



IASLC



INTERNATIONAL
ASSOCIATION
FOR THE STUDY
OF LUNG CANCER

Conquering Thoracic Cancers Worldwide

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Registrational Data from LIBRETTO-001 Trial Demonstrate Compelling and Durable Activity of Selpercatinib (LOXO-292) in *RET* Fusion-Positive Lung Cancer

Barcelona— Selpercatinib was granted [Breakthrough Therapy Designation](#) by the U.S. Food & Drug Administration in 2018 after initial data from the clinical trial LOXO-292 Investigated to Block *RET*-altered Tumors (LIBRETTO-001) showed the therapy demonstrated robust anti-tumor activity in a group of *RET* fusion-positive non small cell lung cancer patients, as well as strong evidence of durability.

Now, the same researchers, led by Alexander Drilon, M.D., of Memorial Sloan Kettering Cancer Center in New York City, report data on a primary analysis set of 105 NSCLC patients on selpercatinib. The researchers presented their updated data on LIBRETTO-001 today at the **IASLC 2019 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer**. The LIBRETTO-001 trial includes 87 sites in 16 countries.

Patients with *RET* fusion-positive non-small cell lung cancer comprise up to two percent of all NSCLC cases but there are no targeted therapies currently approved for patients with this form of lung cancer. Selpercatinib (LOXO-292) is an oral and highly selective investigational drug in clinical development for the treatment of patients with cancers that harbor abnormalities in the Rearranged During Transfection gene (*RET*). Genomic alterations involving *RET*, which include fusions and activating point mutations, lead to overactive *RET* signaling and uncontrolled cell growth.

Researchers presented data from the phase 1/2 LIBRETTO-001 trial, where they noted a high response rate in the primary analysis set of NSCLC patients previously treated with platinum-based chemotherapy, with 68 percent achieving responses and a median duration of response of 20.3 months. The intracranial objective response rate was 91 percent (n=10/11) for patients with target lesions in the brain at baseline.

In the safety data set of all 531 patients enrolled to the study, 5 treatment-related AEs occurred in ≥15 percent of patients: dry mouth, diarrhea, hypertension, increased AST and increased ALT. Most AEs were grade 1-2. Only 9 of 531 (1.7 percent) patients discontinued LOXO-292 for treatment-related AEs.

“In this large cohort, selpercatinib’s response rate, durability, robust intracranial activity and safety show promise. Furthermore, this continues to confirm that *RET* fusions are clinically targetable alterations, placing them in the company of activating *EGFR/ALK/ROS1* alterations. We are encouraged by this data

as there is currently an unmet need to provide genomically tailored therapy to patients with *RET* fusion-positive NSCLCs.” Drilon reported.

About the WCLC:

The WCLC is the world’s largest meeting dedicated to lung cancer and other thoracic malignancies, attracting more than 7,000 researchers, physicians and specialists from more than 100 countries. The goal is to increase awareness, collaboration and understanding of lung cancer, and to help participants implement the latest developments across the globe. The conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit wclc2019.iaslc.org.

About the IASLC:

The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated solely to the study of lung cancer and other thoracic malignancies. Founded in 1974, the association's membership includes more than 7,500 lung cancer specialists across all disciplines in over 100 countries, forming a global network working together to conquer lung and thoracic cancers worldwide. The association also publishes the *Journal of Thoracic Oncology*, the primary educational and informational publication for topics relevant to the prevention, detection, diagnosis and treatment of all thoracic malignancies. Visit www.iaslc.org for more information.

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