NOW ENROLLING

SOURCE

Sarcoma Study of MORAb-004 Utilization:
Research and Clinical Evaluation

A Study of the Safety and Efficacy of the Combination of Gemcitabine and Docetaxel with MORAb-004 in Metastatic Soft Tissue Sarcoma

Trial Objective
To evaluate the progression-free survival (PFS) of subjects treated with the combination of gemcitabine and docetaxel plus MORAb-004 versus gemcitabine and docetaxel plus placebo in subjects with metastatic soft tissue sarcoma (mSTS) in 4 defined subgroups:

- Liposarcoma
- Leiomyosarcoma
- Undifferentiated pleomorphic sarcoma and myxofibrosarcoma
- Other STS*

Trial Design
Discrete and sequential 2-part, Phase II, multicenter, efficacy/safety study (N=200)

- Part 1: open-label, dose-escalation, safety lead-in study
- Part 2: randomized, double-blind, placebo-controlled study

Primary Endpoint
- PFS determined by RECIST 1.1

Secondary Endpoints
- Overall survival
- Overall response rate based on RECIST 1.1
- PFS rate at 12, 24, and 48 weeks
- Safety, tolerability, and PK/PD profile of MORAb-004
- Correlate patterns of biomarker expression (TEM-1 and members of TEM-1 pathway) in tumor samples with clinical endpoints

*Subjects with a histologic diagnosis of high-grade sarcoma not otherwise specified, angiosarcoma, synovial sarcoma, rhabdomyosarcoma, hemangiopericytoma/solitary fibrous tumor, or other liposarcoma.

RECIST=Response Evaluation Criteria in Solid Tumors.

For SOURCE eligibility criteria, as well as information about other Eisai/Morphotek clinical trials, please visit www.clinicaltrials.gov/NCT01574716.

This agent is investigational and the information presented here is not meant to convey conclusions of safety or effectiveness prior to regulatory approval. There is no guarantee that this agent will be available commercially.


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