

NewLink Genetics: Multiple Readouts from HyperAcute Program in 2014-15; Exploring Two Different Approaches at Inhibiting IDO Pathway

NewLink Genetics' (NLNK) HyperAcute immunotherapy platform is designed to stimulate the patient's immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human, tumor-specific cell lines that have been modified to express a carbohydrate (alpha-gal) to which humans have preexisting immunity. Once introduced in the body, these modified cancer cells stimulate an immune response that trains the body's natural defense to seek similar cancer cells in the patient. NLNK is developing HyperAcute products for pancreatic, lung, melanoma, prostate and renal cancer.

- **Pancreatic cancer the most advanced HyperAcute program.** Following an encouraging phase 2 study in surgically resected patients, NLNK initiated a phase 3 study (IMPRESS) in those patients, and another phase 3 study (PILLAR) in patients with locally advanced pancreatic cancer. NLNK recently announced that following the first interim look, the IMPRESS trial will continue (with no new safety signals seen), with the second interim look expected in 2015.
- **2014 and 2015 should bring more data on the HyperAcute program.** Preliminary data from the PILLAR study is expected around 4Q-14/1Q-15; preliminary data from the phase 2b/3 lung cancer trial is also expected in same time frame, while phase 1 data from a kidney cancer trial is expected in 1H-15. NLNK is also planning to test its HyperAcute melanoma therapy in combination with BMY's Yervoy in an upcoming phase 2 study.

NLNK's other platform involves checkpoint inhibitors that explore two different approaches at inhibiting the IDO pathway. IDO is an enzyme that drives breakdown of tryptophan, which in turn can suppress T cell function and enable local tumor immune escape. NLNK's lead IDO pathway inhibitor program, indoximod, is in phase 2 trials in breast cancer (with chemo), prostate cancer (with Dendreon's Provenge). In earlier phase trials, indoximod is being tested (or will be) in breast cancer, pancreatic cancer, skin cancer (with Yervoy), and in brain tumors. NLNK's other IDO pathway inhibitor, NLG-919, has recently entered the clinic in a phase 1 trial in solid tumors.

Source: Credit Suisse/Divan, March 28, 2014

Oncology Indication: Multiple

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