

FDA accepts Roche's supplemental biologics license application for Tecentriq

23 January 2019 | News | By Sonali Wankhade

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Roche announced that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Tecentriq[®] (atezolizumab) in combination with Abraxane[®] [albumin-bound paclitaxel; nab-paclitaxel] and carboplatin for the initial (first-line) treatment of people with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR or ALK genomic tumour aberrations. The FDA is expected to make a decision on approval by 2 September 2019.

“We look forward to working with the FDA in order to bring this Tecentriq-based combination to people with non-squamous non-small cell lung cancer as soon as possible,” said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. “Lung cancer is a challenging disease to treat, and this review takes us one step closer towards offering a new treatment option that has shown a clinically meaningful survival benefit in the treatment of this type of disease.”

This sBLA is based on results from the Phase III IMpower130 study, which met its co-primary endpoints of overall survival (OS) and progression-free survival (PFS) in the initial treatment of people with metastatic non-squamous NSCLC.