milan, Italy; <sup>7</sup>Memorial Sloan Kettering Cancer Center, New York, NY, USA; <sup>8</sup>Cleveland Clinic, Cleveland, OH, USA; <sup>9</sup>Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, MD, USA; <sup>10</sup>Vanderbilt University Medical Center, Nashville, TN, USA; <sup>11</sup>Faculty of Medicine, RWTH Aachen University, and Center for Integrated Oncology (CIO-ABCD), Aachen, Germany; <sup>12</sup>Royal Brisbane and Women's Hospital, Brisbane, Australia; <sup>13</sup>The Alfred Hospital, Melbourne, Australia; <sup>14</sup>University of Oxford, Oxford, UK; <sup>15</sup>Institut Gustave Roussy, Villejuif, France; <sup>16</sup>Stanford Cancer Institute/Stanford University School of Medicine, Stanford, CA, USA; <sup>17</sup>12 de Octubre University Hospital, Madrid, Spain; <sup>18</sup>University of Copenhagen, Copenhagen, Denmark; <sup>19</sup>Guy's and St Thomas' NHS Foundation Trust, London, UK; <sup>20</sup>Washington University School of Medicine, St. Louis, MO, USA; <sup>21</sup>Universitätsklinikum Ulm, Ulm, Germany; <sup>22</sup>Azienda Ospedaliero-Universitaria Careggi, Florence, Italy; <sup>23</sup>The University of Kansas Cancer Center, Kansas City, KS, USA; <sup>24</sup>The Sanger Institute, Cambridge, UK; <sup>25</sup>Incyte Corporation, Wilmington, DE, USA; <sup>26</sup>Royal Adelaide Hospital, Adelaide, Australia

# CALR Mutations Are Frequent in Myelofibrosis With No Mutant-Specific Treatment Available

- Myelofibrosis (MF) is a myeloproliferative neoplasm (MPN) characterized by bone marrow fibrosis, anemia, splenomegaly, debilitating symptoms, morbidity, and mortality<sup>1</sup>
- Mutations in exon 9 of calreticulin (mutCALR) are found in ~25-35% of patients with MF<sup>2,3</sup>
  - Higher CALR variant allele frequency (VAF) in MF has been associated with more advanced disease, including anemia and elevated peripheral blasts<sup>4</sup>
- Current treatments in MF are not mutant targeted and have limited efficacy in reducing mutCALR VAF<sup>5</sup>

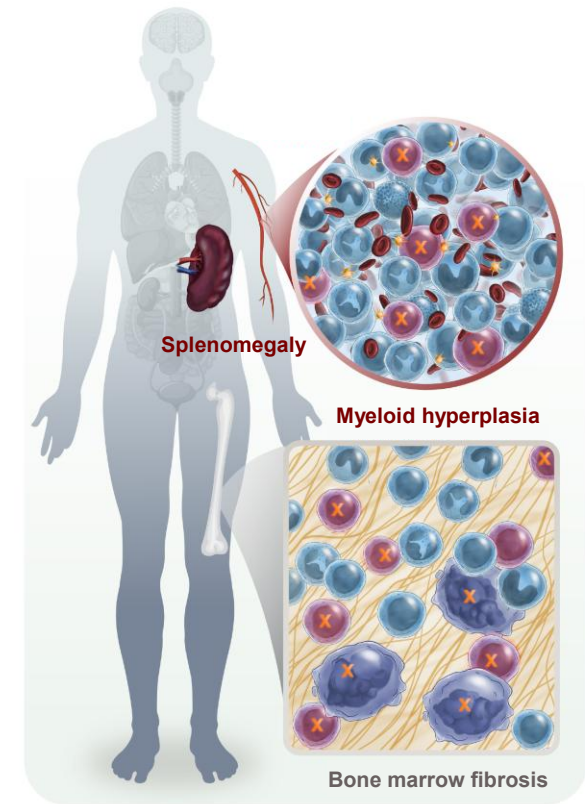


Illustration by DrawImpacts.

1. Arber DA, et al. *Blood*. 2016;127:2391-2405. 2. Klampfl T, et al. *N Engl J Med*. 2013;369:2379-2390. 3. Nangalia J, et al. *N Engl J Med*. 2013;369:2391-2405. 4. Guglielmelli P, et al. *Blood Cancer J*. 2023;13:21.

5. Tefferi A. *Am J Hematol*. 2023;98:801-821.

# INCA033989 Is a mutCALR-Targeted Therapy for Patients With MF and Essential Thrombocythemia (ET)

- INCA033989 has a unique mechanism of action compared with other available therapies
  - INCA033989 is a novel, fully human, high-affinity, Fc-silenced, immunoglobulin G1 monoclonal antibody that selectively targets mutCALR in complex with thrombopoietin receptor to inhibit oncogenic signaling and proliferation of cells<sup>1</sup>

