Upcoming events: first hurdle for Newlink's pancreas immunotherapy

Welcome to your weekly digest of approaching regulatory events and clinical readouts. The first interim look from a phase III trial of the cancer vaccine Hyperacute Pancreas in resected pancreatic cancer is expected in the third quarter; Newlink Genetics previously reported promising phase II data.

Cancer vaccines have long been hampered by clinical setbacks, and pancreatic cancer is also notoriously difficult to treat. Newlink still lacks a big pharma partner and this initial analysis will be first real test of the company’s most advanced project, with read-across to the whole Hyperacute immunotherapy platform.

First of three

The pivotal phase III trial, Impress, is in 722 patients, evaluating Hyperacute Pancreas (algenpantucel-L) as an add-on to standard of care (gemcitabine alone or with chemoradiation) versus standard of care alone. The primary endpoint is change in overall survival.

The initial analysis will be triggered by 222 deaths, half of the 444 required for final unblinding. According to analysts at Stifel, unblinding at this early stage would require interim data to show statistical significance that translates into about a 45% improvement in overall survival.

Cannacord analysts note that given the lack of a futility analysis there are few drawbacks from this initial look. However, because of the high overall survival hurdle it seems more likely that the trial will be stopped for efficacy on the second or third analysis. That is expected to occur in the first quarter and second half of next year, respectively, with significance expected to be hit at 30% and 20% improvement in overall survival.

Hyperacute Pancreas has supportive phase II trial data; the trial in 69 patients with resected pancreatic cancer met its primary endpoint of one-year disease-free survival (DFS) at 62%, with median DFS of 14.1 months. The secondary endpoint of overall survival at 12 months was 86%, with a median of 24.1 months. This represented a 7.5-month improvement over matched historical controls.

Hyperacute Pancreas is Newlink Genetics' lead pipeline candidate, with 2018 sales forecast to reach $447m by 2018, according to EvaluatePharma. The NPV is $972m, double the company's market capitalisation. Hyperacute technology uses human cancer cells that are tumour specific and modified to express alpha-gal, which is said to stimulate an immune response, and is also being tested in melanoma and lung and prostate cancers.

The field of cancer vaccines is littered with clinical failures; most recently data released at Asco revealed that KAEI-GemVax's pancreatic cancer vaccine GV1001 did not prolong overall survival (Asco – Little fanfare for GemVax and Merck KGaA setbacks, June 4, 2013).

Last month Newlink Genetics' shares reached a record high since the company's 2011 IPO, possibly running up ahead of this interim look at the study. Still, the company is without a partner and will likely remain so until its technology is proven, so it needs positive signs to emerge from the pivotal study.

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All information is sourced to analyst notes and the EvaluatePharma Calendar of Events tool.

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