Tremelimumab granted Orphan Drug Designation

Tremelimumab granted Orphan Drug Designation by US FDA for treatment of malignant mesothelioma

AstraZeneca today announced that the US Food and Drug Administration has granted Orphan Drug Designation for the anti-CTLA-4 monoclonal antibody, tremelimumab, for the treatment of malignant mesothelioma.

Mesothelioma is a rare, aggressive cancer that most often affects the lining of the lungs and abdomen. Available treatments for mesothelioma are very limited, particularly for patients with advanced disease.

"There is a significant need for new treatment options for patients with mesothelioma because fewer than five percent of patients currently survive beyond five years, even when they receive timely diagnosis and care. Our aim is to rapidly advance the development of tremelimumab as a potential new treatment option for these patients," said Robert Iannone, Senior Vice President, Head of Immuno-oncology, Global Medicines Development at AstraZeneca.

The Orphan Drug Designation programme provides orphan status to drugs and biologics, which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US1.

Tremelimumab is part of the broad pipeline of immuno-oncology assets being developed by AstraZeneca and its biologics research and development arm, MedImmune, which are designed to harness the body's own immune system to fight cancer. It is a fully human monoclonal antibody, which stimulates the immune system to destroy cancer cells through binding to the protein CTLA-4, expressed on the surface of activated T-lymphocytes.

In addition to being investigated as a monotherapy treatment for patients with mesothelioma, tremelimumab is currently being studied in combination with AstraZeneca's anti PD-L1 investigational immunotherapy, MEDI4736, in tumour types including non-small cell lung cancer and head and neck cancer. It is also being studied in combination with Iressa (gefitinib) in EGFR mutated non-small cell lung cancer and with MEDI6469 (a murine OX40 agonist) in solid tumours.

1US Food and Drug Administration. Developing Products for Rare Diseases & Conditions http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm Accessed on 31 March 2015

About AstraZeneca in Oncology

Oncology is a therapeutic area in which AstraZeneca has deep-rooted heritage. It will be potentially transformational for the company's future, becoming the sixth growth platform. Our vision is to help patients by redefining the cancer treatment paradigm and one-day eliminate cancer as cause of death. By 2020, we are aiming to bring six new cancer medicines to patients.

Our broad pipeline of next-generation medicines is focused on four main disease areas - ovarian, lung, breast, and haematological cancers. These are being targeted through four key platforms - immuno-oncology, the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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