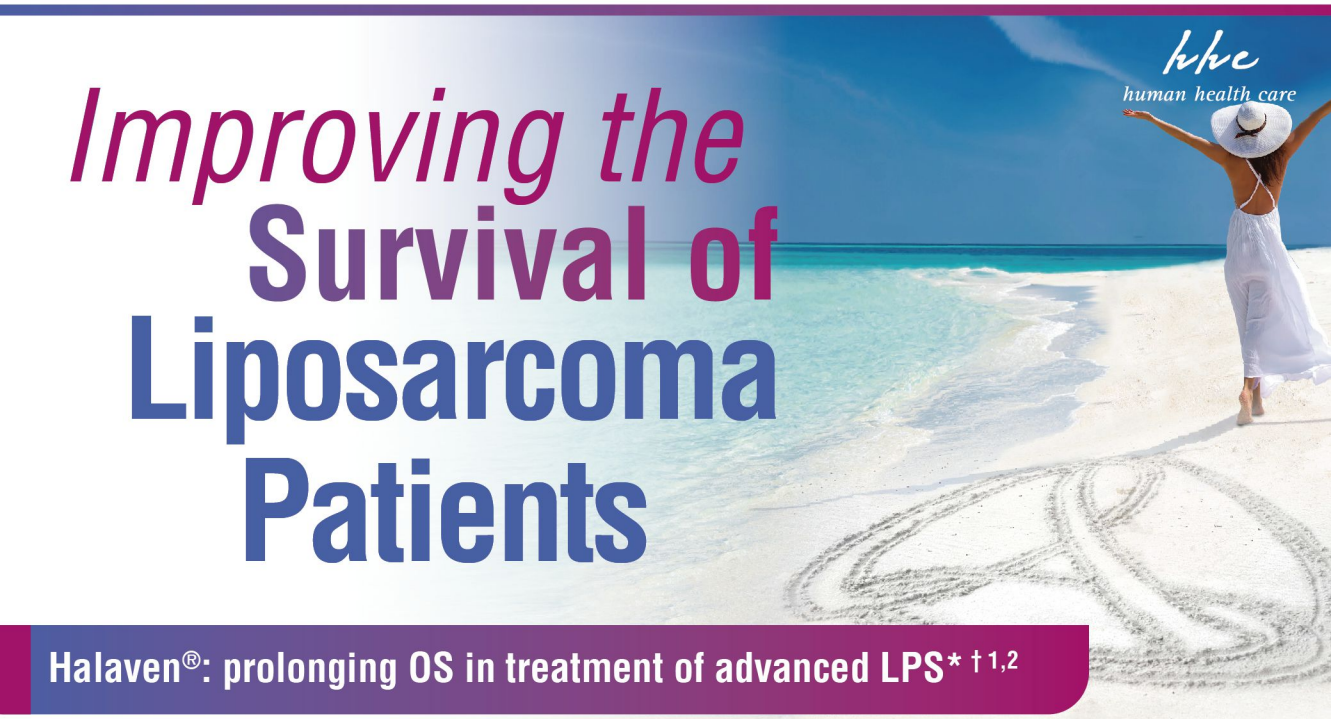
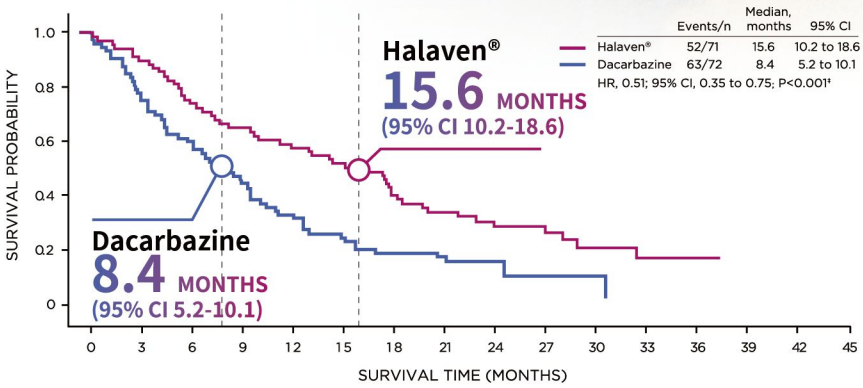
Eisai

