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New Breakthrough Treatment for Patients with ALK-Positive Lung Cancer

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LORVIQUA is the first biomarker-driven therapy approved by HSA to treat patients with anaplastic lymphoma kinase (ALK)-positive lung cancer, after treatment with second-generation ALK TKIs

Pfizer on 25th Nov 2019, announced that a new breakthrough therapy, LORVIQUA has been approved by Health Sciences Authority (HSA) for patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC), whose disease have progressed after treatment with second-generation ALK tyrosine kinase inhibitors (TKIs). Safety and efficacy of LORVIQUA demonstrated in multinational Phase 2 study involving National University Cancer Institute, Singapore (NCIS) and National Cancer Centre Singapore (NCCS).

The new oral therapy is specifically developed to target mutations which first- and second-generation TKIs have failed to treat, providing patients with an effective alternative to chemotherapy.

Filling an Unmet Need for ALK-Positive Lung Cancer Patients

Globally, NSCLC accounts for 80% to 85% of lung cancers, of which 3% to 5% of NSCLC tumours are ALK-positive1, resulting from a gene rearrangement that causes tumour growth. Patients with ALK-positive lung cancer are more likely to be female, diagnosed before the age of 50, have never smoked or a history of light smoking.

While there have been breakthroughs for the treatment of ALK-positive lung cancer, disease progression is inevitable and likely to spread to the brain. The five-year survival rates are low as most tumours acquire resistance to initial therapies, requiring patients to seek a second, and sometimes third, line of therapy within one to three years. In order to reach the tumour cells in the brain, LORVIQUA is developed as a brain-penetrant drug to provide patients with a highly targeted treatment option.

Singapore's Involvement in Global Clinical Trials

LORVIQUA's approval, which was granted under the United States Food and Drug Administration (FDA) Accelerated Approval programme in 2018 and subsequently by HSA, is based on the results of a multinational Phase 2 study of LORVIQUA in patients with ALK-positive NSCLC.

Almost 50% of the patients treated with LORVIQUA experienced at least a partial or complete shrinkage of their tumours. In addition, the patients showed significant improvement in physical, emotional and social well-being, including alleviated lung cancer symptoms.

The timely completion of the clinical study was achieved with Singapore sites contributing over 10% of the total study enrolment with the National University Cancer Institute, Singapore is one of the top enrolling sites worldwide.

Dr Ross Soo, Senior Consultant, Department of Haematology-Oncology, National University Cancer Institute, Singapore said, "In the past, patients in similar stages were treated the same way – a mix of surgery, chemotherapy and radiation. As our understanding of ALK-positive NSCLC evolved, so did the knowledge and use of personalised medicines. However, common challenges associated with treating ALK-positive lung cancer, including resistance and the spread of cancer to the brain, have created a need for newer treatment options."

"NCIS is constantly looking at novel anti-cancer therapies and ways to improve the quality of life of our patients. My patients who participated in the clinical trials have shown tumour shrinkage, and we are honoured to have contributed to the success of the study and to greater knowledge of new lung cancer treatment."

Dr Tanujaa Rajasekaran, Consultant, Division of Medical Oncology, National Cancer Centre Singapore said, "Controlling brain metastasis is especially challenging in ALK-positive lung cancer. This new therapy has shown excellent intracranial responses and it addresses an unmet need in this patient population."

Based on the evidence supporting LORVIQUA as an effective treatment option for ALK-positive NSCLC patients, LORVIQUA was granted priority review and approval by HSA.

Advances in Lung Cancer Treatment

Using a drug design process and computer-modelling software, Pfizer's scientists synthesised LORVIQUA's unique molecular structure based on the known structure of the lung cancer cells, enabling the third-generation ALK TKI drug to target the widest spectrum of secondary ALK resistant mutations arising from previous treatments.

With LORVIQUA, Pfizer now offers medicines to treat patients with three types of biomarker-driven lung cancers – ALK-rearrangements, EGFR-mutations and ROS1 fusions. Through the Phase 3 CROWN study, Pfizer will continue to invest in LORVIQUA's potential to benefit ALK-positive lung cancer patients. The ongoing study will compare LORVIQUA and crizotinib as first-line treatment for patients with ALK-positive lung cancer.

"Through our growing research pipeline and collaboration efforts, we are committed to pioneer new therapies to address unmet needs. LORVIQUA's approval in Singapore offers hope to patients who may not have other treatment options after second-generation ALK TKIs. We hope that more patients can benefit from this innovative therapy," said Enver Erkan, Country Manager, Pfizer Singapore.