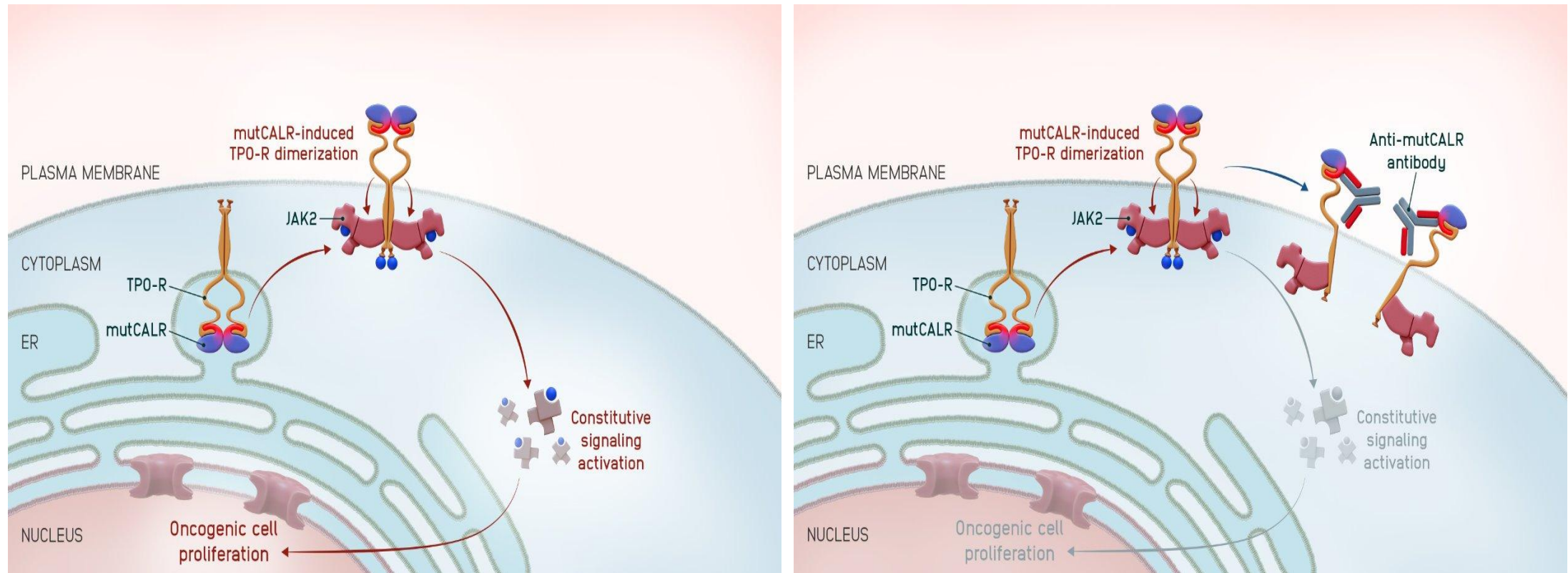


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1. Reis, et al. *Blood*. 2024;22:2336-2348.

ER, endoplasmic reticulum; JAK2, Janus kinase 2; MF, myelofibrosis; mutCALR, mutations of calreticulin; TPO-R, thrombopoietin receptor (myeloproliferative leukemia protein).

# Two Ongoing Phase 1 Studies Evaluating INCA033989 in Patients With MF and ET

## Study Design

### Dose Escalation

#### MF

- ≥18 years of age with a diagnosis of primary or post-ET MF
- Presence of mutCALR exon 9
- Spleen volume imaging ≥450 mL or palpable splenomegaly of ≥5 cm
- Monotherapy
  - Intolerant, resistant after ≥12 weeks, or ineligible for JAKi treatment
- Combination therapy
  - Prior ruxolitinib treatment for ≥12 weeks with a suboptimal response

#### ET

- High risk; documented resistance/intolerance to ≥1 line of prior cytoreductive therapy

### Primary Endpoints

- Dose-limiting toxicities
- Treatment-emergent adverse events

### Secondary Endpoints

- SVR25 and SVR35 at weeks 12 and 24\*
- Anemia response<sup>1</sup>
- Symptom improvement based on the MPN-SAF TSS
- Changes in allele burden of mutCALR

### Dose Expansion

MF (monotherapy)

MF (INCA033989 + ruxolitinib)

JAKi-naïve MF (randomly assigned to monotherapy or INCA033989 + ruxolitinib)

ET

- **INCA033989-101** (NCT05936359; outside the US) and **INCA033989-102** (NCT06034002; US only) are phase 1, first-in-human, multicenter, open-label studies evaluating INCA033989 in patients harboring a *CALR* exon-9 mutation with high-risk ET or MF (as monotherapy or in combination with ruxolitinib)
- INCA033989 was administered intravenously every 2 weeks (24-2500 mg)

\*A spleen response required confirmation by MRI or CT showing SVR25 or SVR35.

1. Tefferi A. *Blood*. 2024;144:1813-1820.

CALR, calreticulin; CT, computed tomography; ET, essential thrombocythemia; JAKi, Janus kinase inhibitor; MF, myelofibrosis; MPN-SAF, Myeloproliferative Neoplasms Symptom Assessment Form; MRI, magnetic resonance imaging; mutCALR, mutations of calreticulin; SVR25, spleen volume reduction ≥25%; SVR35, spleen volume reduction ≥35%; TSS, total symptom score.



# Demographics and Disease Characteristics

Variable	INCA033989 Monotherapy (N=52)	INCA033989 + Ruxolitinib (N=20)
Median age (range), years	59.5 (34, 76)	61.0 (38, 82)
Female, n (%)	17 (32.7)	4 (20.0)
Median time from initial diagnosis (range), years	7.4 (0, 25.3)	3.1 (0.4, 16.4)
DIPSS risk status, n (%)		
Low risk	6 (11.5)	0
INT-1 risk	21 (40.4)	8 (40.0)
INT-2 risk	25 (48.1)	9 (45.0)
High risk	0	3 (15.0)
CALR exon 9 mutation type, n (%)		
Type 1	30 (57.7)	12 (60.0)
Type 2	11 (21.2)	7 (35.0)
Other	11 (21.2)	1 (5.0)
Median CALR VAF (range),* %	36 (24, 53)	39 (30, 85)
No prior JAKi therapy, n (%)	10 (19.2)	N/A
Mean baseline ruxolitinib daily dose (range), mg	N/A	33.5 (10, 50)

Variable	INCA033989 Monotherapy (N=52)	INCA033989 + Ruxolitinib (N=20)
Median platelets (range), GI/L	316.5 (41, 1290)	229.5 (76, 506)
Median leukocytes (range), GI/L	6.1 (1.5, 27.2)	10.6 (2.4, 85.0)
Median hemoglobin (range), g/dL	10.0 (7.0, 14.3)	9.4 (7.2, 12.6)
Median MPN-SAF TSS (range)	21 (0, 65)	15.5 (3, 56)
Median spleen volume (range), mL	1372 (226, 5060)	2351 (848, 5338)
INCA033989 dose level, n (%)		
24 mg	3 (5.8)	N/A
50 mg	3 (5.8)	N/A
70 mg	3 (5.8)	3 (15.0)
100 mg	3 (5.8)	N/A
200 mg	5 (5.8)	N/A
250 mg	4 (7.7)	5 (25.0)
400 mg	4 (7.7)	N/A
750 mg	13 (25.0)	5 (25.0)
1500 mg	9 (17.3)	4 (20.0)
2500 mg	5 (5.8)	3 (15.0)

Data cutoff: September 25, 2025.

