Selumetinib granted Orphan Drug Designation by FDA

SELUMETINIB granted Orphan Drug Designation by US FDA for treatment of UVEAL MELANOMA

AstraZeneca today announced that the US Food and Drug Administration has granted Orphan Drug Designation for the MEK inhibitor selumetinib, for the treatment of uveal melanoma.

Uveal melanoma is a rare disease in which cancer cells form in the tissues of the eye. It is the most common primary intraocular malignancy in adults and comprises 5% of all melanomas1,2.

"Uveal melanoma is a rare and devastating disease for which there are currently no effective treatment options once it spreads beyond the tissues of the eye. Selumetinib could potentially become the first effective treatment for these patients. The Orphan Drug Designation is an important regulatory advancement as we further our development plans for selumetinib in uveal melanoma," said Antoine Yver, Head of 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 US3.

Selumetinib, originally licensed from Array BioPharma Inc., inhibits the MEK pathway in cancer cells to prevent the tumour from growing. Data from a phase III study evaluating selumetinib in combination with chemotherapy in patients with first-line metastatic uveal melanoma is expected to be available later this year. In addition to uveal melanoma, selumetinib is being investigated in Phase III studies in KRAS mutation positive lung cancer and thyroid cancer and in Phase II in children with neurofibromatosis Type 1.

Initial data from a combination study of selumetinib with other AstraZeneca pipeline molecules including AZD9291 (T790M-directed EGFR inhibitor) and MEDI4736 (anti-PD-L1) in non-small cell lung cancer will be presented at the American Society of Clinical Oncology (ASCO) annual meeting 2015.

1Egan KM, et al. Surv Ophthalmol 1988; 32: 239-51

2.Ramaiya KJ, Harbour JW. Expert Rev Ophthalmol 2007; 2: 939-46

3US 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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