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What A Nobel Prize Winner Knew And Savvy Biotech Investors Should

by: Fortunate Isles October 13, 2011

The 2011 Nobel Prize in Physiology or Medicine was awarded to Bruce A. Beutler and Jules A. Hoffman "for their discoveries concerning the activation of innate immunity" and Ralph M. Steinman "for his discovery of the dendritic cell and its role in adaptive immunity." This year's Nobel Laureates have changed our fundamental understanding of how the immune system recognizes diverse substances called antigens, and how it generates its distinct responses by deciphering the activation and communication between innate and adaptive immunity.

These discoveries are the basis for cancer immunotherapy, a promising form of cancer treatment. At its most basic, cancer immunotherapy involves a vaccine that contains tumor cells or proteins from tumor cells called antigens, that stimulates a patient's immune system to produce unique cells that kill cancer cells and possibly prevent relapse. But what did Nobel Laureate Ralph Steinman know that a savvy biotech investor should?

Steinman knew that a cancer vaccine could be many things—an antigen / adjuvant, DNA, anti-idiotype, vector-based, dendritic cell or a whole cell tumor vaccine — and it could function passively or actively. Some adjuvants, like Vical's (VICL) Vaxfectin, are particularly effective in DNA-based vaccines. Others can activate helper T cells and can be used with vaccines that have a broader immune response. GlaxoSmithKline's (GSK) AS15 adjuvant system may have a prominent role across the cancer vaccine market, or it might be limited to antigen / adjuvant compounds like GSK's antigen-specific melanoma antigen epitope-3, MAGE-A3, currently undergoing Phase III trials for non-small cell lung cancer and melanoma. Vector-based cancer vaccines are those that use microorganisms like viruses or bacteria for vaccine delivery. Their proponents cite production cost as a competitive advantage over whole cell tumor or dendritic cell vaccines. But if a patient's antibodies neutralize these party crashers, as has been found to happen, it hardly matters. Whole cell tumor vaccines have the advantage of immunizing a patient with a large collection of antigens without the maker having to know exactly which antigens might be the ones that result in tumor rejection. But it might be that this lack of specificity in communication that helps the tumor evade the body's defense system in the first place. Perhaps a dendritic cell vaccine, based on the DC's unique capabilities to activate killer T cells and orchestrate a targeted message to the immune system might be the key. Ralph Steinman thought so; Dr. Steinman personalized dendritic cells with pancreatic cancer antigens for use in treating his own cancer.

So what is an investor to do? Volatility abounds throughout markets and the life science sector is no exception. But despite the weakened economy, the life science sector in North America is still set to grow in the fourth quarter, with about $2 billion being put toward new laboratories, manufacturing sites and facilities. With global cancer prevalence on the rise due to an aging population, market forecasts for cancer vaccines alone show double-digit CAGRs with projections of 25% between 2009-2012, and that the market size is poised to grow to $7 billion in 2015 by some estimates.

Cancer vaccines and cancer vaccine markets in 1997 and 2011 are vastly different beasts. It makes no more sense to compare the cancer immunotherapy markets of 1997 and 2011 than it does to compare a 1997 cell phone to a 2011 smartphone or a 1997 cell phone market to a 2011 smartphone market. The Roche Group's (RHHBY.BK) Rituxin, launched in 1997, was the first in class of a group of blockbuster passive cancer immunotherapy treatments, the best examples of which are monoclonal antibodies, complex proteins that mimic those made by the immune system's B cells. But the market landscape is pretty different now than in 1997 when Rituxin enjoyed a twelve-year monopoly on that market. Dendreon's (DNDN) Provenge is the first commercialized active immunotherapy treatment for cancer, and its makers may not be so lucky. Almost 50 clinical programs involving active cancer immunotherapies were underway just last year with a significant fraction in critical Phase III trials and almost twenty percent were prostate cancer therapeutics like Provenge. This potentially gives Provenge only a slight head start in the largest therapeutic area market segment in active immunotherapies for cancer, prostate cancer.

Like any disruptive technology, players in the cancer vaccine market are going to require the infrastructure to succeed in a quickly changing healthcare landscape. First to approval and first to market might also mean first to pave the way for competitors. In a field where a single letter (a Q or a J) can mean the difference between a quick Medicare reimbursement and early adoption or other players with well-positioned marketing partners gaining a competitive edge, there is no room for error. But how can we spot the next player on the cancer vaccine field when being fast just isn't enough? In a time when economic considerations for families, governments and healthcare providers alike are a concern, the best players in the cancer space must deliver value. That means products that extend patient survival significantly and have far fewer side effects than the current state of the art. It also means besting competing products in efficacy and compatibility in reimbursement scenarios where relevant. Finally, treatment cost and timelines must be competitive.

Looking at companies developing products for a particularly aggressive brain cancer like glioblastoma multiforme (GBM) can provide some insight. GBM patients with the best care currently have a median survival rate of only 15 months and a two-year survival rate of 26.5%. Avastin, the blockbuster monoclonal antibody drug sold by the Roche Group, has been found to cause gastrointestinal perforation and brain hemorrhage and other adverse effects in some GBM patients. CellDex's (CLDX) Act III is based on a single antigen and is only effective for a select subset of GBM patients. Northwest Biotherapeutics' (NWBO) dendritic cell based vaccine DCVax-L showed a 68% survival

rate at two years, whereas Immunocellular Therapeutics' (IMUC.OB) had an 80.2% rate for its dendritic cell based vaccine ICT-107. But it is Immunocellular Therapeutics' lean manufacturing process that allows it to deliver complex products that could be its greatest value. If it can be scaled up, the company's unique process may allow it to deliver products at a much more competitive cost and rate than other companies with comparably complex products such as Dendreon's Provenge.

We started last week with a Nobel Prize awarded to one of the pioneers of cancer immunotherapy. Is there a better way for a savvy biotech investor to round out this week than looking at the companies that presented this week at "Cancer Immunotherapy: A Long-Awaited Reality" Conference at the New York Academy of Medicine? You're a savvy investor. You decide.

Disclosure: I have no positions in any stocks mentioned, and no plans to initiate any positions within the next 72 hours.

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