KURZPROTOKOLL
Mifamurtide C23003

Öffentlicher Titel	Phase IV Studie zur Behandlung von neu diagnostiziertem Osteosarkom mit Mifamurtid
Wissenschaftl. Titel	Observational, noninterventional surveillance study of patients with newly diagnosed Osteosarcoma
Kurztitel	Mifamurtide C23003
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase IV
Erkrankung	Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): Osteosarkom
Ziele	- The short-term safety profile of mifamurtide during treatment (mifamurtide in combination with chemotherapy), typically lasting 36 weeks. - The short-term safety profile will include assessments of: a) Adverse events of special interest (AESIs), including important identified and potential risks; b) The frequency and pattern of mifamurtide-related infusion AEs (including cytokine-related AEs), which typically occur within 24 hours of drug administration - The long-term safety profile of mifamurtide during and following treatment (mifamurtide in combination with chemotherapy), lasting up to 5 years from the last dose of mifamurtide or until death. The long-term safety profile will include assessment of AESIs, consisting of important identified and potential risks. - Disease status; Disease-free survival; Overall survival
Einschlusskriterien	- Male or female aged 2 to 40 years - Confirmed pathological diagnosis of newly-diagnosed, nonmetastatic, resectable, primary, high-grade osteosarcoma - Metastatic disease is defined as a lung lesion > 10 mm or 3 lesions > 0.5 mm on computerized tomography (CT) scan, or any bone lesion Bone metastases are defined as any lesion identified by bone scan and confirmed by alternative imaging (magnetic resonance imaging/CT-positron emission tomography [MRI/CT-PET]) - Other metastatic lesions confirmed by cross-sectional imaging - Have completed definitive surgery (or other local ablation technique) - Have a treatment regimen that includes mifamurtide and a minimum of 2 recognized chemotherapy agents in the treatment of osteosarcoma (cisplatin, doxorubicin, high-dose methotrexate, or ifosfamide) - Female patients must be postmenopausal for at least 1 year before the screening visit or surgically sterile, or if of childbearing potential, have a negative pregnancy test at the time of commencing therapy and agree to practice an effective method of contraception from the time of signing the informed consent through 1 week after the last dose of study drug, or agree to completely abstain from heterosexual intercourse - Male patients, even if surgically sterilized (ie, status postvasectomy), must agree to practice effective barrier contraception during the entire study treatment period and through 1 week after the last dose of study drug, or agree to completely abstain from heterosexual intercourse - Organ function deemed satisfactory to receive planned chemotherapy containing at minimum 2 of the recognized chemotherapy agents in the treatment of osteosarcoma (cisplatin, doxorubicin, high-dose methotrexate, or ifosfamide
Ausschlusskriterien	- Have low-grade osteosarcoma, or parosteal or periosteal sarcoma - Have osteosarcoma associated with Paget’s disease - Current treatment with any anticancer investigational products at the time of enrollment in this surveillance study - If the patient received mifamurtide in a previous trial, or the patient’s disease progressed
Alter	2 - 40 Jahre

Sponsor	Millenium Pharmaceuticals
Förderer	Millenium Pharmaceuticals
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01194284 EudraCT 2009-017204-89
Therapie	Mifamurtide (MEPACT®).