\*Measured centrally in peripheral blood by next-generation sequencing (INCA033989 monotherapy, n=51; INCA033989 + ruxolitinib, n=18).

CALR, calreticulin; DIPSS, Dynamic International Prognostic Scoring System; INT, intermediate; JAKi, Janus kinase inhibitor; MPN-SAF, Myeloproliferative Neoplasms Symptom Assessment Form; N/A, not applicable; TSS, total symptom score; VAF, variant allele frequency.

# INCA033989 Monotherapy is Well Tolerated in Patients With MF

## Summary of Treatment-Emergent Adverse Events (TEAEs)

TEAE, n (%)	N=52
Any TEAE	50 (96.2)
Treatment-related	30 (57.7)
Grade ≥3	16 (30.8)
Serious	5 (9.6)*
Fatal	0
Discontinuation due to TEAEs	2 (3.8)†
Dose reduction due to TEAEs	2 (3.8)‡
Infusion interruption due to TEAEs	3 (5.8)
Dose delay due to TEAEs	12 (23.1)
Dose-limiting toxicity	0

- Overall, 45 (86.5%) patients were still receiving treatment and 7 (13.5%) discontinued<sup>¶</sup>
- No dose-limiting toxicities were observed; the maximum tolerated dose was not reached (dose range 24-2500 mg)
- Eleven patients experienced increased AST TEAEs; 45% (n=5) with grade 1 AST elevation at baseline
  - TEAEs resolved in 9 of the 11 patients (grade 1 TEAEs ongoing in 2 patients)
  - One patient (50 mg) had a dose reduction due to grade 3 increased AST, which resolved, and a subsequent dose increase to 1500 mg was tolerated
- No association of TEAEs with dose was observed

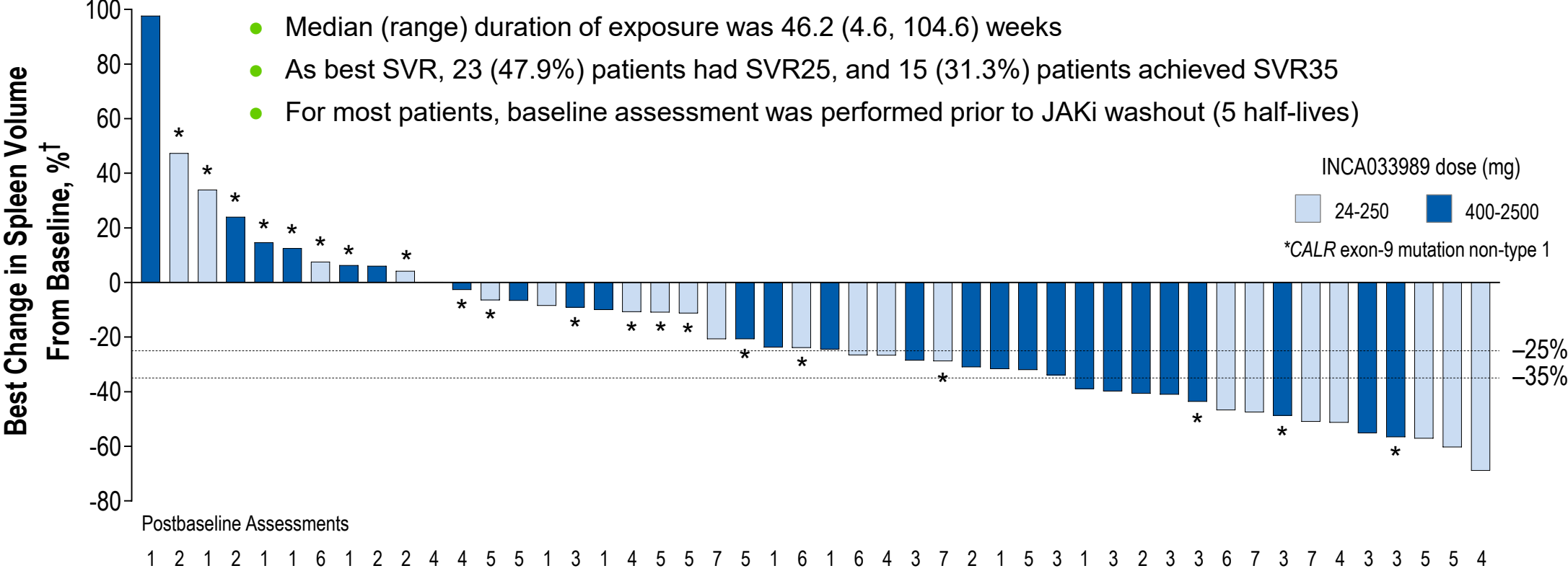
## Most Common TEAEs (≥15% of Patients)

TEAE, <sup>¶¶</sup> n (%)	N=52			
	Any Grade	Grade 1	Grade 2	Grade ≥3 <sup>§</sup>
Anemia	16 (30.8)	7 (13.5)	5 (9.6)	4 (7.7)
Fatigue	14 (26.9)	9 (17.3)	5 (9.6)	0
Thrombocytopenia	13 (25.0)	7 (13.5)	2 (3.8)	4 (7.7) <sup>¶¶</sup>
Arthralgia	11 (21.2)	5 (9.6)	6 (11.5)	0
AST increased	11 (21.2)	8 (15.4)	2 (3.8)	1 (1.9)
Cough	11 (21.2)	9 (17.3)	2 (3.8)	0
Diarrhea	11 (21.2)	10 (19.2)	1 (1.9)	0
Headache	11 (21.2)	7 (13.5)	4 (7.7)	0
Leukopenia	11 (21.2)	1 (1.9)	6 (11.5)	4 (7.7) <sup>¶¶</sup>
Nausea	11 (21.2)	9 (17.3)	2 (3.8)	0
Pruritus	11 (21.2)	10 (19.2)	1 (1.9)	0
Hyperglycemia	10 (19.2)	6 (11.5)	3 (5.8)	1 (1.9)
Neutropenia	10 (19.2)	0	5 (9.6)	5 (9.6) <sup>¶¶</sup>
Nasal congestion	8 (15.4)	6 (11.5)	2 (3.8)	0
Pain in extremity	8 (15.4)	7 (13.5)	1 (1.9)	0

