Savolitinib (AZD6094) preliminary Phase Ib clinical data in lung cancer presented at the 2015 ASCO Annual Meeting


AZD9291 is AstraZeneca’s investigational inhibitor of the epidermal growth factor receptor (EGFR). Preliminary data on the activity of AZD9291 in patients with EGFR mutation positive NSCLC who had failed currently-approved EGFR tyrosine kinase inhibitors was presented at the American Society of Clinical Oncology (ASCO) meeting in June 2014. In mid-2014 AstraZeneca commenced the TATTON study, a multi-arm Phase Ib study of AZD9291 in combination with either savolitinib (AZD6094) (c-MET inhibitor), MEDI4736 (anti-PD-L1 mAb) or selumetinib (MEK1/2 inhibitor) in EGFR mutation positive NSCLC. For those patients who received AZD9291 and savolitinib, the primary objective of the TATTON study was to establish a safe and effective combination dose. All patients were screened for their T790M status (+/-) as well as some, if sufficient tissue samples were available, for their c-Met (+/-) status.

The following poster was presented at the American Society of Clinical Oncology annual meeting in Chicago on 30 May 2015.

Title: Preliminary results of TATTON, a multi-arm phase Ib trial of AZD9291 combined with MEDI4736, AZD6094 or selumetinib in EGFR-mutant lung cancer.

Authors: Oxnard G.R., et al.

Abstract: #2509 – available at abstracts.asco.org/156/AbstView_156_148945.html

Session: Developmental Therapeutics – Clinical Pharmacology and Experimental Therapeutics

Date & Time: Saturday 30 May 8:00 AM–11:30 AM

A total of 12 patients were dosed with either 600mg or 800mg daily doses of savolitinib (AZD6094) in combination with 80mg (once daily) AZD9291. In terms of the primary aims of the study, the 600mg combination dose was well tolerated with toxicity profiles that allow for combination at doses previously demonstrated to be biologically active. Of the 11 evaluable patients in the study, 6 partial responses (confirmed and unconfirmed) have been observed to date. Responses to date include 4 of 7 patients with confirmed T790M negative status.

The presentation will be made available at http://chi-med.com/eng/irinfo/presentations.htm.

Christian Hogg, Chief Executive Officer of Chi-Med said: “Savolitinib is a highly selective c-Met inhibitor designed to eliminate the toxicities experienced by the first wave of c-Met inhibitors in their early development. We are now very pleased to see encouraging early efficacy data emerge in non-small cell lung cancer to add to the efficacy already reported in papillary renal cell carcinoma and colorectal cancer.”

Ends
Notes to Editors

About the c-Met Signal pathway and savolitinib (AZD6094)

The c-Met (also known as HGFR) signalling pathway has specific roles particularly in normal mammalian growth and development. However, this pathway has been shown to function abnormally in a range of different cancers.

Savolitinib is a potent ATP-competitive c-Met inhibitor with high selectivity over a 274 kinase panel. Pre-clinical studies of savolitinib have demonstrated tumour growth inhibitory activity in a series of human tumour xenografts, especially for those tumours with c-Met gene amplification or c-Met over-expression. Phase I dose escalation studies were initiated in Australia and China in 2012 and 2013 respectively. Savolitinib has demonstrated good safety, tolerability and favourable pharmacokinetic properties in late stage cancer patients, and has shown encouraging anti-tumour activity in several tumour-types. Detailed results of the Phase I clinical trial were presented at the annual meeting of the American Society of Clinical Oncology in May 2014, and can also be found at http://chi-med.com/eng/irinfo/presentations.htm.

In December 2011, HMP entered into a global licensing, co-development and commercialisation agreement with AstraZeneca in relation to savolitinib and is currently conducting eight proof-of-concept clinical studies in the US, Europe, and Asia in kidney (papillary renal cell carcinoma), lung, and gastric cancer patients with aberrant c-Met.

About AZD9291

AZD9291 is an investigational, highly selective, irreversible inhibitor of both activating sensitising epidermal growth factor receptor mutation positive (“EGFRm”) and the resistance mutation, T790M, while sparing the activity of wild type EGFR. Latest data from the ongoing AURA phase I/II study of AZD9291 as a mono-therapy to treat NSCLC patients can be found at www.astrazeneca.com. AZD9291 has been granted Breakthrough Therapy designation by the US FDA in 2014 for the treatment of patients with metastatic, EGFR T790M mutation-positive NSCLC who have progressed during treatment with an FDA-approved, EGFR tyrosine kinase inhibitor.

About HMP

HMP is a novel drug R&D company focusing on discovering, developing and commercialising innovative therapeutics in oncology and autoimmune diseases. With a team of around 250 scientists and staff, its pipeline is comprised of novel oral compounds for cancer and inflammation in development in North America, Europe, Australia and Greater China.
HMP is majority owned by Chi-Med. For more information, please visit: hmplglobal.com.

**About Chi-Med**

Chi-Med is a China-based healthcare group focused on researching, developing, manufacturing and selling pharmaceuticals and health-related consumer products. Its Drug R&D Division focuses on discovering and developing innovative therapeutics in oncology and autoimmune diseases. Its China Healthcare Division manufactures, markets and distributes prescription and over-the-counter pharmaceuticals in China. Its emerging Consumer Products Division focuses on organic and natural consumer products in Asia.

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