Halaven® eribulin



Improving the Survival of Liposarcoma Patients

Halaven®: prolonging OS in treatment of advanced LPS*†[1,2]



49%

RISK OF DEATH REDUCTION

Significant OS benefit with Halaven® vs dacarbazine in the more aggressive/ highly metastasizing subtypes that show low response to typical chemotherapies*†[1-3]

Dedifferentiated LPS

18.0 months vs 8.1 months

HR=0.43 (95% CI 0.23-0.79)

9.9 months longer OS

Pleomorphic LPS

22.2 months vs 6.7 months

HR=0.18 (95% CI 0.04-0.85)

15.5 months longer OS

†Halaven® was evaluated in Study 309, a randomised, multicentre, phase 3 trial in advanced L-type sarcomas. Total patients in the study were 452, including 153 LPS patients. Eligible patients must have had ≥2 prior systemic regimens for advanced disease, including an anthracycline (unless contraindicated).

*The significant OS results were quoted from the subgroup analysis of the Phase 3 Study 309 trial.

‡Prespecified analysis in the ITT population, P value from 2-sided stratified log-rank test.

CI, confidence interval; HR, hazard ratio; LPS, liposarcoma; OS, overall survival

Make a better treatment with Halaven® to maintain QoL in Liposarcoma patients[4]

Halaven® manageable toxicity profile[1]

Halaven-treated patients: Neutropenia and leukopenia were more common;
Dacarbazine-treated patients: Anaemia and thrombocytopenia were more common.

Statistically significant differences in QoL were observed between dacarbazine and Halaven® patients [4]

Higher global health status‡

Better physical function‡

Fast and convenient administration[5]

2-5 minutes infusion on Day 1 and 8 (21-day cycle)

QoL, quality of life
‡relative to dacarbazine

References:
1. Schöffski P, et al. Lancet. 2016;387:1629-1637. **2.** Demetri GD, et al. J Clin Oncol. 2017; 35:3433-3439. **3.** Anju MS, et al. J Mol Histol. 2024 May 2. doi:10.1007/s10735-024-10195-4.Epub ahead of print. PMID: 38696048.**4.** Hudgens S, et al. Sarcoma. 2017; 2017:2372135. **5.** Halaven HKPI

HALAVEN® Abbreviated Prescribing Information
HALAVEN® (Eribulin) 0.44mg/ml solution for injection
Composition: Each 2ml vial contains eribulin mesilate 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 recommended dose of eribulin in patients with mild hepatic impairment (Child-Pugh A) is 0.97 mg/m^2 administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle. The recommended dose of eribulin in patients with moderate hepatic impairment (Child-Pugh B) is 0.62 mg/m^2 administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle. Severe hepatic impairment (Child-Pugh C) has not been studied but it is expected that a more marked dose reduction is needed if eribulin is used in these patients. Some patients with moderately or severely impaired renal function (creatinine clearance < 50 ml/min) may have increased eribulin exposure and may need a reduction of the dose. For all patients with renal impairment, caution and close safety monitoring is advised. Patients may experience nausea or vomiting. Antiemetic prophylaxis including corticosteroids should be considered. HALAVEN is for intravenous use. 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. The dose reduction recommendations shown below are also shown as the dose of eribulin to be administered based on the strength of the ready to use solution. 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 $\geqslant$ 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 (DOSAGE AND ADMINISTRATION). 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 concomitant treatment with medicinal products known to prolong the QT interval, including Class Ia and III antiarrhythmics, and electrolyte abnormalities. Hypokalemia 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:** neutropenia, leucopenia, anaemia, thrombocytopenia with associated infections, peripheral neuropathy, anorexia, nausea, vomiting, diarrhoea, constipation, stomatitis, fatigue, alopecia, increased liver enzymes, sepsis and musculoskeletal pain syndrome. **Storage:** To be stored under 25°C. Further information is available upon request.

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Halaven® eribulin