Uploaded to the VFC Website

2016

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Eisai's Halaven receives FDA approval for treatment of patients with metastatic liposarcoma

Published on January 29, 2016 at 12:03 PM

Eisai Inc. announced today that the U.S. Food and Drug Administration (FDA) approved Halaven® (eribulin mesylate) Injection (0.5 mg per mL) for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen. This marks the second indication for which Halaven has been approved by the FDA based on a statistically significant extension of survival.

"There is an unmet medical need for patients with soft tissue sarcoma whose disease no longer responds to treatment," said George Demetri, MD, Professor of Medicine at Harvard Medical School and Director of the Center for Sarcoma and Bone Oncology at Dana-Farber Cancer Institute. "Halaven has been shown to help patients with advanced liposarcoma live longer, a meaningful result for patients with this rare and hard-to-treat disease."

This approval was based on the results of the pivotal Phase 3 trial, Study 309, which demonstrated that previously treated liposarcoma patients who received Halaven (n=71) experienced a median overall survival (OS) of 15.6 months compared with 8.4 months for those who received dacarbazine (n=72) (HR 0.51; 95% CI: 0.35-0.75), making it the first single agent to demonstrate an OS benefit in this stage of the disease. Median progression-free survival (PFS), a secondary endpoint, was longer in patients with liposarcoma treated with Halaven than in those who received dacarbazine (2.9 months vs. 1.7 months; HR 0.52; 95% CI: 0.35-0.78).

"Although liposarcoma accounts for less than 1% of all malignant tumors, it is a challenging journey for patients, since diagnosis and treatment can be difficult," said Alison Olig, Executive Director at Sarcoma Alliance. "The approval of Halaven is important for these patients, as it represents a new treatment choice where limited options have existed."

The adverse events seen in Study 309 were consistent with the known profile of Halaven. Serious side effects from treatment with Halaven may include neutropenia, peripheral neuropathy, embryo-fetal toxicity and QT prolongation. The most common adverse reactions (incidence greater than or equal to 25%) in study patients with liposarcoma and leiomyosarcoma treated with Halaven were fatigue (62%), nausea (41%), alopecia (35%), constipation (32%), peripheral neuropathy (29%), abdominal pain (29%) and pyrexia (28%). The most common (≥5%) Grade 3-4 laboratory abnormalities reported in patients receiving Halaven were neutropenia (32% vs. 8.9% in the dacarbazine arm), hypokalemia (5.4% vs. 2.8%) and hypocalcemia (5% vs. 1.4%). The most common serious adverse reactions reported in patients receiving Halaven were neutropenia (4.9%) and pyrexia (4.5%). The most common adverse reactions resulting in discontinuation of Halaven were fatigue and thrombocytopenia (0.9% each). Additional Important Safety Information including use in specific populations is presented below.

Halaven was first approved in the United States on November 15, 2010, for patients with metastatic breast cancer who have received at least two chemotherapeutic regimens for the treatment of metastatic disease. Previous therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. Halaven is the first and only single agent to significantly extend overall survival in the third-line for patients with metastatic breast cancer.

"The initial approval of Halaven for metastatic breast cancer more than five years ago and today's approval for advanced liposarcoma underscore the ability of this treatment to provide an overall survival benefit in two difficult-to-treat cancers," said Kenichi Nomoto, Ph.D., President, Oncology Product Creation Unit, Eisai Product Creation Systems. "As a company focused on *human health care* (*hhc*), we are proud of our commitment to providing new treatment options to address the unmet medical needs of patients."

First in the halichondrin class, Halaven is a microtubule dynamics inhibitor with a distinct binding profile. Discovered and developed by Eisai, Halaven is a synthetic analog of halichondrin B, a natural product that was isolated from the marine sponge *Halichondria okadai*. Based on *in vitro* studies, Halaven exerts its effect via a tubulin-based antimitotic mechanism, ultimately leading to apoptotic cell death after prolonged and irreversible mitotic blockage. In addition, treatment of human breast cancer cells with Halaven caused changes in cell structure and gene expression as well as decreased migration and invasiveness *in vitro*. Halaven treatment in preclinical models of human breast cancer was also associated with increased vascular perfusion and permeability in the tumor cores,

resulting in reduced tumor hypoxia, and changes in the expression of genes in tumor specimens associated with a change in phenotype.

The FDA approved Halaven for the treatment of advanced liposarcoma following a priority review, which is designated for drugs the FDA believes, if approved, have the potential to provide a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious condition. Halaven was granted orphan drug designation for soft tissue sarcoma in the United States in May 2012.

Source:
Eisai Inc.