

KURZPROTOKOLL
Mifamurtide C23003

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| 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 | <ul style="list-style-type: none">- 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 | <ul style="list-style-type: none">- 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 | <ul style="list-style-type: none">- 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 |

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