KURZPROTOKOLL
MO40597_GAZELLE

Öffentlicher Titel	Obinutuzumab bei fortgeschrittenem, nicht vorbehandeltem follikulären Lymphom
Wissenschaftl. Titel	A Multicentric, Open-Label, Single Arm Study of Obinutuzumab Short Duration Infusion (SDI) in Patients With Previously Untreated Advanced Follicular Lymphoma
Kurztitel	MO40597_GAZELLE
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase IV
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - neu diagnostiziert / de novo

Einschlusskriterien

- Patients with previously untreated Stage III or IV FL or Stage II bulky disease scheduled to receive obinutuzumab plus chemotherapy due to at least one of the following criteria:
- 1. Bulky disease, defined as a nodal or extranodal (except spleen) mass >= 7 cm in the greatest diameter
- 2. Local symptoms or compromise of normal organ function due to progressive nodal disease or extranodal tumor mass
- 3. Presence of B symptoms (fever [> 38ºC], drenching night sweats, or unintentional weight loss of > 10% of normal body weight over a period of 6 months or less)
- 4. Presence of symptomatic extranodal disease (e.g., pleural effusions, peritoneal ascites)
- 5. Cytopenias due to underlying lymphoma (i.e., absolute neutrophil count < 1.0 x 109/L, hemoglobin < 10 g/dL, and/or platelet count < 100 x 109/L)
- 6. Involvement of >= 3 nodal sites, each with a diameter of >= 3 cm g.) Symptomatic splenic enlargement
- Histologically documented CD-20-positive FL, as determined by the local laboratory
- Eastern Cooperative Oncology Group (ECOG) performance status 02
- Adequate hematologic function (unless abnormalities are related to FL)
- Life expectancy of >= 12 months
- For women who are not postmenopausal (>= 12 consecutive months of non-therapy-induced amenorrhea) or surgically sterile (absence of ovaries and/or uterus): agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 18 months after the last dose of obinutuzumab, for at least 3 months after the last dose of bendamustine or according to institutional guidelines for CHOP or CVP chemotherapy, whichever is longer
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm

Ausschlusskriterien

- Relapsed / refractory FL
- Prior treatment for FL with chemotherapy, radiotherapy, or immunotherapy
- Grade IIIb FL
- Histological evidence of transformation of FL into high-grade B-cell NHL
- Treatment with systemic immunosuppressive medications, including, but not limited to, prednisone/prednisolone/methylprednisolone, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents within 2 weeks prior to Day 1 of Cycle 1
- History of solid organ transplantation
- History of anti-CD20 antibody therapy
- History of severe allergic or anaphylactic reaction to humanized, chimeric, or murine monoclonal antibodies

- Known sensitivity or allergy to murine products
- Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells or any of the study drugs
- Active bacterial, viral, fungal, or other infection or any major episode of infection requiring treatment with IV antibiotics within 4 weeks of Day 1 of Cycle 1
- Positive test results for chronic HBV infection (defined as positive HBsAg serology)
- Positive test results for hepatitis C (hepatitis C virus [HCV] antibody serology testing)
- Known history of HIV positive status
- History of progressive multifocal leukoencephalopathy (PML)
- Vaccination with a live virus vaccine within 28 days prior to Day 1 of Cycle 1 or anticipation that such a live, attenuated vaccine will be required during the study
- History of prior other malignancy with the exception of: a. Curatively treated carcinoma in situ of the cervix, good-prognosis ductal carcinoma in situ of the breast, basal- or squamous-cell skin cancer, Stage I melanoma, or low-grade, early-stage localized prostate cancer b. Any previously treated malignancy that has been in remission without treatment for >= 2 years prior to enrollment
- Evidence of any significant, uncontrolled concomitant disease that could affect compliance with the protocol or interpretation of results, including significant cardiovascular disease (such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the previous 6 months, unstable arrhythmia, or unstable angina) or significant pulmonary disease (such as obstructive pulmonary disease or history of bronchospasm)
- Major surgical procedure other than for diagnosis within 28 days prior to Day 1 of Cycle 1, Day 1, or anticipation of a major surgical procedure during the course of the study
- Any of the following abnormal laboratory values:
- 1. Creatinine > 1.5 x the upper limit of normal (ULN) (unless creatinine clearance normal) or creatinine clearance < 40 mL/min
- 2. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) > 2.5 x ULN
- 3. Total bilirubin >= 1.5 x the ULN: Patients with documented Gilbert disease may be enrolled if total bilirubin is <= 3.0 x the ULN.
- 4. International normalized ratio (INR) > 1.5 in the absence of therapeutic anticoagulation
- 5. Partial thromboplastin time or activated partial thromboplastin time > 1.5 x ULN in the absence of a lupus anticoagulant
- For patients who will be receiving CHOP: left ventricular ejection fraction (LVEF) < 50% by multigated acquisition (MUGA) scan or echocardiogram
- Pregnant or lactating, or intending to become pregnant during the study
- Any investigational therapy within 28 days prior to the start of Cycle 1

Alter

18 Jahre und älter

Prüfzentren

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Sponsor

Roche Pharma AG

Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03817853 EudraCT 2018-003255-38
Links	Studiendokumente zum Download (roXtra)