

**HIGHLY ANTICIPATED NEW TREATMENT OPTION NOW AVAILABLE FOR CANADIANS WITH
SELECT TYPE OF THYROID CANCER**

LENVIMA[™] (lenvatinib) Demonstrated an Unprecedented Improvement in Progression-Free Survival (PFS) and a Statistically Significant Overall Response Rate in Patients with Radioactive Iodine-refractory Differentiated Thyroid Cancer (RAI-R DTC)

MISSISSAUGA, ON, April 12, 2016 - Eisai Limited announced today that *LENVIMA*[™] (lenvatinib) ["*LENVIMA*"] is now available in Canada for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. *LENVIMA* is a tyrosine kinase inhibitor, which works by blocking certain proteins from helping cancer cells grow and divide.

"*LENVIMA* performed very favorably in comparison to placebo in a pivotal phase 3 study, where a 14.6 month improvement in PFS, the primary endpoint of the trial, was demonstrated. For this population of patients, for whom therapeutic options are very limited, this is a very important finding. We have an effective agent that provides a much needed treatment option for our patients," says Dr. Ruether, Medical Oncologist, Tom Baker Cancer Center Assistant Professor University of Calgary.

In the pivotal Phase 3 SELECT clinical trial, published in the *New England Journal of Medicine*, which included 392 patients, *LENVIMA* demonstrated a statistically significant improvement in PFS in patients with RAI-R DTC compared with placebo. The median PFS, or delay in the length of time during and after treatment in which the disease did not worsen, with *LENVIMA* and placebo was 18.3 months and 3.6 months, respectively (HR 0.21; 95% CI: 0.16-0.28; p<0.001). In addition, an overall response rate, the sum of partial and complete response rates, of 65% was seen in patients treated with *LENVIMA* versus 2% with placebo, which included a complete response achieved in 1.5% of patients treated with *LENVIMA* versus 0% with placebo. Based on RECIST v1.1 criteria, a partial response is defined as a minimum 30% decrease in the sum of diameters of target lesions and a complete response is defined as a complete disappearance of tumors. The most common *LENVIMA* treatment-related adverse events were hypertension (67.8%), diarrhea (59.4%), fatigue (59.0%), decreased appetite (50.2%), weight loss (46.4%) and nausea (41.0%).¹

Differentiated thyroid cancer (DTC) is the most common form of thyroid cancer and accounts for approximately 90 to 95 per cent of all thyroid cancers.² Although most differentiated thyroid cancers can be treated with surgery and radioactive iodine treatment, there are few treatment options available once the cancer has progressed; therefore it remains a disease with significant unmet medical need. RAI-R DTC refers to thyroid cancer that no longer responds to radioactive iodine (RAI) therapy.

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"The approval of a new therapy to treat those who have recurrent or metastatic disease is good news to Thyroid Cancer Canada," says Theresa Marie Underhill, President of Thyroid Cancer Canada and thyroid cancer survivor. "Currently, there are limited treatment options for those patients who have progressive, differentiated thyroid cancer whose disease has progressed despite being treated with radioactive iodine. Having a powerful new treatment in our arsenal, one that offers a significant, effective option is a big step in treating this disease."

"Eisai is committed to Oncology and meeting the unmet medical need of patients and their families. We are pleased to make LENVIMA available for appropriate patients in Canada," says Daniel Asch, General Manager, Eisai Limited. "Our human health care mission, a commitment to innovative solutions towards disease prevention, cure and care for the health and well-being of people, is at the forefront of everything we do."

About the LENVIMA™ (lenvatinib) Pivotal Clinical Trial

The SELECT (Study of E7080 Lenvatinib in Differentiated Cancer of the Thyroid) study was a multicenter, randomized, double-blind, placebo-controlled Phase 3 study to compare the PFS of patients with locally recurrent or metastatic RAI-R DTC and radiographic evidence of disease progression within 12 months prior to randomization, treated with LENVIMA (24 mg) once daily or placebo.

The full results of this study were presented at the 2014 ASCO Annual Meeting and published in February 2015 in the *New England Journal of Medicine*.

For more information on LENVIMA, including all warnings, precautions and adverse event information, please refer to the Product Monograph ("PM"):

English PM: <http://www.eisai.ca/pdf/new/Lenvima-EN-PM-22Dec2015.pdf>

French PM: <http://www.eisai.ca/pdf/new/Lenvima-FR-PM-22Dec2015.pdf>

Thyroid Cancer in Canada

Thyroid cancer is a rare disease with an estimated 6,300 Canadians being diagnosed in 2015,³ but the incidence is increasing more rapidly than any other cancer worldwide.⁴ In Canada, thyroid cancer is now the number one cancer incidence in young Canadians.⁵ Differentiated thyroid cancer (DTC) accounts for approximately 90% to 95% of thyroid cancers.⁶ The initial management of DTC is surgery, commonly followed by thyroxine therapy and radioactive iodine (RAI) treatment for higher risk cases. The disease reoccurs within 5 years in approximately 10% of DTC patients and one third of them will become RAI-refractory. RAI-R DTC is an aggressive disease with a median overall survival of 2.5 to 3.5 years.⁷

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About Eisai Limited

Eisai established the Canadian pharmaceutical company Eisai Limited in 2010. As a wholly-owned subsidiary of Eisai Inc., Eisai Limited is based in Mississauga, Ontario, one of the largest biopharmaceutical clusters in North America. For more information about Eisai in Canada, please visit www.eisai.ca.

About Eisai Inc.

At Eisai Inc., human health care is our goal. We give our first thoughts to patients and their families. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, manufacturing and marketing capabilities. To learn more about Eisai Inc., please visit us at www.eisai.com/US.

Eisai's global areas of R&D focus include neuroscience; oncology; metabolic disorders; vascular, inflammatory and immunological reactions; and antibody-based programs.

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² Thyroid Cancer Canada, accessed March 14, 2016 <http://www.thyroidcancercanada.org/thyroid-cancer-explained.php>

³ Canadian Cancer Society, accessed March 14, 2016 <http://www.cancer.ca/en/cancer-information/cancer-type/thyroid/statistics/?region=on>

⁴ Health Canada, Drugs and Health Products, Why Lenvima was approved, accessed March 14, 2016 <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd-smd-2016-lenvima-180877-eng.php>

⁵ Thyroid Cancer Canada, accessed March 14, 2016 <http://www.thyroidcancercanada.org/thyroid-cancer-explained.php>

⁶ Health Canada, Drugs and Health Products, Why Lenvima was approved, accessed March 14, 2016 <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd-smd-2016-lenvima-180877-eng.php>

⁷ Health Canada, Drugs and Health Products, Why Lenvima was approved, accessed March 14, 2016 <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd-smd-2016-lenvima-180877-eng.php>