ASTRAZENECA ISSUES UPDATE ON ACCELERATED ONCOLOGY PIPELINE IN ADVANCE OF 2013 ASCO ANNUAL MEETING

First patient enrolled in Phase III clinical trial for moxetumomab pasudotox as a treatment for unresponsive or relapsed hairy cell leukaemia patients

Olaparib planned to progress to Phase III for platinum-sensitive relapsed ovarian cancer patients with BRCA mutations in 2013

Selumetinib planned to progress to Phase III for non small cell lung cancer patients with KRAS mutations in 2013

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AstraZeneca today announced that it will be moving three of its cancer compounds forward to Phase III clinical development. As set out at its Investor Day in March, oncology is one of the company's core therapy areas and accelerating the development of a number of new molecular entities in its pipeline is a strategic priority.

MedImmune, AstraZeneca's global biologics research and development arm, has enrolled the first patient in the Phase III clinical trial for moxetumomab pasudotox. The trial is sponsored by the Cancer Therapy Evaluation Program (CTEP), a programme within the Division of Cancer Treatment and Diagnosis at the US National Cancer Institute, and will evaluate moxetumomab pasudotox as a potential treatment in adult patients with hairy cell leukaemia who have not responded to or relapsed after standard therapy.

"This is further evidence of AstraZeneca's commitment to invest in distinctive science in our core therapy areas and to accelerate our Phase III pipeline," said Dr. Bahija Jallal, Executive Vice President, MedImmune. "We believe that targeted therapies which address the underlying mechanisms of disease are the future of personalised healthcare, to help meet the unmet needs in treating cancer patients. MedImmune's partnership with the National Cancer Institute is an example of our focus on innovative technologies designed to target cancer cells in more effective ways."

The company also announced that it will present new Phase II data for olaparib, its investigational oral poly ADP ribose polymerase (PARP) inhibitor, at the American Society of Clinical Oncology (ASCO) Congress in Chicago on 31 May to 4 June, demonstrating its potential as a maintenance treatment for platinum-sensitive relapsed ovarian cancer patients with BRCA gene mutations. Based on these data, AstraZeneca is planning to move olaparib forward to Phase III clinical trials for this patient population in the second half of 2013.

Olaparib features in an oral presentation (abstract # 5505 for maintenance therapy of relapsed platinum-sensitive ovarian cancer) and five poster discussions (abstract # 4013 in gastric cancer; abstract # 2514 in BRCA1/2 mutation positive breast and ovarian cancer; abstract # 11024 as a monotherapy in patients with advanced cancer and a germline BRCA1/2 mutation; abstract # 2579 in advanced solid tumors and abstract # 2581 in EGFR-mutation positive patients with advanced non small cell lung cancer). These abstracts are available on the ASCO website, which can be accessed via the following link:

http://abstracts2.asco.org/.

Data from a study sponsored by the National Cancer Institute will also be presented at ASCO on selumetinib, a selective MEK kinase inhibitor, in patients with advanced uveal melanoma. Data from an AstraZeneca sponsored study in patients with advanced cutaneous melanoma that harbors a mutation of the BRAF gene will also be presented.

Selumetinib features in two oral presentations (abstract # CRA9003 in gnaq/Gna11 mutation positive uveal melanoma and abstract # 9004 in first-line treatment for advanced BRAF mutant cutaneous or unknown primary melanoma) and five poster discussions (abstract # 8026 in advanced non small cell lung cancer selected by KRAS mutations; abstract # TPS4145 in metastatic pancreatic cancer after prior chemotherapy; abstract # 3587 as second-line therapy for KRAS-mutated metastatic colorectal cancer; abstract # 4014 in chemotherapy-refractory advanced pancreatic adenocarcinoma and abstract # 9068 in wild-type BRAF advanced melanoma.) These abstracts are available on the ASCO website, which can be accessed via the following link: http://abstracts2.asco.org/.

Separately, a Phase III study of selumetinib in combination with docetaxel as a second-line therapy for patients with KRAS mutation-positive and metastatic non small cell lung cancer is planned to commence in the second half of 2013.

Menelas Pangalos, Executive Vice President, Innovative Medicines and Early Development at AstraZeneca said: “As one of our three core therapy areas, we are committed to investing in innovative science in oncology to address areas of high unmet medical need. The progress we are making with olaparib and selumetinib, combined with our broader early phase portfolio across small molecules and biologics, puts us in a strong position to deliver our pipeline of targeted cancer medicines.”

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NOTES TO EDITORS

About moxetumomab pasudotox
Moxetumomab pasudotox is an investigational cancer treatment that has been tested in Phase I in people with hairy cell leukaemia. The Phase I study showed significant response rates for moxetumomab pasudotox in the hairy cell leukaemia population with a manageable safety profile, accelerating this program into a Phase III registration trial. The primary endpoint of the Phase III trial will be to measure the rate of durable complete response in patients treated with moxetumomab pasudotox as a 40mcg/kg intravenous infusion delivered over 30 minutes on days 1, 3, 5 of each 28-day cycle until complete response, progressive disease, initiation of alternate cancer therapy, or unacceptable toxicity. Secondary endpoints include overall response rate, relapse-free survival and progression-free survival.

Moxetumomab pasudotox is a CD22 immunotoxin composed of a binding portion of an anti-CD22 antibody fused to a toxin. After binding to CD22, the molecule is internalised, processed and releases its modified protein toxin that inhibits protein translation, leading to tumour cell death.

About olaparib
Olaparib is an innovative, potential first-in-class oral poly ADP ribose polymerase (PARP) inhibitor that exploits DNA repair pathway deficiencies to preferentially kill cancer cells. This

mode of action gives olaparib the potential for activity in a range of tumour types with DNA repair deficiencies. PARP is associated with a range of tumour types, in particular with breast and ovarian cancers.

The Phase II study is a randomised, double-blind clinical trial to evaluate the efficacy of olaparib maintenance therapy compared to placebo in high grade platinum-sensitive relapsed serous ovarian cancer patients. The pre-planned subgroup analysis retrospectively evaluated patients with confirmed gBRCA mutation status and tBRCA mutation status from archival tumour samples.

Results from the full study population were first presented at ASCO in 2011.

About selumetinib
Selumetinib is an MEK inhibitor that has been shown in Phase I/II studies to be clinically active and tolerated as monotherapy and in combination with standard of care chemotherapy regimens in clinical studies across a range of solid tumours. The Phase II data is from a randomised study of selumetinib compared with temozolomide (chemotherapy) in patients with metastatic uveal (eye) melanoma sponsored by the National Cancer Institute and from a double blind, randomised study of selumetinib in combination with dacarbazine as a first-line treatment for advanced cutaneous melanoma patients with BRAF mutations.

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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