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Eisai and Merck Enter Collaboration to Explore Novel Combination Regimens of Anti-PD-1 Therapy with Multi-targeting RTK Inhibitor and Microtubule Dynamics Inhibitor in Multiple Types of Cancer

Combination clinical studies of lenvatinib, eribulin and pembrolizumab to be explored

Tokyo, Japan and Kenilworth, NJ – March 4, 2015 –



About LENVIMA™ (lenvatinib mesylate)

LENVIMA, discovered and developed by Eisai, is an oral molecular targeted agent that selectively inhibits



LENVIMA for RPLS until fully resolved. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of neurologic symptoms.

Hemorrhagic events occurred in 35% of LENVIMA-treated patients and in 18% of the placebo group. The incidence of Grade 3-5 hemorrhage was similar between arms at 2% and 3%, respectively. The most frequently reported hemorrhagic event was epistaxis (11% Grade 1 and 1% Grade 2). Discontinuation due to hemorrhagic events occurred in 1% of LENVIMA-treated patients. There was one case of fatal intracranial hemorrhage among 16 patients who received LENVIMA and had CNS metastases at baseline. Withhold LENVIMA for the development of Grade 3 hemorrhage until resolved to Grade 0 to 1. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of hemorrhage. Discontinue LENVIMA in patients who experience Grade 4 hemorrhage.

LENVIMA impairs exogenous thyroid suppression. Elevation of TSH level above 0.5 mU/L was observed post baseline in 57% of LENVIMA-treated patients. Monitor TSH levels monthly and adjust thyroid replacement medication as needed.

LENVIMA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LENVIMA and for at least 2 weeks following completion of therapy.

Advise women not to breastfeed during treatment with LENVIMA.

Adverse Reactions

The most common adverse reactions observed in LENVIMA-treated patients vs. placebo treated patients respectively were hypertension (73% vs 16%), fatigue (67% vs 35%), diarrhea (67% vs 17%), arthralgia/myalgia (62% vs 28%), decreased appetite (54% vs 18%), weight decreased (51% vs 15%), nausea (47% vs 25%), stomatitis (41% vs 8%), headache (38% vs 11%), vomiting (36% vs 15%), proteinuria (34% vs 3%), palmar-plantar erythrodysesthesia syndrome (32% vs 1%), abdominal pain (31% vs 11%), and dysphonia (31% vs 5%).

For more information about LENVIMA™, please see the [full product information](#) or visit



Peripheral neuropathy (5%) was the most common adverse reaction resulting in discontinuation.

Pregnancy Category D

HALAVEN is expected to cause fetal harm when administered to a pregnant woman and patients should be advised of these risks.

QT Prolongation

In an uncontrolled ECG study in 26 patients, QT prolongation was observed on Day 8, independent of eribulin concentration, with no prolongation on Day 1. ECG monitoring is recommended for patients with congestive heart failure; bradyarrhythmias; concomitant use of drugs that prolong QT interval, including Class Ia and III antiarrhythmics; and electrolyte abnormalities.

Correct hypokalemia or hypomagnesemia prior to initiating HALAVEN and monitor electrolytes periodically during therapy. Avoid in patients with congenital long QT syndrome.

Hepatic and Renal Impairment

For patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic and/or moderate or severe (CrCl 15-49 mL/min) renal impairment, a reduction in starting dose is recommended.

Most Common Adverse Reactions

Most common adverse reactions (≥ 25%) reported in patients receiving HALAVEN were neutropenia (82%), anemia (58%), asthenia/fatigue (54%), alopecia (45%), peripheral neuropathy (35%), nausea (35%), and constipation (25%).

The most common serious adverse reactions reported in patients receiving HALAVEN were febrile neutropenia (4%) and neutropenia (2%).

For more information about HALAVEN, please see the [full product information](#) or visit www.HALAVEN.com.



About Eisai in Oncology





approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2014 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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