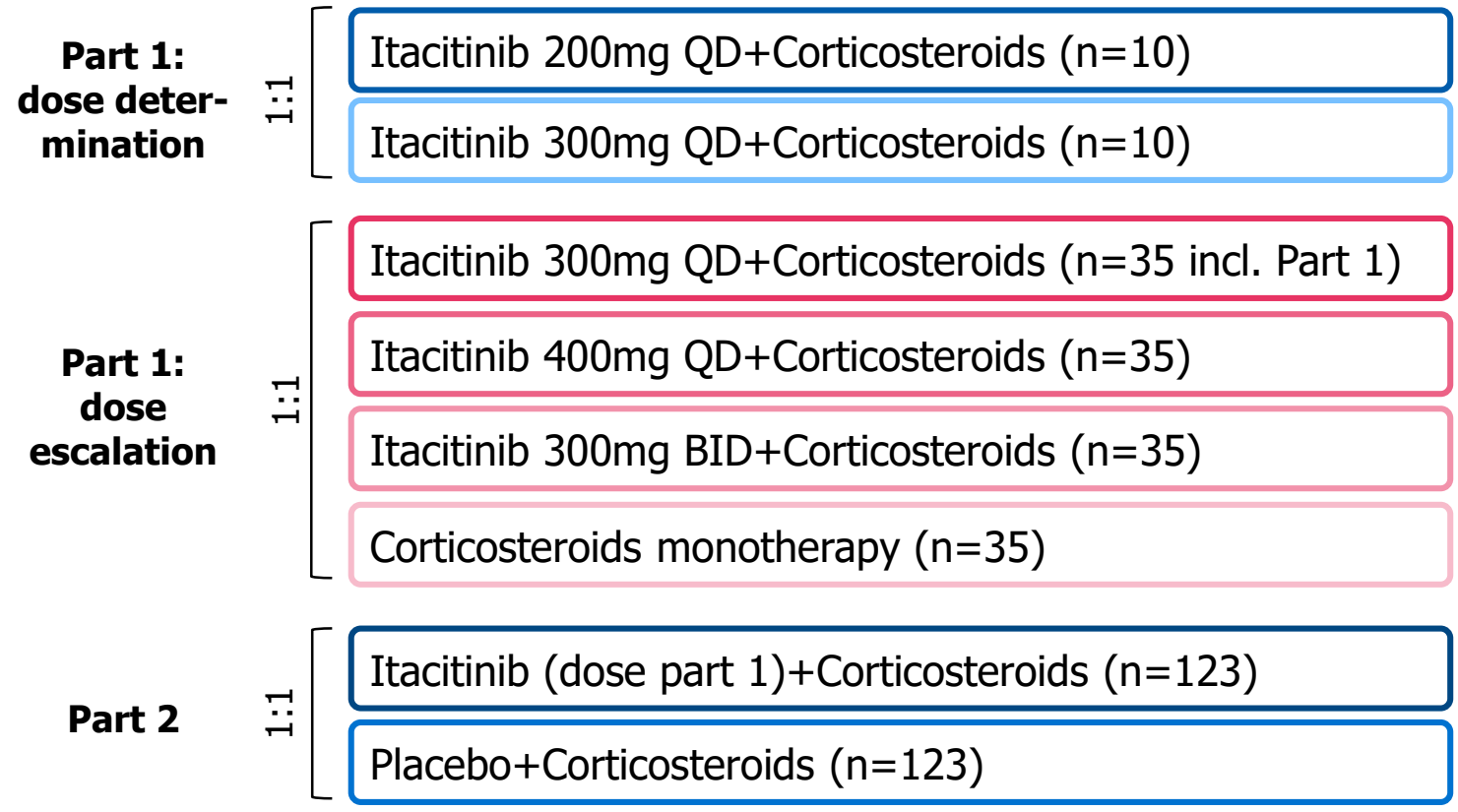
GRAVITAS-309 NCT03584516 | Phase 2/3 | Chronic Graft-versus-Host-Disease (cGVHD)

Randomized, 2-part, multicenter Phase 2/3 study of Itacitinib and corticosteroids as initial treatment in chronic GVHD



Primary end point

- Part 1: Dose determination and expansion: Number of dose-limiting toxicities
- Part 2: Response rate at month 6

Secondary end points

- Response rate, time to response, PK, DoR, OS, non-relapse mortality
- Safety

Select inclusion criteria

- Age ≥18
- Active, clinically diagnosed, moderate or severe cGVHD per NIH Consensus Criteria
- Underwent allo-HCT
- Karnofsky Performance Status ≥60%
- Evidence of myeloid (ANC ≥ $1x10^9$/L) and platelet engraftement (platelet count ≥ $25x10^9$/L)
- Willingness to avoid pregnancy or fathering of children

Select exclusion criteria

- Receipt of >3 days/72 hours of systemic corticosteroid treatment for cGVHD
- Any other systemic treatment for cGVHD, incl. ECP
- Prior treatment with JAK inhibitor within 8 weeks before randomization, unless patient who received JAK inhibitor for aGVHD achieved CR or PR
- Evidence of relapsed primary malignancy, or receipt of treatment for relapse after allo-HCT was performed, including DLIs for for treatment of moleculr relapse

The efficacy and safety of the investigational compound discussed[a] have not been established. There is no guarantee that this compound[a] will become commercially available for the use(s) under investigation.

For more information, visit IncyteClinicalTrials.com, contact us at +800 00027423 or by email at clintrials@incyte.com, or click on the QR code on the right to visit the trial on clinicaltrials.gov

For reporting adverse events, contact eumedinfo@incyte.com or +49 8007239013

[a] Itacitinib

aGVHD: acute graft-versus-host-disease; Allo-HCT: allogeneic hematopoietic stem cell translantation; ANC: absolute neutrophil count; BID: twice daily; cGVHD: chronic graft-versus-host-disease; CR: complete response; DLI: donor lymphocyte infusion; DoR: duration of response; ECP: extracorporeal photopheresis; JAK: Janus kinase; NIH: National Institutes of Health; OS: Overall Survival; PK: pharmacokinetics; PR: partial response; QD: once daily;
https://www.clinicaltrials.gov/ct2/show/NCT03584516; Accessed 30 September 2021

DE/ITAC/NP/21/0004, 30 September, 2021