KURZPROTOKOLL
AG-221-AML-004 (IDHentify)

Öffentlicher Titel	Phase III Studie zu AG-221 bei älteren Patienten mit fortgeschrittener AML und IDH2-Mutation
Wissenschaftl. Titel	A Phase 3, Multicenter, Open-label, Randomized Study Comparing the Efficacy and Safety of AG-221 (CC-90007) Versus Conventional Care Regimens in Older Subjects With Late Stage Acute Myeloid Leukemia Harboring an Isocitrate Dehydrogenase 2 Mutation
Kurztitel	AG-221-AML-004 (IDHentify)
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Akute myeloische Leukämie (AML): Rezidiviert/refraktär
Einschlusskriterien	- Subject is 60 years of age at the time of signing the Informed Consent Form (ICF) - Subject has primary (ie, de novo) or secondary (progression of Myelodysplastic syndromes (MDS) or myeloproliferative neoplasms ([MPN], or therapy-related) Acute myeloid leukemia (AML) according to World Health Organization (WHO) classification - Subject has received second- or third-line/regimen of AML therapy - Subject has the following disease status: - a. Refractory to or relapsed after second- or third-line/regimen of intensive therapy for AML (eg, the "7 + 3" regimen): - b. Refractory to or relapsed after second- or third-line low-intensity AML therapy (eg, LDAC, azacitidine or decitabine): at least 5% leukemic blasts in bone marrow after at least 2 treatment cycles
Ausschlusskriterien	- Subject is suspected or proven to have acute promyelocytic leukemia based on morphology, immunophenotype, molecular assay, or karyotype - Subject has Acute myeloid leukemia (AML) secondary to chronic myelogenous leukemia (CML) - Subject has received a targeted agent against an IDH2 mutation - Subject has received systemic anticancer therapy or radiotherapy < 14 days prior to the start of study treatment. Note that hydroxyurea is allowed prior to the start of study treatment for the control of leukocytosis in subjects with white blood cell (WBC) counts > 30 x 109/L (however, hydroxyurea should not be given within 72 hours prior to and after administration of azacitidine). - Subject has received non-cytotoxic or investigational agents < 14 days or 5 half-lives, whichever is longer, prior to the start of study treatment - Subject has undergone HSCT within 60 days prior to the start of study treatment, or on immunosuppressive therapy post Hematopoietic stem cell transplantation (HSCT) at the time of screening, or with clinically significant graft-versus-host disease (GVHD). The use of a stable dose of oral steroid post-HSCT and/or topical steroids for ongoing skin Graft-versus-host disease (GVHD) is permitted.
Alter	60 Jahre und älter
Molekularer Marker	IDH2
Fallzahl	280
Sponsor	Celgene GmbH
Förderer	Celgene GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02577406 EudraCT 2015-000344-42
Links	Studiendokumente zum Download (roXtra)