\*Abdominal pain and tendonitis (n=1; 70 mg); MBL (progressed to MCL) and small intestinal obstruction (n=1; 400 mg); arthritis (n=1; 1500 mg); basal cell carcinoma (n=1; 100 mg); and pyrexia (n=1; 1500 mg). All serious TEAEs were considered unrelated to INCA033989, except tendonitis. †MBL (progressed to MCL; n=1; 400 mg) and neutropenia (n=1; 750 mg). ‡AST increase (n=1) and thrombocytopenia (n=1). §Other grade ≥3 TEAEs: abdominal pain (n=2), dental caries, hypertension, joint effusion, lipase increased, MBL (progressed to MCL), edema peripheral, small intestinal obstruction, tendonitis, and viral upper respiratory tract infection (each n=1). ¶Thrombocytopenia and Leukopenia: grade 4 (n=2); Neutropenia: grade 4 (n=3). ¶¶Adverse event (n=2); lack of efficacy (n=2); physician decision (n=1); progressive disease (n=2). ¶¶¶Patients were counted once under the highest grade.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; MBL, monoclonal B-cell lymphocytosis; MCL, mantle cell lymphoma; n, number of individual patients.

# Spleen Volume Reductions Observed With INCA033989 Monotherapy

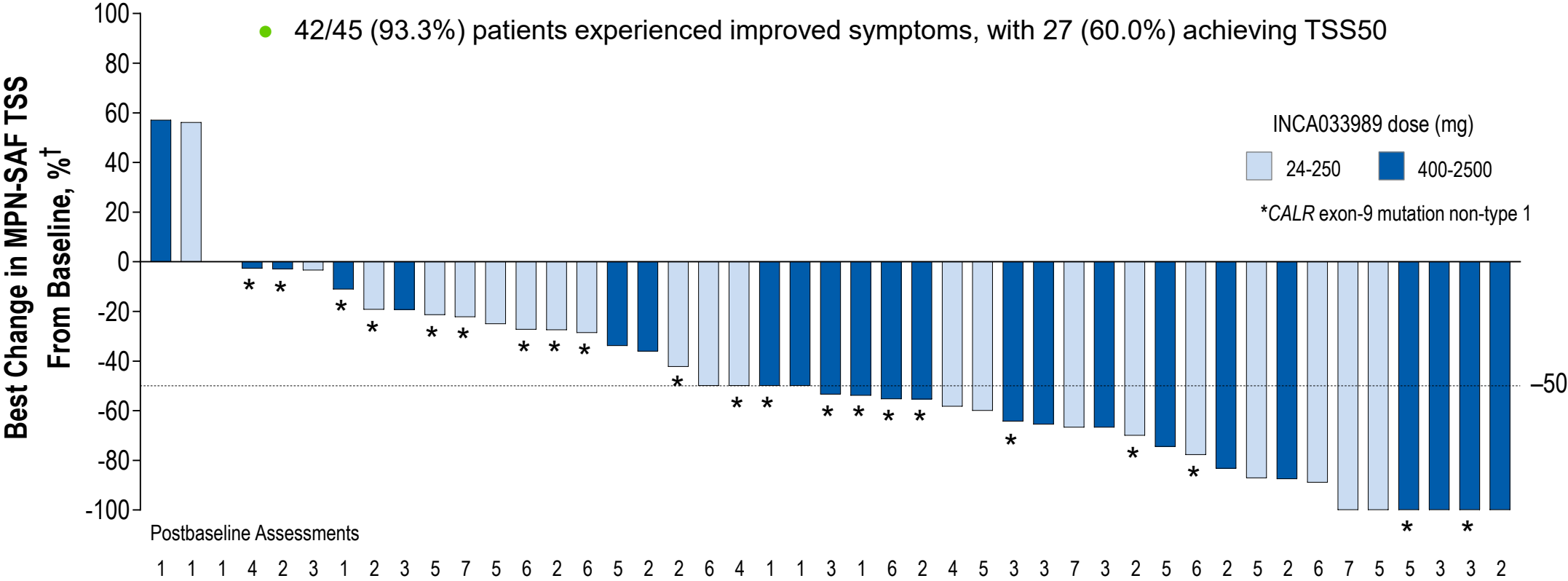


	SVR at Week 24 (N=36)		
	Total	No Prior JAKi	R/R or Intolerant to JAKi‡
SVR25, n/N (%)	15/36 (41.7)	5/7 (71.4)	10/29 (34.5)
SVR35, n/N (%)	12/36 (33.3)	4/7 (57.1)	8/29 (27.6)

†N=48; 4 patients excluded due to lack of postbaseline assessments but remain on study. Postbaseline assessments performed every 12 weeks. ‡R/R or intolerant to JAKi, including 7 patients with incomplete data (6 of 7 known prior JAKi treatment ≥12 weeks).

JAKi, Janus kinase inhibitor; R/R, relapsed/refractory; SVR25, spleen volume reduction ≥25%; SVR35, spleen volume reduction ≥35%.

