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AstraZeneca receives European marketing authorisation for Imfinzi

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The approval is based on results from the Phase III PACIFIC trial.

AstraZeneca and MedImmune, its global biologics research and development arm, have announced that the European Commission has granted marketing authorisation for Imfinzi (durvalumab) as monotherapy for the treatment of locally-advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ?1% of tumour cells and whose disease has not progressed following platinum-based chemotherapy and radiation therapy (CRT). The approval is based on results from the Phase III PACIFIC trial.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business, said: “Patients in Europe diagnosed with locally-advanced, unresectable non-small cell lung cancer now have a new treatment option. Imfinzi is the only immunotherapy to be approved in this curative-intent setting, and we are proud to bring a new standard of care for this difficult disease.”

Dr. Luis Paz-Ares, co-principal investigator of the PACIFIC trial, from the Hospital Universitario Doce de Octubre, Madrid, Spain, said: “Lung cancer is the leading cause of cancer-related death in Europe and approximately a third of European patients with NSCLC present with locally-advanced disease. For decades, the standard of care for these patients has been chemotherapy and radiation therapy followed by active surveillance, after which the majority of patients progress to advanced disease. Imfinzi has demonstrated a compelling survival benefit for these patients in this area of significant unmet need.”