Halaven®
eribulin

Moments Matter

Proven efficacy in
Extending Overall Survival
in pre-treated metastatic breast cancer & liposarcoma patients[1#,2*]

Pivot et al was a pooled analysis of two Phase 3 clinical trials (Studies 301 and 305). While Study 305 compared eribulin with treatment of physician's choice, Study 301 compared eribulin with capecitabine, in women with locally advanced or metastatic breast cancer who had received at least one prior chemotherapy regimen for advanced disease. Overall survival was significantly improved in the eribulin versus control arm [median OS 15.0 months versus 12.6 months, HR 0.85 (95% CI 0.76-0.94); P <0.01].

* Schoffski et al was a Phase 3 study evaluating the efficacy of eribulin versus dacarbazine in previously treated patients with unresectable, advanced or metastatic soft tissue sarcoma of one of two subtypes - leiomyosarcoma or liposarcoma. Overall survival was significantly improved in the eribulin versus dacarbazine arm [median OS 13.5 months versus 11.5 months, HR 0.77 (95% CI 0.62-0.95); Liposarcoma subgroup: median OS 15.6 months versus 8.4 months, HR 0.51 (95% CI 0.35-0.75)].

Abbreviations: CI, confidence interval; HR, hazard ratio; OS, overall survival

References: 1. Pivot X, et al. Annals of Oncology. 2016;27:1525-1531. **2.** Schoffski P, et al. Lancet. 2016;387(10028):1629-37.

Halaven® Abbreviated Prescribing Information
HALAVEN® (Eribulin) 0.44mg/ml solution for injection
Composition: Each 2ml vial contains eribulin mesylate equivalent to 0.88mg eribulin. Indication: HALAVEN is indicated for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. HALAVEN is indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease. Dosage and administration: The recommended dose of eribulin as the ready to use solution is 1.23mg/m^2 which should be administered intravenously over 2 to 5 minutes on Days 1 and 8 of every 21-day cycle. The dose may be diluted in up to 100 ml of sodium chloride 9 mg/ml (0.9%) solution for injection. It should not be diluted in glucose 5% infusion solution. Please note: In the EU the recommended dose refers to the base of the active substance (eribulin). Calculation of the individual dose to be administered to a patient must be based on the strength of the ready to use solution that contains 0.44 mg/ml eribulin and the dose recommendation of 1.23 mg/m^2. In the pivotal trials, the corresponding publication and in some other regions e.g. the United States and Switzerland, the recommended dose is based on the salt form (eribulin mesilate). Contraindications: Hypersensitivity to the active substance or to any of the excipients and breast-feeding. Warnings and precautions: Myelosuppression is dose dependent and primarily manifested as neutropenia. Monitoring of complete blood counts should be performed on all patients prior to each dose of eribulin. Treatment with eribulin should only be initiated in patients with ANC values ≥1.5 x 10^9/l and platelets > 100 x 10^9/l. Febrile neutropenia occurred in < 5% of patients treated with eribulin. Patients experiencing febrile neutropenia, severe neutropenia or thrombocytopenia, should be treated according to the recommendations in section 4.2 in full prescribing information. Severe neutropenia may be managed by the use of granulocyte colony-stimulating factor (G-CSF) or equivalent at the physician's discretion in accordance with relevant guidelines. Patients should be closely monitored for signs of peripheral motor and sensory neuropathy. The development of severe peripheral neurotoxicity requires a delay or reduction of dose. ECG monitoring is recommended if therapy is initiated in patients with congestive heart failure, bradyarrhythmias or concomittant treatment with medicinal products known to prolong the QT interval, including Class Ia and III antiarrhythmics, and electrolyte abnormalities. Hypokalemia, hypocalcaemia or hypomagnesemia should be corrected prior to initiating HALAVEN and these electrolytes should be monitored periodically during therapy. Eribulin should be avoided in patients with congenital long QT syndrome. Adverse events > 20%: neutropenia, leucopenia, anaemia, decreased appetite, peripheral neuropathy, nausea, constipation, fatigue/ asthenia, pyrexia, alopecia, arthralgia and myalgia. Storage: To be stored under 25°C. Further information is available upon request. Please refer to full prescribing information for details.

HK-LC-11-005 MAY 2024 4iC_3105

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