Recent progress with vaccine strategies to prevent or delay recurrence following adjuvant therapy

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Recent advances in cancer immunotherapies and vaccine technologies, as well as patient profiling, have advanced the field towards translating these insights into addressing significant unmet medical needs. While most oncology treatments on the market today were first tested and approved in patients with late stage disease, reducing tumor bulk has rarely provided a robust development pathway for cancer vaccines. New approaches are required to evaluate the potential benefit of immunotherapies, and perhaps the immune system is more suited to preventing recurrence in an adjuvant therapy setting where there is minimum disease burden. We present the case of NeuVax (nelipepimut or E75), one of the most studied and tested cancer peptide vaccines. Originally eluted from human breast and ovarian tumor samples in complex with HLA-A2, E75 is a short peptide (9 amino acids) derived from the extracellular domain of HER2. It is a HER2-derived epitope that has been proven to bind to both HLA-A2 and A3, and predicted to bind other alleles as well such as HLA-A26 and A24. The E75/HLA complex displayed on APCs elicits a robust and highly specific CD8+, cytotoxic T-lymphocyte (CTL) response against HER2-expressing tumor cells. Based on promising Ph 2 results which demonstrated significant reductions in recurrence rates, the FDA granted a Special Protocol Assessment (SPA) to Galena for a pivotal Phase 3 trial in low to intermediate HER2 breast cancer patients in the adjuvant setting for the prevention of recurrence.

Biography
Mark J. Ahn, Ph.D. is President & Chief Executive Officer, and Director of Galena Biopharma (Nasdaq: GALE) and Professor (adjunct), Biosciences, Creighton University. Prior to Galena, Dr. Ahn was Principal at Pukana Partners, Ltd. that provides strategic consulting to life science companies; and previously served as Chair, Science & Technology Management, Victoria University. Dr. Ahn was also founder, President, and Chief Executive Officer of Hana Biosciences. He also served as Vice President, Hematology and corporate officer at Genentech, Inc., as well as held positions of increasing responsibility at Amgen and Bristol-Myers Squibb Company. Dr. Ahn also serves on public and venture capital-backed Board of Directors for Access Pharmaceuticals, Mesynthes and Scribes STAT. He has published over 50 peer reviewed journal articles.

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