



PRESS RELEASE

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LILLY FÅR EUROPEISKT MARKNADSGODKÄNNANDE FÖR RETSEVMO® (SELPERKATINIB), DEN FÖRSTA BEHANDLINGEN FÖR AVANCERAD LUNG- OCH SKÖLDKÖRTELCANCER MED FÖRÄNDRINGAR I RET-GENEN

- *Retsevmo är en oral behandling, framtagen för att hindra cancerceller att växa genom att angripa mekanismen hos särskilda RET-fusionpositiva, avancerade eller metastaserade cancertyper.^{1,2}*
- *LIBRETTO-001 Phase 1/2-studien, på vilken godkännandet baseras, visade att 64% av tidigare behandlade patienter med icke-småcellig lungcancer hade en genomsnittlig responsduration på 17,5 månad. 78,9% av tidigare behandlade RET-fusionpositiva patienter med sköldkörtelcancer hade en responsduration på 18,4 månader medan 69,1% av de tidigare behandlade patienterna med RET-muterad medullär sköldkörtelcancer hade en responsduration som ännu inte fastställts.^{3,4}*

STOCKHOLM, 22 februari, 2021 – Eli Lilly and Company tillkännagav idag att Europeiska kommissionen har godkänt Retsevmo® (selperkatinib) som monoterapi avsett för:

- behandling av vuxna med RET-fusionpositiv avancerad icke-småcellig lungcancer (NSCLC) som kräver systemterapi, efter tidigare immunterapi och/eller platinainnehållande kemoterapi.
- behandling av vuxna med RET-fusionpositiv avancerad sköldkörtelcancer som kräver systemterapi, efter tidigare behandling med sorafenib och/eller lenvatinib.
- behandling av vuxna och ungdomar från 12 år med RET-muterad avancerad medullär sköldkörtelcancer (MTC) som kräver systemterapi, efter tidigare behandling med kaboantinib och/eller vandetanib.

- PRESSMEDDELANDET FORTSÄTTER PÅ ENGELSKA -

Lung cancer is the second most common cancer in the world, with over 2.2 million people having received a diagnosis in 2020.⁵ Among lung cancer patients, NSCLC contributes to 80%-90% of all cases.^{6,7} RET fusion-positive tumours occur in 1-2% of NSCLCs and are more commonly found in people who are younger than 60 years.⁸

There were an estimated 586,202 new thyroid cancer cases across the globe in 2020, with cases being three times more common in women than in men.⁹ MTC is rare form of thyroid cancer and contributes to 1%-5% of all thyroid cancers, however, has poorer long-term outcomes compared to other types.^{10,11}

“Lilly is committed to delivering life-changing medicines to people living with cancer and we are delighted that the European Medicines Agency has granted authorisation of selpercatinib for people with advanced or metastatic RET-driven lung and thyroid cancers.” said Jyun-Yan Yang, M.D., Senior Medical Director, Northern Europe. “The development of targeted therapies can offer patients new treatment options with improved outcomes, potentially giving them more time with their loved ones.”

The discovery of oncogenic driver alterations in patients with lung cancer has led to significant advances in available treatments options. Targeted therapies have the potential to offer improved efficacy and better patient outcomes, while addressing unmet medical needs.^{12,13,14}

The treatment was granted authorisation based on the LIBRETTO-001 Phase 1/2 trial's endpoints of objective response rate (ORR) and duration of response (DoR). Selpercatinib was evaluated in the single-arm, multi-center Phase 1/2 LIBRETTO-001 trial, a trial of over 700 patients with RET-driven cancers. In the trial, 64% of previously treated patients responded to treatment had an objective response and 63% continued to respond after one year.

The most common serious adverse drug reactions (ADRs) are hypertension (0.9%), increased aspartate aminotransferase (AST) (1.6%) and increased alanine aminotransferase (ALT) (1.6%).¹ Permanent discontinuation of selpercatinib for treatment emergent adverse events, regardless of attribution occurred in 6.0% of patients. ADRs resulting in permanent discontinuation (2 or more

patients) included increased ALT (0.4%), increased AST (0.3%), hypersensitivity (0.4%), and thrombocytopenia (0.3%).

- ENDS -

To arrange an interview or for further information please contact:

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Notes to Editors

About Retsevmo™ (selpercatinib)

Selpercatinib is a targeted therapy, which means it was designed to target the specific driver of certain RET-driven advanced or metastatic cancers.

About RET-Driven Cancers

RET is a gene that everyone has but, for some people, changes in RET can drive cells to multiply abnormally, creating a potentially cancerous tumour.¹⁵

Biomarker testing will identify patients whose tumors have a RET fusion in NSCLC or thyroid cancer or a RET mutation in MTC. Next-generation sequencing (NGS), either with tumor tissue biopsy or liquid biopsy, can be an appropriate biomarker test to determine actionable genomic alterations, including RET, although other biomarker testing methods are available.

About LIBRETTO-001

The LIBRETTO-001 Phase 1/2 trial is the largest clinical trial of patients with RET-driven cancers treated with a RET inhibitor. The trial included a dose escalation phase (Phase 1) and a dose expansion phase (Phase 2). The Phase 2 portion of the trial had major efficacy outcomes of ORR and DoR, and prespecified secondary endpoints of CNS ORR and CNS DoR, as determined by an independent review committee according to Response Evaluation Criteria in Solid Tumors (RECIST v1.1). Results from the NSCLC population were last presented at the 2019 IASLC World Congress on Lung Cancer (WCLC), while results from the thyroid populations were last presented at the European Society for Medical Oncology (ESMO) 2019 Congress.

About Lilly Oncology

For more than 50 years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the

globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.se

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