LIPOSARCOMA

SHOULD YOU CONSIDER HALAVEN FOR YOUR ADVANCED LIPOSARCOMA PATIENTS?

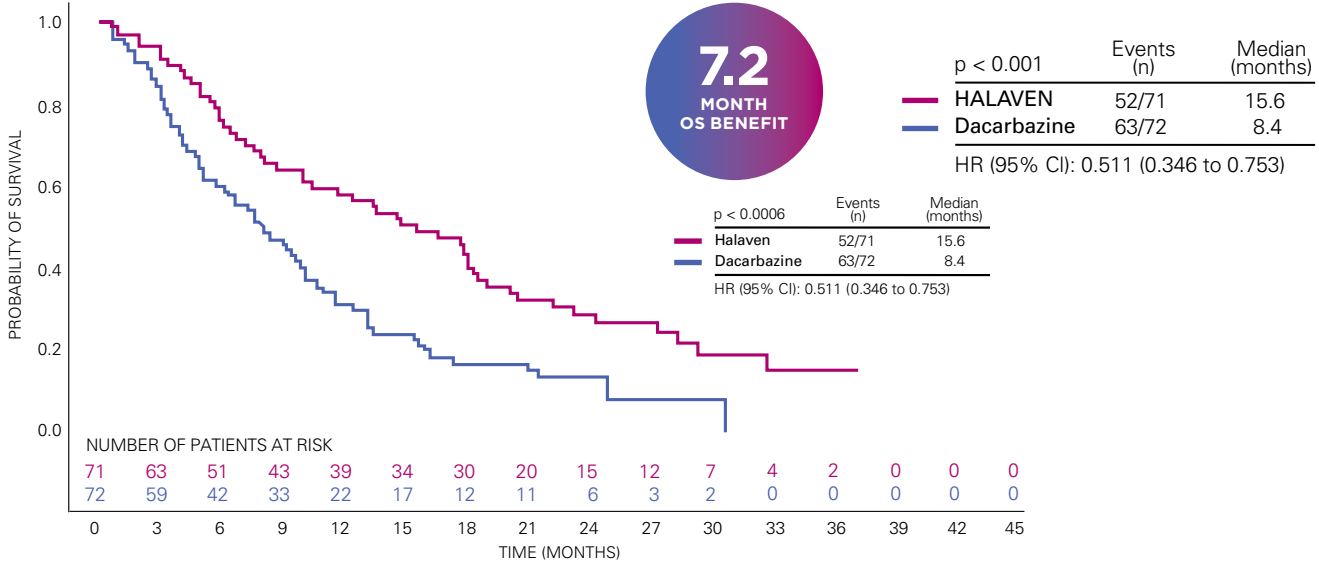
Halaven®
(eribulin mesilate) Injection

Eisai

HALAVEN: SIGNIFICANT OVERALL SURVIVAL BENEFIT VS DACARBAZINE*[1,2]

*Significantly higher overall survival vs dacarbazine in unresectable, advanced or metastatic liposarcoma previously treated with chemotherapy (15.6 months vs 8.4 months, p < 0.001)[1–3]

OVERALL SURVIVAL IN ADVANCED OR METASTATIC LIPOSARCOMA (PRE-SPECIFIED SUBGROUP ANALYSIS)

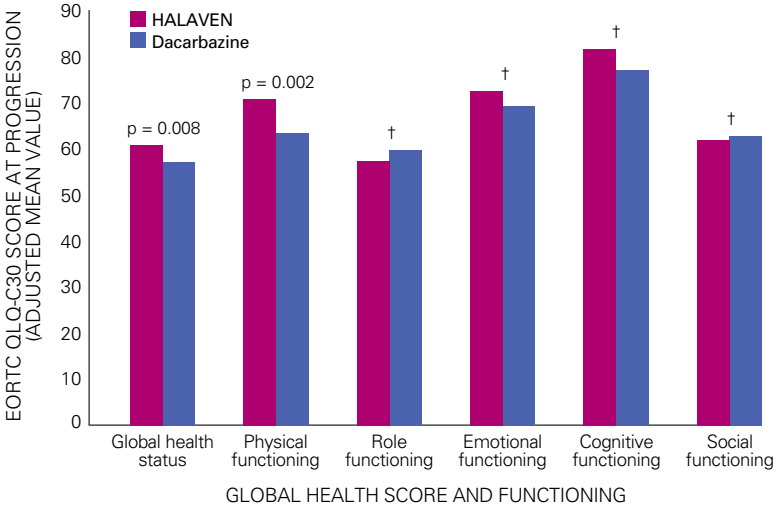


Adapted from Demetri *et al*. Data from a subgroup analysis of Study 309, a randomised, open-label, multicentre, multinational, phase 3 study in patients (n = 452) with advanced leiomyosarcoma or liposarcoma who had received ≥2 prior systemic regimens for advanced disease, including an anthracycline (unless contraindicated). Patients were randomised 1:1 to receive either HALAVEN 1.4 mg/m^2 on days 1 and 8 of a 21-day cycle or dacarbazine 850 mg/m^2, 1000 mg/m^2 or 1200 mg/m^2, every 21 days, until disease progression or unacceptable toxicity (starting dose selected by the local investigator at initiation). Primary endpoint of overall survival was met (HALAVEN 13.5 months vs dacarbazine 11.5 months; p = 0.0169). The pre-specified, independently stratified subgroup population that was analysed by Demetri *et al.* had to have histologically confirmed liposarcoma diagnoses.[1–3]

HALAVEN: SIGNIFICANT HEALTH-RELATED QoL IMPROVEMENT VS DACARBAZINE*[4]

*Significantly higher global health status and physical functioning scores at progression vs dacarbazine in the liposarcoma histology subgroup[4]