# Most Patients Experienced Symptom Improvements With INCA033989 Monotherapy



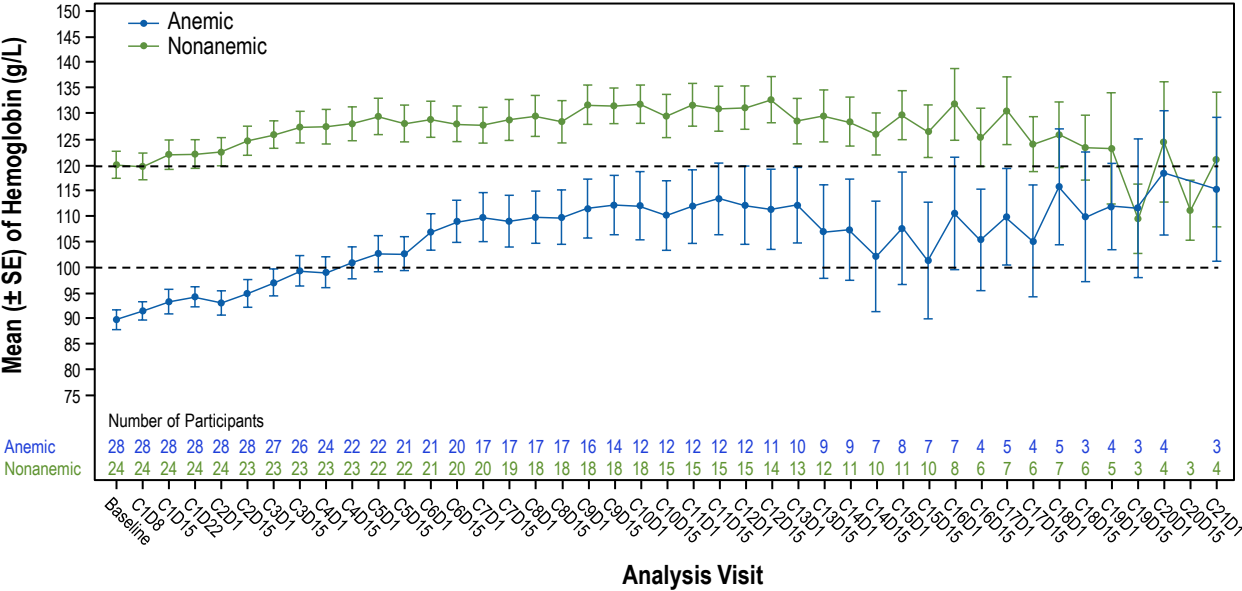
TSS50 at Week 24 (N=33)			
	Total	No Prior JAKi	R/R or Intolerant to JAKi <sup>‡</sup>
TSS50, n/N (%)	13/33 (39.4)	3/5 (60.0)	10/28 (35.7)

<sup>†</sup>N=45; 7 patients excluded due to lack of postbaseline assessment. Postbaseline assessments performed every 12 weeks. <sup>‡</sup>R/R or intolerant to JAKi, including 7 patients with incomplete data (6 of 7 known prior JAKi treatment ≥12 weeks). JAKi, Janus kinase inhibitor; MPN-SAF, Myeloproliferative Neoplasm-Symptom Assessment Form; R/R, relapsed/refractory; TSS, total symptom score; TSS50, ≥50% reduction in MPN-SAF TSS.



# Most Patients Experienced Robust Anemia Improvements With INCA033989 Monotherapy

Mean Hemoglobin During Study by Anemic Status\*



Best Anemia Response in Evaluable Patients

Variable	Total (N=25)	TDA (n=5)	Non-TDA (n=20)
Best anemia response, n (%)			
Major response	10 (40.0)	1 (20.0)	9 (45.0)
Minor response	4 (16.0)	2 (40.0)	2 (10.0)
Stable anemia	8 (32.0)	1 (20.0)	7 (35.0)
Progressive anemia	2 (8.0)	1 (20.0)	1 (5.0)
Missing†	1 (4.0)	0	1 (5.0)

- At baseline, median (range) hemoglobin among patients with anemia was 92 (70, 108) g/L
- Anemia response occurred in 14/25 (56%) of evaluable‡ anemic patients; most patients achieved a major response

\*Criteria for baseline anemia and response based on Tefferi A. *Blood*. 2024;114:1813. Major and minor anemia responses were according to IWG-ELN response criteria. Dotted lines indicate anemia threshold (100 g/L) and lower limit of normal (120 g/L). †Patient who terminated treatment before 12 weeks. ‡3/28 anemic patients were not evaluable for response due to missing data at 12 weeks. IWG-ELN, International Working Group–European LeukemiaNet; TDA, transfusion-dependent anemia.

# INCA033989 is Well Tolerated in Combination With Ruxolitinib in Patients With MF

Summary of TEAEs

TEAE, n (%)	N=20
Any TEAE	20 (100.0)
Treatment-related*	13 (65.0)
Grade ≥3	11 (55.0)
Serious	5 (25.0) <sup>†</sup>
Fatal	0
Discontinuation* due to TEAEs	2 (10.0) <sup>‡</sup>
Dose reduction* due to TEAEs	1 (5.0)
Infusion interruption* due to TEAEs	1 (5.0)
Dose delay* due to TEAEs	8 (40.0)
Dose-limiting toxicity	0

Most Common TEAEs (≥15% of Patients)

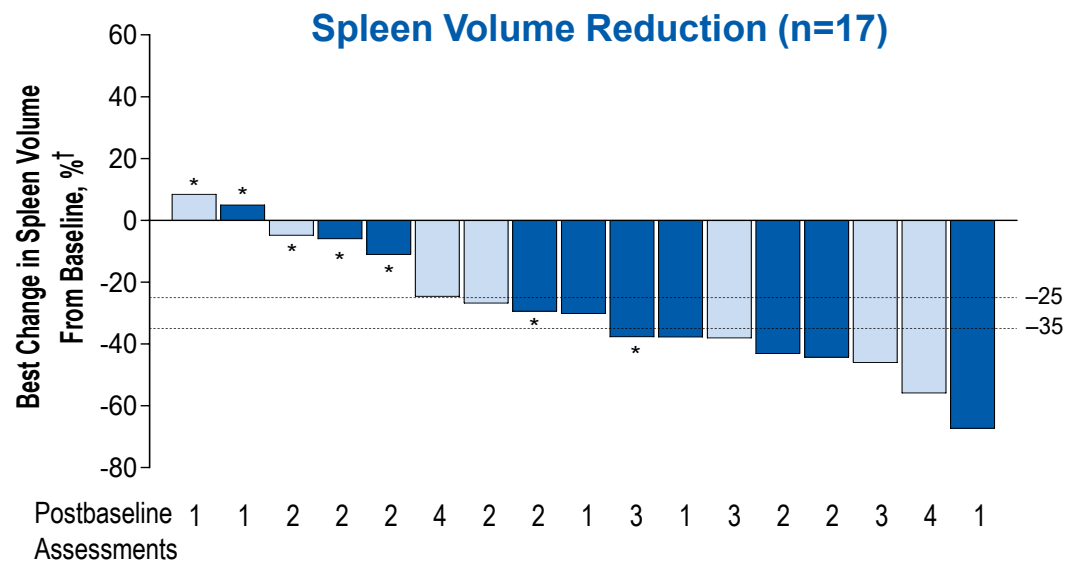
TEAE, <sup>¶¶</sup> n (%)	N=20			
	Any Grade	Grade 1	Grade 2	Grade ≥3 <sup>§</sup>
Anemia	9 (45.0)	2 (10.0)	1 (5.0)	6 (30.0) <sup>¶</sup>
Thrombocytopenia	7 (35.0)	3 (15.0)	2 (10.0)	2 (10.0)
ALT increased	4 (20.0)	2 (10.0)	2 (10.0)	0
Diarrhea	4 (20.0)	4 (20.0)	0	0
Fatigue	4 (20.0)	4 (20.0)	0	0
AST increased	3 (15.0)	2 (10.0)	1 (5.0)	0
Cough	3 (15.0)	1 (5.0)	2 (10.0)	0

