Inklusionskriterier ved registrering:	Ja	Nej
1. Participant is considered a suitable candidate for HCT and has an acceptable source of allogeneic donor cells, as defined per institutional practice (allogeneic HCT for any donor source [matched sibling, unrelated donor (URD), mismatched URD, related haploidentical, or umbilical cord blood] and any graft source [umbilical cord, BM, peripheral blood (PB)], and any conditioning [myeloablative conditioning (MAC), reduced intensity conditioning (RIC), or non-myeloablative conditioning (NMA)] will be permitted).		
2. Institutional Review Board/Independent Ethics Committee (IRB/IEC) approved written informed consent and privacy language as per national regulations (e.g., Health Insurance Portability and Accountability Act Authorization (HIPAA) for US sites) obtained from the participant or legally authorized representative prior to any study-related procedures (including withdrawal of prohibited medication, if applicable).		
3. Participant is considered a legal adult by local regulation at the time of signing informed consent form (ICF).		
4. Participant consents to allow access to his or her diagnostic BM aspirate or PB sample and/or the DNA derived from that sample, if available, that may be used to validate a companion diagnostic that is being developed in parallel with gilteritinib.		
5. Participant has confirmed, morphologically documented AML in CR1. For the purposes of registration, CR1 will be defined as < 5% blasts in the BM with no morphologic characteristics of acute leukemia (e.g., Auer Rods) in the BM with no evidence of extramedullary disease such as central nervous system involvement or granulocytic sarcoma. a) Participant has not received more than 2 cycles of induction chemotherapy to achieve CR1. The induction cycles can be the same regimen or different regimens. The regimen(s) may contain conventional agents, investigational agents, or a combination of both. b) Participants with CR with incomplete count recovery (CRp or CRi) are allowed. Incomplete platelet recovery (CRp) is defined as CR with platelet count < 100 x 109/L. Incomplete blood count recovery (CRi) is defined as CR with residual neutropenia < 1 x 109/L with or without complete platelet recovery. Red blood count (RBC) and platelet transfusion independence is not required. c) The maximum time allowed from establishment of CR1 to registration is 12 months.		
6. Participant has presence of the FLT3/ITD activating mutation in the BM or PB as determined by the local institution at diagnosis.		
7. Participant must meet the following criteria as indicated on the clinical laboratory tests: a) Serum creatinine within normal range, or if serum creatinine outside normal range, then glomerular filtration rate (GFR) > 40 mL/min/1.73m2 as calculated with the Cockcroft-Gault equation with adjustment if total body weight is ≥ 125% of ideal body weight. b) Total bilirubin (TBL) ≤ 2.5 mg/dL, except for participants with Gilbert's syndrome. c) Serum AST and/or alanine aminotransferase (ALT) < 3 x institutional upper limit of		

Inklusionskriterier ved registrering:	Ja	Nej
normal (ULN).		
8. Participant has left ventricular ejection fraction (LVEF) at rest ≥ 40%.		
9. Participant has diffusing capacity of the lung for carbon monoxide (DLCO) (corrected for hemoglobin) ≥50%predicted and/or forced expiratory volume in 1 second (FEV1) ≥50% predicted.		
10. Female participants must either: a) Be of non-childbearing potential: ● postmenopausal (defined as at least 1 year without menses) prior to screening or ● documented as surgically sterilized (at least 1 month prior to the screening visit) b) Or, if of childbearing potential, ● Agree not to try to become pregnant during the study for 6 months after the final study drug administration ● And have a negative serum pregnancy test at screening ● And, if heterosexually active, agree to consistently use highly effective contraception per locally accepted standards in addition to a barrier method starting at screening and throughout the study period and for 6 months after the final study drug administration.		
11. Female participants must agree not to breastfeed or donate ova throughout the study drug treatment period and for 6 months after the final study drug administration.		
12. Male participants (even if surgically sterilized), and their partners who are women of childbearing potential must be using highly effective contraception in addition to a barrier method throughout the study drug treatment period and for 127 days after the final study drug administration.		
13. Male participants must not donate sperm starting at screening and throughout the study period and for 105 days after the final study drug administration.		
14. Participant is able to take an oral medication.		
15. Participant agrees not to participate in another interventional study while on treatment.		

Eksklusionskriterier ved registrering:	Ja	Nej
1. Participant has had a prior allogeneic transplant		
2. Participant has Karnofsky performance status score < 70%		
3. Participant requires treatment with concomitant drugs that are strong inducers of CYP3A (APPENDIX H) within 14 days of start of study drug.		
4. Participant requires treatment with concomitant drugs that target serotonin 5-hydroxytryptamine receptor 1 ($5HT_1R$) or 5-hydroxytryptamine receptor 2B ($5HT_{2B}R$) or sigma nonspecific receptor with the exception of drugs that are considered absolutely essential for the care of the participant(APPENDIX H).		
5. Participant has a Fridericia-corrected QT interval (QTcF) > 450 msec (average of triplicate determinations) per central read.		
6. Participant has long QT Syndrome at screening.		
7. Participant has a known infection with human immunodeficiency virus (HIV).		
8. Participant has active hepatitis B infection as determined by nucleic acid amplification test (NAAT) or surface antigen assay. Participants who have acquired immunity from past exposure (HBcAb positive/HBsAb positive/HBsAg negative) are eligible.		
9. Participant has active hepatitis C infection as determined by NAAT. NAAT must be performed if the participant has positive serologu for hepatitis C. Participants who have had past exposure and have no detectable virus either through spontaneous clearance or treatment are eligible.		
10. Participant has an uncontrolled infection. If a bacterial or viral infection is present, the participant must be receiving definitive therapy and have no signs of progressing infection for 72 hours prior to registration. If a fungal infection is present, the participant must be receiving definitive systemic anti-fungal therapy and have no signs of progressing infection for 1 week prior to registration. ● Progressing infection is defined as hemodynamic instability attributable to sepsis or new symptoms, worsening physical signs or radiographic findings attributable to infection. • Persisting fever without other signs or symptoms will not be interpreted as progressing infection.		
11. Participant has had a myocardial infarction within 6 months prior to registration or New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled angina, severe uncontrolled ventricular arrhythmias, or electrocardiographic evidence of acute ischemia.		
12. Participant has a serious medical or psychiatric illness likely to interfere with participation in this clinical study.		

Eksklusionskriterier ved registrering:	Ja	Nej
13. Participant is breast feeding or pregnant		
14. Participant has prior malignancies, except lobular breast carcinoma in situ, fully resected basal cell or squamous cell carcinoma of skin or treated cervical carcinoma in situ. Cancer treated with curative intent > 5 years previously will be allowed. Cancer treated with curative intent < 5 years previously will not be allowed.		

Dato: ____/____ 20__Læge (underskrift): _____ Læge (init): _____