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MARKET WATCH

Upcoming catalysts in Q1 2015

Important market catalysts are expected in the first quarter of 2015 for anticancer drug candidates with novel mechanisms of action that have the potential to change treatment paradigms in their respective indications: a potential approval decision on olaparib (developed by AstraZeneca) for the treatment of ovarian cancer; and top-line clinical trial results for two therapies developed by NewLink Genetics — indoximod for the treatment of breast, brain, melanoma and pancreatic cancer, and HyperAcute immunotherapies for the treatment of lung and pancreatic cancer.

Olaparib is a small-molecule poly (ADP-ribose) polymerase (PARP) inhibitor. AstraZeneca filed for approval by the US Food and Drug Administration (FDA) in the first quarter of 2014 using subgroup results from a Phase II trial (which was known as Study 19) that showed that progression-free survival (PFS) was longer in patients with platinum-sensitive, relapsed ovarian cancer with *BRCA* mutations who were taking olaparib compared with placebo (11.2 months versus 4.3 months). In June 2014, the FDA's Oncologic Drugs Advisory Committee voted 11 to 2 to delay market approval until the results are released from the Phase III SOLO-2 trial, which is recruiting only patients with *BRCA* mutations. The panellists were concerned that patients who received olaparib may have had worse response rates with subsequent lines of chemotherapy, thus attenuating an overall survival benefit. Top-line data release from SOLO-2 is not expected until the third quarter of 2015, and so we anticipate that AstraZeneca will receive a complete response letter, assuming that the FDA follows the advisory committee recommendation. The Prescription Drug User Fee Act date for a decision is 3 January 2015. In addition, marketing authorization for olaparib in Europe is expected to be granted during the first quarter of 2015 following a recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) in October 2014.

Indoximod is a small-molecule inhibitor of indoleamine 2,3-dioxygenase (IDO) and is in development for solid tumours, including breast, brain and pancreatic cancer as well as melanoma. Initial Phase I studies indicated signs of activity, and showed that indoximod has good oral bioavailability and a favourable half-life and is tolerated well by patients. NewLink Genetics expects preliminary top-line results for Phase II trials in all four oncology indications in the first quarter of 2015, which could provide a significant market boost to the company if success is seen in any of these hard-to-treat cancers.

NewLink Genetics is also expecting top-line results from Phase III trials for its cancer immunotherapy platform, which is called HyperAcute and consists of tumour-specific cell lines that have been modified to enhance their immunogenicity. HyperAcute therapies are being pursued for multiple oncology indications, with development most advanced in lung, melanoma and pancreatic cancers. Top-line results from a trial in non-small-cell lung cancer (known as NLG0301) and from two trials in patients with borderline resectable or locally advanced unresectable pancreatic cancer (known as IMPRESS and PILLAR) are expected by the end of the first quarter of 2015. Data from a previous Phase II trial suggest that HyperAcute may work better in patients with elevated levels of anti-mesothelin antibodies, but patients have not been prospectively stratified using this potential biomarker in the Phase III programme. If results from both IMPRESS and PILLAR are positive, the company expects to submit a Biologics License Application to the FDA in 2015.

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The author declares no competing interests.