- Overall, 17 (85.0%) patients were still receiving treatment and 3 (15.0%) discontinued treatment<sup>||</sup>
- No dose-limiting toxicities were observed; the maximum tolerated dose was not reached (dose range 70-2500 mg)
- Four patients experienced increased AST and/or ALT; all events were grade 1 or 2, and 2 events remain ongoing

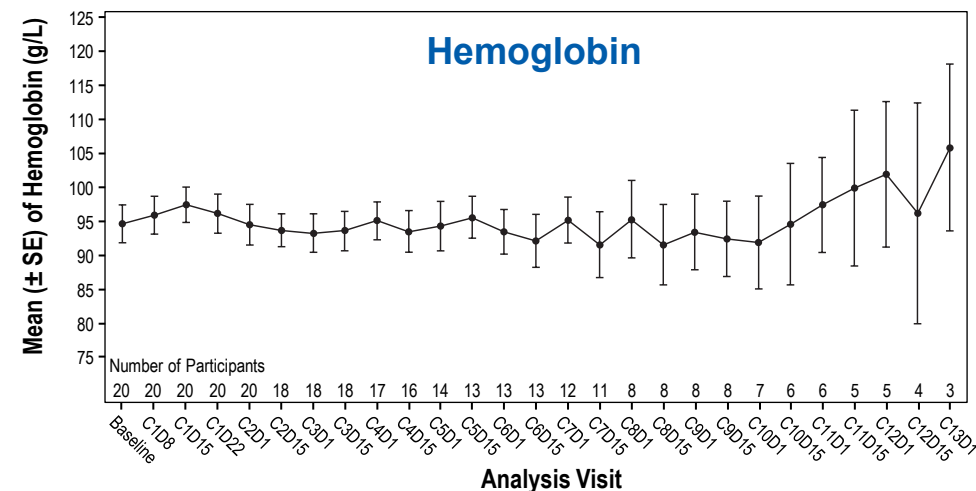
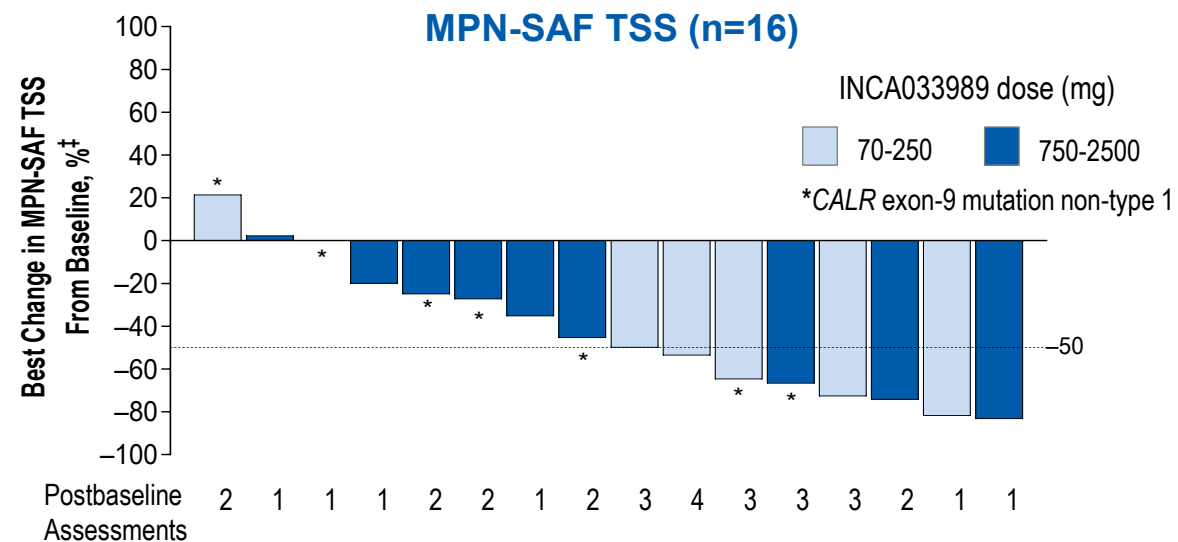
\*Related to INCA033989. <sup>†</sup>Acute myocardial infarction (n=1; 750 mg); anemia (n=1; 1500 mg); basal cell carcinoma (n=1; 250 mg); diffuse large B-cell lymphoma (n=1; 70 mg); stomatitis (n=1; 750 mg). <sup>‡</sup>Anemia (n=1; 250 mg); diffuse large B-cell lymphoma (n=1; 70 mg). <sup>§</sup>Other grade ≥3 TEAEs: neutropenia (n=2), abscess limb, acute myocardial infarction, diffuse large B-cell lymphoma, obstructive sleep apnea syndrome, and stomatitis (each n=1). <sup>¶</sup>Grade 4 (n=1). <sup>||</sup>Adverse event (n=2); physician decision (n=1). <sup>¶¶</sup>Patients were counted once under the highest grade.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; MF, myelofibrosis; n, number of individual patients; TEAE, treatment-emergent adverse event.

