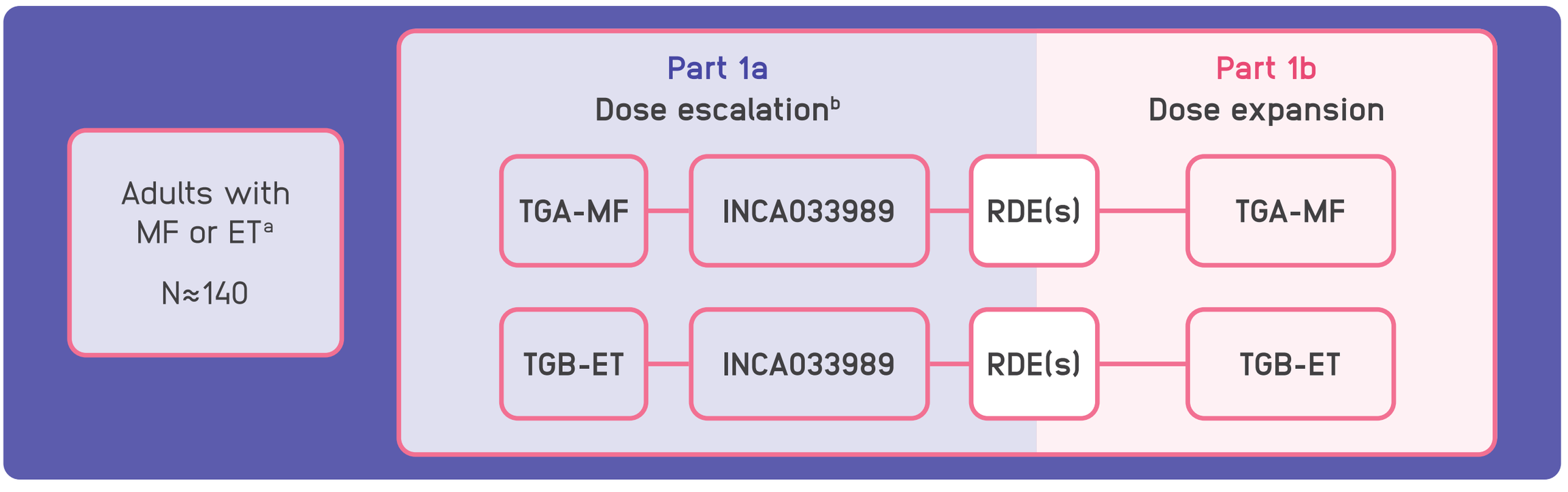
INCA 33989-102

Myelofibrosis or Essential Thrombocythemia
Phase 1 | NCT06034002

INCA033989 (mutCALR-Selective mAb) as Monotherapy in Patients With MF or ET[1,2]

A Safety and Tolerability Study



[a] MF or ET as defined in the protocol. [b] INCA033989 will be administered at a protocol-defined dose and in 28-day cycles to identify the MTD and/or RDE(s).

Primary endpoints

- Dose-limiting toxicities
- Incidence of TEAEs
- TEAEs leading to dose modification or discontinuation

Secondary endpoints

- All patients: PK, change from baseline for *CALR* allele burden level
- MF: response per IWG-MRT and ELN, SVR35 and SVR25 at weeks 12 and 24, anemia response
- ET: response per IWG-MRT and ELN, symptom improvement (MPN-SAF TSS)

Select inclusion criteria

- Documented *CALR* exon**-**9 mutation
- **Patients with MF:** PMF or post-ET MF (2022 WHO criteria) previously treated with JAKi for >12 weeks; resistant or refractory to, ***or*** intolerant, ***or*** has lost response to JAKi treatment, ***or*** Int- or high-risk DIPSS MF and ineligible for JAKi treatment; bone marrow myeloblast count <10%; and evidence of evaluable residual burden of disease
- **Patients with ET:** ET (2022 WHO criteria), high risk, resistance to or intolerance of ≥1 prior cytoreductive therapy (eg, HU, IFN, thalidomide, busulfan, lenalidomide, anagrelide) per ELN criteria, and platelet counts >450×10^9/L

Select exclusion criteria

- Presence of any hematologic malignancy other than ET, PMF, or post-ET MF
- History of major bleeding or thrombosis within the last 3 months prior to study enrollment
- Prior/planned HSCT
- Active invasive malignancy over the previous 2 years
- History of clinically significant or uncontrolled cardiac disease
- Active HBV/HCV infection or known history of HIV infection
- Have received any prior chemotherapy, immunomodulatory drug therapy, immunosuppressive therapy, biological therapy, endocrine therapy, targeted therapy, antibody, or hypomethylating agent used to treat the patient's disease within 5 half-lives or 28 days prior to first dose of study treatment (whichever is shorter)
- Treatment with G-CSF, GM-CSF, or TPO-R agonists at any time ≤4 weeks before the first dose of study treatment

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The efficacy and safety of the investigational compound discussed have not been established. There is no guarantee that this compound will become commercially available for the uses under investigation.

For more information, visit **IncyteClinicalTrials.com** or contact us at **1-855-4MED-INFO** (855-463-3463) or **clintrials@incyte.com**.

A copy of this panel can be accessed using the QR code below.

CALR, calreticulin; DIPSS, Dynamic International Prognostic Scoring System; ELN, European LeukemiaNet; ET, essential thrombocythemia; G-CSF, granulocyte-colony stimulating factor; GM-CSF, granulocyte macrophage–colony stimulating factor; HBV, hepatitis B virus; HCV, hepatitis C virus; HSCT, hematopoietic stem cell transplant; HU, hydroxyurea; IFN, interferon; Int, intermediate; IWG-MRT, International Working Group-Myeloproliferative Neoplasms Research and Treatment; JAKi, Janus kinase inhibitor; mAb, monoclonal antibody; MF, myelofibrosis; MPN-SAF, Myeloproliferative Neoplasm Symptom Assessment Form; MTD, maximum tolerated dose; mutCALR, mutant calreticulin; PK, pharmacokinetics; PMF, primary myelofibrosis; RDE, recommended dose for expansion; SVR25, spleen volume response (≥25% reduction); SVR35, spleen volume response (≥35% reduction); TEAE, treatment-emergent adverse event; TGA, treatment group A; TGB, treatment group B; TPO-R, thrombopoietin receptor; TSS, Total Symptom Score; WHO, World Health Organization.

1. ClinicalTrials.gov. Accessed Jul 2024. https://clinicaltrials.gov/study/NCT06034002 2. Data on file, Incyte Corporation.

This information is current as of July 25, 2024.