

PRESS RELEASE

# Oncodesign has entered into a services agreement with Eisai to develop a new personalized medicine program in earlier line metastatic breast cancer treatment

- The program aims to identify useful patient stratification biomarkers for Eisai's eribulin mesylate using patient-derived xenograft models.
- Fully implemented, the biomarker development services could generate revenues up to 1.25M Euros for Oncodesign.

**Dijon (France), December 17, 2014** – ONCODESIGN (FR0011766229 - ALONC), a biotechnology company serving the pharmaceutical industry in the discovery of new therapeutic molecules to fight cancer and other serious illnesses with no known effective treatment, announced today the signing of an agreement with Eisai Inc. Oncodesign will conduct in vivo pharmacology studies and Eisai will provide gene expression profiling analysis using Oncodesign's patient-derived xenograft models (PDX) to investigate the potential of eribulin mesylate ("eribulin") in earlier line treatment of metastatic breast cancer.

Eribulin (marketed by Eisai in the United States as HALAVEN<sup>®</sup> Injection) is indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. Eribulin is a non-taxane, microtubule dynamics inhibitor developed by Eisai and approved in more than 50 countries to treat patients with metastatic breast cancer.

Biomarkers are designed to assist physicians in selecting effective therapies for their patients, based on the individual characteristics of each person. The use of clinically relevant breast PDX models generates results to quickly and accurately investigate potential predictive biomarkers and sensitive patient subgroups.

Oncodesign could receive revenues up to 1.25M Euros for their contribution towards the total eribulin biomarker development program, of which 0.9M Euros have already been received.

Philippe Genne, Chairman and CEO of Oncodesign, commented, "We are very excited to be partnering with a leading and innovative pharmaceutical company like Eisai. Preclinical research was recently conducted by Oncodesign in collaboration with Eisai using pharmaco-imaging to further investigate the mechanism of action for eribulin. The results of the upcoming PDX pharmacology studies and gene expression profiling could provide insights into patient responses to Eisai's eribulin."

# About ONCODESIGN: www.oncodesign.com

Founded 19 years ago by Dr. Philippe Genne, the Company's CEO and majority shareholder, ONCODESIGN is a biotechnology company that maximizes the pharmaceutical industry's chances of success in discovering new therapeutic molecules to fight cancer and other serious illnesses with no known efficient treatment. Backed by unique experience acquired through more than 500 clients, including the world's largest pharmaceutical companies, and relying on a comprehensive technological platform combining state-of-theart medicinal chemistry, advanced animal modeling and medical imaging, ONCODESIGN is able to predict and identify for every molecule, very upstream, its therapeutic use and its potential to become an efficient drug. Applied to kinase inhibitors, molecules that represent a market estimated at over 40 billion dollars in 2016 and accounting for almost 25% of the pharmaceutical industry's R&D investments, ONCODESIGN's technology has already enabled the targeting of 7 promising molecules with substantial therapeutic potential, in oncology and elsewhere, and the signing of partnerships, potentially worth €350 million in upfront payments should predefined milestones be reached, with pharmaceutical groups Sanofi, Ipsen and UCB. Based in Dijon, France, in the heart of the town's university and hospital hub, ONCODESIGN has 74 staff.

# Contacts

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# About HALAVEN<sup>®</sup> (eribulin mesylate) Injection:

#### **Important Safety Information**

# • Decreased White Blood Cells (Neutropenia)

- Doctors should do blood tests to monitor patients' blood cells before they receive each dose of HALAVEN, and should monitor them more often if they develop lower white blood cells.
- If patients develop severe neutropenia lasting longer than 7 days or neutropenia with a fever, their next dose of HALAVEN should be delayed and reduced. Severe neutropenia occurred in 57% of patients who received HALAVEN and lasted more than 1 week in 12% of patients.
- Neutropenia with a fever occurred in 5% of patients; 2 patients died from complications of neutropenia with a fever.
- Neutropenia with a fever can result in serious infections that could lead to hospitalization or death. Patients should call their healthcare providers immediately if they have any of the following symptoms: fever (temperature above 100.5 degrees F), chills, coughing, burning or pain when they urinate.

# • Nerve Disorders (Peripheral Neuropathy)

- HALAVEN can cause numbness, tingling, or burning in a patient's hands and feet (peripheral neuropathy). Patients should be monitored closely for signs of neuropathy. If they develop severe neuropathy, treatment with HALAVEN should be delayed until the neuropathy improves and the next dose of HALAVEN should be reduced.
- Severe peripheral neuropathy occurred in 8% of patients who received HALAVEN. Neuropathy lasting more than one year occurred in 5% of patients. 22% of patients developed a new or worsening neuropathy that had not recovered after an average of 269 days.
- Peripheral neuropathy was the most common side effect that caused patients to stop receiving HALAVEN.

- Pregnancy and Nursing
  - HALAVEN may harm a patient's unborn baby. Patients must avoid becoming pregnant while they are receiving HALAVEN. They should tell their healthcare providers right away if they become pregnant or think they are pregnant while they are receiving HALAVEN.
  - Patients and their healthcare providers should decide if they will receive HALAVEN or breastfeed. They should not do both.
- Heartbeat Changes
  - HALAVEN can cause changes in a patient's heartbeat (called QTc prolongation). This can cause irregular heartbeats that may lead to death.
  - Healthcare providers will decide if patients need heart monitoring (electrocardiogram or ECG), or blood tests during their treatment with HALAVEN to watch for this problem.
- Liver and Kidney Problems
  - In patients with mild or moderate liver problems, and/or moderate kidney problems, a lower starting dose of HALAVEN is recommended.
- Most Common Side Effects
  - The most common side effects reported in >25% of patients receiving HALAVEN were low white blood cells (82%), low red blood cells (58%), weakness/tiredness (54%), hair loss (45%), numbness, tingling or burning in your hands and feet (35%), nausea (35%), and constipation (25%).
  - The most common serious side effects reported in patients receiving HALAVEN were neutropenia with or without a fever (4% and 2%, respectively).

Please see the <u>HALAVEN full prescribing information</u>.

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