# Most Patients Experienced Spleen Volume Reductions and Symptom Improvements With INCA033989 + Ruxolitinib



- As best SVR, 11 patients achieved SVR25, and 8 patients achieved SVR35
- Among evaluable patients at week 24 (n=12), 6 (50%) had SVR25 and 3 (25%) had SVR35
- 13/16 (81.3%) patients experienced symptom improvements; 3/9§ (33.3%) patients achieved TSS50 at week 24
- Among 14 evaluable patients,¶ 86% had stable anemia during the study (TDA, n=1; non-TDA, n=11); 1 patient (non-TDA) had a major anemia response¹

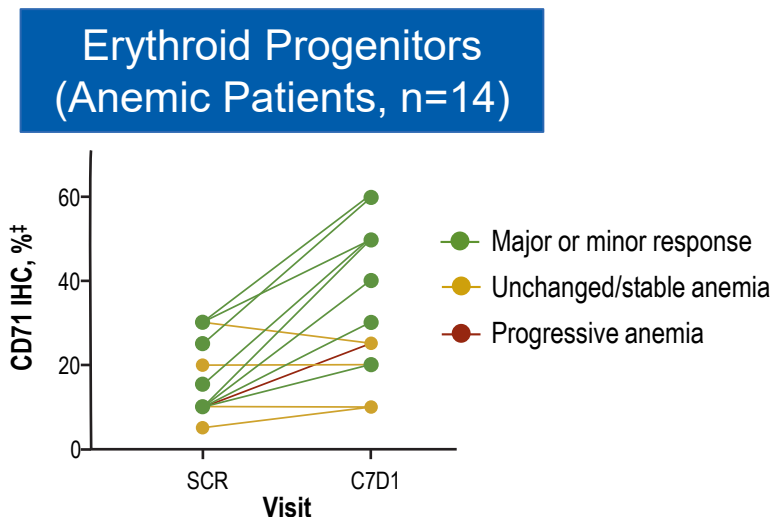
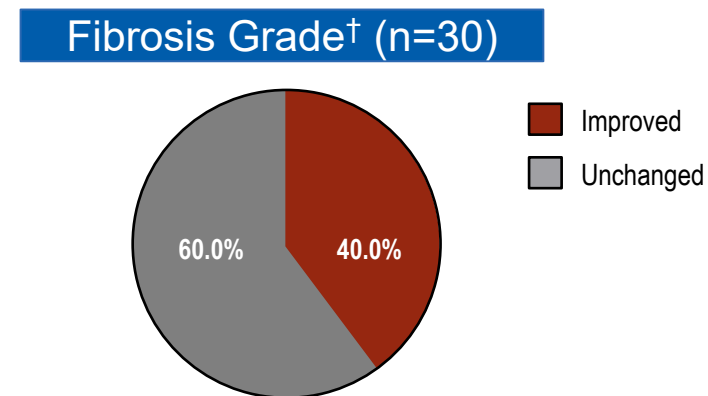
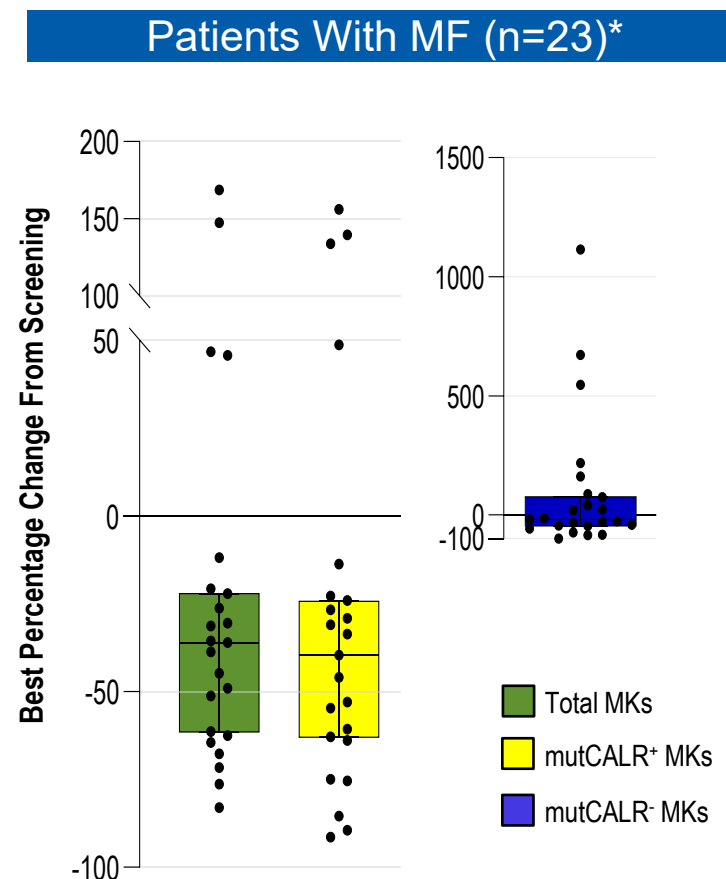
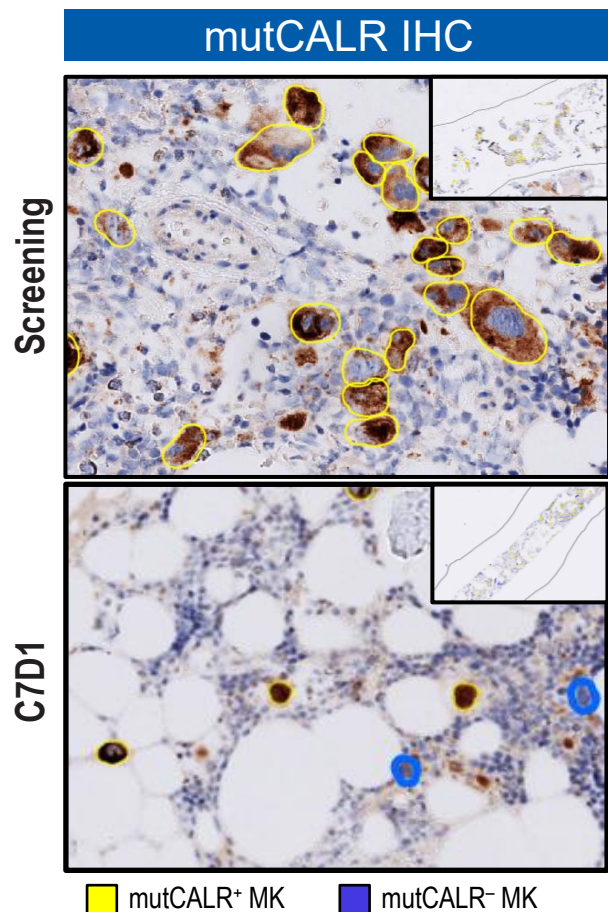


1. Tefferi A. *Blood*. 2024;114:1813.

†N=17; 3 patients excluded due to lack of postbaseline assessment but remain on study. ‡N=16; 4 patients excluded due to lack of baseline or postbaseline assessment but remain on study. §Patients with available percentage change in MPN-SAF TSS at week 24 compared with baseline. ¶4 patients were excluded as they were not anemic at baseline or had not been treated for 12 weeks.

