

# Inclusion & Exclusion Criteria (Core Study)

## Inclusion Criteria

1. Aged  $\geq 18$  years
2. Pre-fibrotic/early PMF (Pre-PMF) or overt PMF at low or intermediate-1 risk according to DIPSS plus diagnosed according to WHO 2016 or 2022 classification
3. White blood cell count  $>10 \times 10^9/L$  or platelet  $\geq 450 \times 10^9/L$
4. Spleen size  $\leq 5$  cm below the left costal margin
5. Good liver function (Total Bilirubin  $\leq 1.5 \times ULN$ , INR  $\leq 1.5 \times ULN$ , Albumin  $>3.5g/dL$ , ALT & AST  $\leq 2.0 \times ULN$ )
6. Hemoglobin  $\geq 10.0$  g/dL
7. Neutrophil count  $\geq 1.0 \times 10^9/L$
8. Creatinine clearance rate  $\geq 30$  mL/min
9. Females of childbearing potential, as well as all women  $<2$  years after the onset of menopause, agree to use an acceptable form of birth control until 60 days following the last dose of the study drug and not breastfeed during the study
10. Written informed consent obtained from the subject and ability for the subject to comply with the requirements of the study

## Exclusion Criteria

1. Any known contraindications or hypersensitivity to IFN- $\alpha$
2. Prior interferon therapy having poor tolerability or lack of efficacy to the previous interferon therapy
3. Ongoing cytoreduction (e.g., hydroxyurea or IFN- $\alpha$ ) if randomizing them into the placebo arm; may lead to immediate rebound increase of peripheral blood counts\*
4. Spleen size  $>5$  cm below the left costal margin on palpation
5. Severe or serious diseases that may affect participation in this study
6. History of major organ transplantation
7. Pregnant or breastfeeding women
8. Any other diseases that will affect the study results or may weaken compliance to protocol
9. Use any investigational drug  $<4$  weeks prior to the first dose of study drug, or not recovered from the effects of prior administration of any investigational drug
10. Eligible for JAK inhibitor therapy

\*Patient with ongoing cytoreduction at the time of screening can be enrolled but the cytoreduction dose should be gradually reduced until the day before Dose 1