GVAX Immunotherapy Produces Encouraging Survival Data in Pancreatic Cancer Patients

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Cell Genesys, Inc, announced follow-up data from a phase II clinical trial of GVAX immunotherapy for pancreatic cancer in 60 patients with operable pancreatic cancer who received the immunotherapy after surgical resection of their tumor and adjuvant radiation and chemotherapy. The updated results showed a median survival of 26.8 months. This compares favorably with published, historical data from multiple single-arm and randomized studies in patients undergoing pancreatic cancer surgery and adjuvant therapy for whom the median survival has been reported to be in the range of 17 to 22 months, including the most recently reported results for gemcitabine (Gemzar) chemotherapy. Of note, 52 of the 60 patients in this study were considered high-risk, based on the unfavorable finding that their cancer had spread to regional lymph nodes. Treatment was well tolerated. The details of the follow-up findings were presented by Daniel Laheru, MD, assistant professor of medical oncology at Johns Hopkins Kimmel Cancer Center, and colleagues, at the 2007 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium held in Orlando, Florida, in January.

Proof of Concept

"We are encouraged by the updated survival data of GVAX immunotherapy in this phase II study compared to previously reported results for surgery and adjuvant therapy of resectable pancreatic cancer and we are currently reviewing plans for further development," said Kristen Hege, MD, vice president of clinical research at Cell Genesys. "We believe these new findings, along with the results from an earlier phase I trial of GVAX immunotherapy for pancreatic cancer, provide further clinical proof of concept for the GVAX cancer immunotherapy platform." The phase II trial was conducted by the Johns Hopkins Kimmel Cancer Center and enrolled 60 patients with resectable pancreatic cancer. The study was designed to evaluate the safety and efficacy of GVAX immunotherapy for pancreatic cancer, which is a non-patient-specific immunotherapy being developed as an "off-the-shelf" pharmaceutical product. All patients underwent extensive surgical resection of their tumors. The immunotherapy was administered as an intradermal (under the skin) injection before and after standard postoperative adjuvant radiation therapy and fluorouracil chemotherapy. Patients received up to five doses—the first prior to adjuvant chemoradiotherapy, the next three following adjuvant therapy at approximately 1-month intervals, and the fifth as a booster injection 6 months later. Patients were monitored for evidence of relapse and survival, as well as the occurrence of adverse events and induction of immune response.

Earlier Trial

An earlier phase I trial of GVAX immunotherapy for pancreatic cancer was conducted at the Johns Hopkins Kimmel Cancer Center in 14 patients who also received the immunotherapy following surgical resection of their tumor and standard adjuvant radiation and chemotherapy. As first reported in the Journal of Clinical Oncology in January 2001, three of eight patients who received the therapeutic dose levels of the immunotherapy had prolonged disease-free survival for a period of at least 8 years. This outcome is considered particularly significant since all three long-term survivors were judged to be at high risk for recurrent cancer due to microscopic evidence of residual pancreatic tumor following surgery and/or metastatic tumor in regional lymph nodes. In addition, the three patients with prolonged disease-free survival did not show evidence of treatment-associated antitumor immunity, including induction of T-cell responses to the candidate tumor-associated antigen, mesothelin.

Other Cancer Types

Clinical trials of GVAX cancer immunotherapies are underway for multiple types of cancer in addition to pancreatic cancer, including prostate cancer and leukemia. The products are comprised of tumor cells that have been modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF).
and then irradiated for safety. GVAX cancer immunotherapies have demonstrated a favorable side-effect profile in over 600 patients treated in clinical trials to date.

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