NewLink Genetics: Pancreatic Cancer Vaccine Unlikely to Be Successful, Phase III Trial Underpowered

We recently hosted a conference call to discuss NewLink Genetics' (NLNK) vaccine for pancreatic cancer. The vaccine is in phase III testing in the IMPRESS trial of patients with stage I or II pancreatic cancer who have had a resection. The company released information that its endpoint was not met during its first interim survival analysis, which occurred when there were 222 deaths in the trial of 722 patients. We doubt the trial will be successful because we believe the vaccine is unlikely to be effective, and the trial design was underpowered because management mis-guessed the survival of the control group.

Cancer vaccines have been an overwhelming failure. Dendreon (DNDN) did get a prostate cancer vaccine approved by the FDA; however, the trial design was so poor it is unclear if the vaccine is effective. NLNK's pancreatic vaccine attempts to prime dendritic cells in vivo, as opposed to DNDN's vaccine, which activates cells in vitro. However, NLNK's vaccine provides no major scientific breakthrough to stimulate cancer immunity.

NLNK's phase II data on the pancreatic vaccine is inconclusive. A 69-patient open-label study compared high-dose to low-dose vaccine. The one-year survival difference between the two groups (96% vs. 79%, respectively) had a p=0.049, but this was not statistically significant because there were at least two endpoints – survival and disease-free survival. The latter is a weak endpoint because the trial was unblinded.

Survival of the control group appears much longer than expected, making the trial underpowered. The company stated in a press conference that the IMPRESS trial was powered with the expectation that the median survival of the control group was 21 months. The company had expected that 222 events (deaths) would have been reached in mid- 2013. Given that the 222 event mark was not reached until March, either the treatment is vastly superior to anything before it (which is highly unlikely) or the control group lived longer than management predicted (much more likely). Given that the control group likely lived much longer than management predicted, even if the vaccine is marginally effective the trial is likely to fail.

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