Öffentlicher Titel  Phase I first-in-human Studie zum PRMT5-Hemmer JNJ-64619178 bei fortgeschrittenen Krebserkrankungen

Wissenschaftl. Titel  A Phase 1, First-in-Human, Open-Label Study of the Safety, Pharmacokinetics, and Pharmacodynamics of JNJ-64619178, an Inhibitor of Protein Arginine Methyltransferase 5 (PRMT5) in Subjects With Advanced Cancers

Kurztitel  64619178EDI1001

Studiennummer KN/ELN  LN_NN_2020_705

Studiengruppe  NN

Studienart  multizentrisch, einarmig, prospektiv, offen

Studienphase  Phase I

Erkrankung  Myelodysplastisches Syndrom (MDS) - Alle Subtypen

Leukämiestadium .

Einschlusskriterien  - B cell non-Hodgkin lymphoma (NHL) or solid tumors, or lower risk MDS - At least 1 measurable site of disease for B cell-NHL and solid tumors - Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 - Adequate organ function - Women of childbearing potential must have a negative highly sensitive serum (beta-human chorionic gonadotropin [beta-hCG]) at screening and prior to the first dose of study drug. Women must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the study and for a period of 90 days after receiving the last dose of study drug

Ausschlusskriterien  - History of, or known, central nervous system (CNS) involvement - Prior solid organ transplantation - Either of the following: a) Received an autologous stem cell transplant less than or equal (<=) 9 months before the first dose of study drug B) Prior treatment with allogenic stem cell transplant - History of malignancy (other than the disease under study) within 3 years before the first administration of study drug. Exceptions include squamous and basal cell carcinomas of the skin and carcinoma in situ of the cervix, or malignancy that in the opinion of the investigator, with concurrence with the sponsor's medical monitor, is considered cured with minimal risk of recurrence within 3 years - Known allergies, hypersensitivity, or intolerance to JNJ-64619178 or its excipient

Alter  >= 18 Jahre

Status  Aktiv

Beginn der Rekrutierung  08.10.2020

Sponsoren  Janssen

Registrierung in anderen Studienregistern  ClinicalTrials.govNCT03573310 (primäres Register)

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