C, cycle; D, day; MPN-SAF, Myeloproliferative Neoplasm-Symptom Assessment Form; SE, standard error; SVR25, spleen volume reduction ≥25%; SVR35, spleen volume reduction ≥35%; TDA, transfusion-dependent anemia; TSS, total symptom score; TSS50, ≥50% reduction in MPN-SAF TSS.

# Improvement in Bone Marrow Pathology With INCA033989



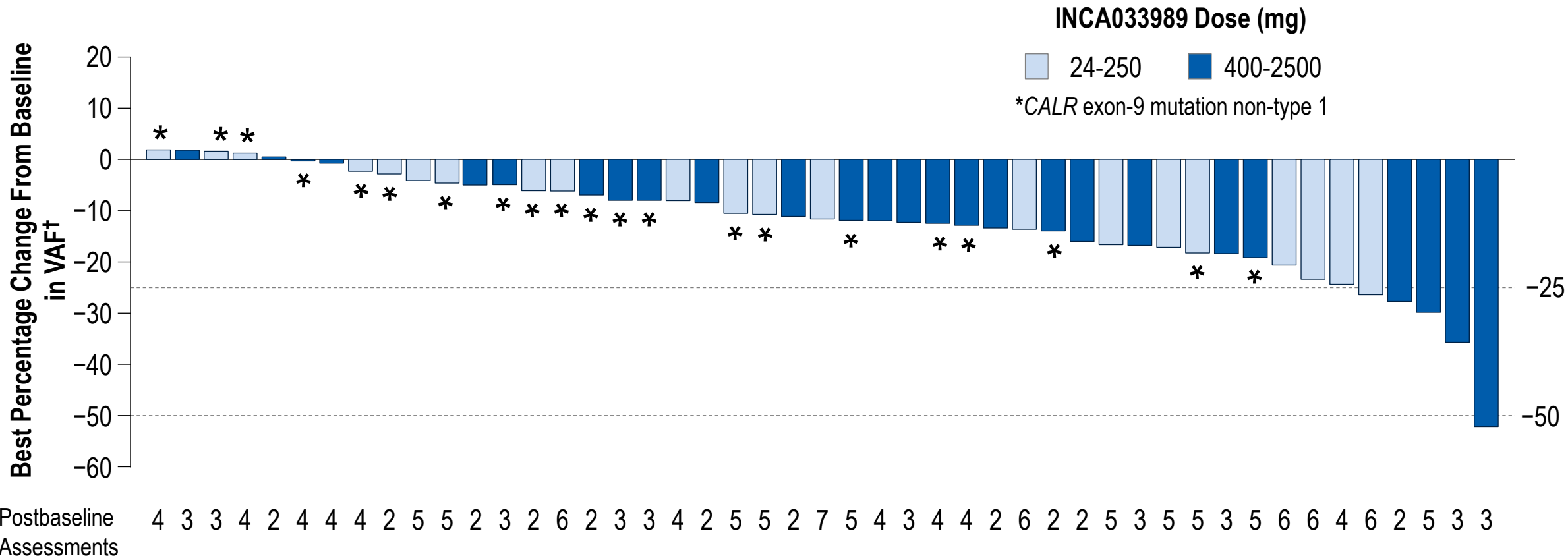
- Reduction of total and mutCALR+ MK in MF is accompanied by increase of wild-type (mutCALR-)

\*1 patient with 0 mutCALR- MK at screening is not shown. Bone marrow mutCALR IHC quantitative assessment of mutCALR+ and mutCALR- MK were conducted by pathologist at screening and at timepoints on-treatment (primarily 3 or 6 cycles).

†Fibrosis grade was centrally assessed for all patients with available screening and C7D1 samples. "Improved": decreased by  $\geq 1$  grade; "Unchanged": stable. ‡CD71 IHC was centrally assessed by a single pathologist; data includes all patients with baseline anemia and available CD71 IHC for screening and C7D1 (n=14).

C, cycle; D, day; IHC, immunohistochemistry; MF, myelofibrosis; MK, megakaryocytes; mutCALR, mutations of calreticulin; SCR, screening; SVR35, spleen volume reduction  $\geq 35\%$ .

# Most Patients Experienced VAF Reduction With INCA033989 Monotherapy



- A reduction in mutCALR VAF from baseline occurred in 42/47 (89.4%) patients with ≥1 postbaseline VAF measurement
  - 5/47 (10.6%) achieved ≥25% best reduction in VAF

†N=47. 5 patients were excluded due to lack of postbaseline assessment. Postbaseline assessments performed C2D15, C4D1, and every 3 cycles thereafter.  
C, cycle; D, day; MPN-SAF, Myeloproliferative Neoplasm-Symptom Assessment Form; mutCALR, mutations of calreticulin; TSS, total symptom score; VAF, variant allele frequency.



# Conclusions

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- INCA033989 was well tolerated, both as monotherapy and in combination with ruxolitinib, in patients with MF who were resistant/intolerant to prior JAKi therapy or ineligible for JAKi treatment
- No dose-limiting toxicities were observed, and a maximum tolerated dose was not reached
  - 87% of patients remain on INCA033989 monotherapy and 85% of patients remain on INCA033989 + ruxolitinib
- Rapid and robust spleen and anemia responses and symptom improvements occurred in both cohorts despite advanced disease and limited follow-up
- mutCALR VAF reduction was observed in the majority of patients
- Exploratory analysis showed reductions of mutCALR<sup>+</sup> MK and improved marrow architecture, supporting the potential of INCA033989 to modify the disease of patients with mutCALR MF
- These data demonstrate a clear and robust proof of concept in MF that will enable pivotal registration studies in the near future
- Development of a subcutaneous formulation is ongoing
- Clinical safety, tolerability, and efficacy in the ET cohort will be presented by **Dr. Vikas Gupta, Dec 8, at 5:15 PM (#1024)**

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