GLOBAL HEALTH SCORE AND FUNCTIONING DOMAINS AT PROGRESSION IN ADVANCED OR METASTATIC LIPOSARCOMA[4]



†Not significant

Adapted from Hudgens *et al.* Health-related QoL analysis (using patient-reported clinical outcomes via QLQ-C30 questionnaire) was a protocol-specified exploratory endpoint and stratified analysis of patients by histological subgroup was pre-specified.[4]

HALAVEN: A MANAGEABLE SAFETY PROFILE[1,3]

- In Study 309, HALAVEN had a manageable safety profile[1]
- The most common adverse events (>30%) with HALAVEN were asthenia/fatigue, neutropenia, nausea, alopecia, peripheral neuropathy and constipation[1]

Please review before prescribing, Product Information is available from www.eisai.com.au/PI

PBS Information: Authority Required (STREAMLINED). Locally advanced or metastatic breast cancer. Advanced (unresectable and/or metastatic) liposarcoma. Refer to PBS Schedule for full authority.

PBS Authority (STREAMLINED): 4649 for breast cancer; 7258 for liposarcoma (initial treatment); 7280 for liposarcoma (continuing treatment)

HALAVEN® (eribulin mesilate) 2ml vial containing 1mg eribulin mesilate. **Minimum Product Information. INDICATIONS:** Halaven is indicated for the treatment of 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 these are contraindicated. Halaven is indicated for the treatment of patients with unresectable liposarcoma who have received prior chemotherapy for advanced or metastatic disease. **CONTRAINDICATIONS:** Hypersensitivity to eribulin mesilate or any excipients; breast feeding. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Myelosuppression primarily presenting as neutropenia (monitoring of complete blood counts in all patients prior to each dose should be performed). Febrile neutropenia reported in <5% patients. Febrile neutropenia, severe neutropenia or thrombocytopenia requires dose delay or reduction. Patients with ALT or AST >3 x ULN or bilirubin >1.5 x ULN have a higher incidence of Grade 4 neutropenia and febrile neutropenia. Peripheral motor and sensory neuropathy was observed (closely monitor patients). Severe peripheral neurotoxicity requires dose delay or reduction; QT prolongation on Day 8 has been observed. ECG monitoring recommended in patients with congestive heart failure, bradyarrhythmias, if also receiving medicinal products known to prolong the QT interval, including Class Ia and III antiarrhythmics, and electrolyte abnormalities. Correct hypokalaemia or hypomagnesaemia prior to initiating and monitor during therapy. Avoid in patients with congenital long QT syndrome. Effects of eribulin mesilate on fertility, the developing foetus and in patients on anti-HER2 therapy are not well studied. Halaven should not be used in pregnant women (Category D) or during breastfeeding. **INTERACTIONS:** Concomitant use with substances which are inhibitors of hepatic transport proteins such as organic anion-transporting proteins and multidrug resistant proteins is not recommended. **ADVERSE EFFECTS:** Very common: neutropenia; leukopenia; anaemia; decreased appetite; peripheral neuropathy; headache; dyspnoea; cough; nausea; constipation; diarrhoea; vomiting; alopecia; arthralgia and myalgia; back pain; pain in extremity; fatigue/asthenia; pyrexia; weight decreased. Common: urinary tract infection; pneumonia; oral candidiasis; oral herpes; upper respiratory tract infection; nasopharyngitis; rhinitis; herpes zoster; febrile neutropenia; thrombocytopenia; lymphopenia; hypokalaemia; hypomagnesaemia; dehydration; hyperglycaemia; hypophosphatemia; hypocalcaemia; insomnia; depression; dysgeusia; dizziness; hypoaesthesia; lethargy; neurotoxicity; lacrimation increased; conjunctivitis; vertigo; tinnitus; tachycardia; hot flush; oropharyngeal pain; epistaxis; rhinorrhoea; abdominal pain; stomatitis; dry mouth; dyspepsia; gastrooesophageal reflux disease; abdominal distention; ALT, AST and GGT increased; hyperbilirubinaemia; rash; pruritus; nail disorder; night sweats; dry skin; erythema; hyperhidrosis; palmar plantar erythrodysaesthesia; bone pain; muscle spasms; musculoskeletal pain; musculoskeletal chest pain; muscular weakness; dysuria; mucosal inflammation; peripheral oedema; pain; chills; chest pain; influenza like illness. **DOSE AND METHOD OF ADMINISTRATION:** For use in units specialised in the administration of cytotoxic chemotherapy under the supervision of a qualified physician. Recommended dose in adults and elderly: 1.4 mg/m^2 eribulin mesilate as the ready to use solution administered intravenously over 2–5 minutes on Days 1 and 8 of a 21-day cycle. Patients may experience nausea or vomiting. Antiemetic prophylaxis including corticosteroids should be considered. Refer to full PI for dose delays and reductions due to toxicities. Renal impairment: Dose reduction is recommended in stage 3–5 chronic kidney disease (0.7 mg/m^2). Hepatic impairment due to metastases: Reduce dose for mild (1.1 mg/m^2) or moderate impairment (0.7 mg/m^2) – see full PI; severe impairment not studied. Hepatic impairment due to cirrhosis: not studied, close monitoring recommended. Paediatrics: no information. Date of most recent amendment: April 2020.

References: 1. Approved Product Information for Halaven. Eisai Australia Pty Ltd. Date of most recent amendment: April 2020. **2.** Demetri G *et al. J Clin Oncol* 2017; 35(30):3433–3439. **3.** Schöffski P *et al. Lancet* 2016;387:1629–1637. **4.** Hudgens S *et al. Sarcoma* 2017; 2017:2372135.

Wellmark 29390. Date of preparation: April 2021. AU-HAL-21-00015.

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