Vaccines:
A New Alternative for Cancer Treatment

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Current cancer treatments are proving to be successful, as is evident by the continued decline in death rates for the four most common types (prostate, breast, lung, and colorectal), as well as for cancers in general.¹ Cancer prevention measures, including behavioral changes, vaccination, and early detection, are largely responsible for the declining incidence of cancer since the early 2000s.²

Despite the declining death rate and incidence, there is still a need for therapeutic advancements; cancer is a disease that affects millions of previously diagnosed Americans each year, and it is estimated that approximately 1.5 million new invasive cancer cases will be diagnosed in 2010.² One of the newest treatment modalities warranting a closer look is the use of vaccines for cancer treatment.

Prior to the development of vaccines for cancer treatment, they were developed for preventative purposes. Preventative vaccines provide immunity by exposing the patient to a non-infectious portion of the virus that has antigenic properties; this in turn will cause the body to mount an immune response and will provide patients with future immunity against the virus if they are exposed to it at a later date.³

The FDA approved RECOMBIVAX HB® (Hepatitis B Vaccine [Recombinant]) and ENGERIX-B® (Hepatitis B Vaccine [Recombinant]) for vaccination against infections caused by all known subtypes of hepatitis B.⁴⁵ By preventing infections caused by the virus, the chance of developing hepatocellular carcinoma, a serious infection complication, is reduced.

More recently, vaccines have been developed to prevent cervical, vulvar, and vaginal cancers. GARDASIL® (Human Papillomavirus Quadrivalent [Types 6, 11, 16,18] Vaccine, Recombinant) is indicated in girls and women 9 through 26 years of age for the prevention of cervical, vulvar, and vaginal cancer caused by HPV types 16 and 18.⁶ CERVARIX® (Human Papillomavirus Bivalent [Types 16 and 18] Vaccine, Recombinant) is indicated for prevention of cervical cancer caused by HPV types 16 and 18 in girls and women 10 through 25 years of age.⁷

Although all of these preventative vaccines decrease the likelihood of a person developing cancer, they offer no benefit to patients already diagnosed with cancer. However, advancements have been made in cancer therapy management, rendering vaccines as an alternative option for treatment of cancer and not just for cancer prevention. The FDA approved PROVENGE® (sipuleucel-T) on
April 29, 2010, as the first-in-class autologous vaccine for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer thus offering benefit to those patients already diagnosed with cancer. Clinical studies have shown that Provenge extends median survival by approximately 4 months and is associated with a 22.5% risk reduction of death compared to the control group.

Some of the most common side effects associated with Provenge include chills, fatigue, fever, back pain, nausea, joint ache, and headache. Provenge is administered in 3 doses, each given approximately 2 weeks apart. It is suggested that patients be pretreated, prior to each infusion, with acetaminophen and diphenhydramine to decrease the likelihood of infusion-related reactions.

In order for the vaccine to be administered, immune cells from the patient, in particular the antigen-presenting cells, must be removed by a process known as leukapheresis. The antigen-presenting cells are then fused with two additional components, prostatic acid phosphatase (PAP) and granulocyte macrophage colony-stimulating factor (GM-CSF), and then reinfused into the body in order to mount an adequate immune response. Provenge looks promising as a treatment alternative for patients with metastatic castrate-resistant prostate cancer, but its place in therapy among the current treatment options is yet to be determined.

The current standard of care for the treatment of castrate-resistant prostate cancer is TAXOTERE® (docetaxel). Taxotere is indicated, in combination with prednisone, for the treatment of patients with androgen-independent (hormone-refractory) metastatic prostate cancer. Taxotere works by disrupting the microtubular network of both cancer and non-cancer cells, thus preventing proper cell division.

In clinical trials, Taxotere showed a statistically significant overall survival advantage, compared to mitoxantrone, when administered at a dose of 75 mg/m² every 3 weeks for 10 cycles. Patients are excluded from treatment with Taxotere if they have hepatic impairment, a Karnofsky performance status <60%, or are neutropenic. Common side effects seen with Taxotere include low white blood cell count, anemia, fatigue, nausea, vomiting, and diarrhea.

Taxotere is administered as a 1-hour intravenous infusion every 3 weeks with continuous administration of prednisone 5 mg orally twice daily. In addition, dexamethasone is recommended for administration as a premedication in order to reduce the severity of infusion-related reactions.
Vaccines in phase III clinical trials include those for the treatment of melanoma and non-small cell lung cancer.

The future seems promising for the development of vaccines as a treatment alternative in other types of cancer as well. Currently there is a pancreatic cancer treatment vaccine in phase III clinical trials.\(^\text{11}\) Pancreatic cancer is the fourth-leading cause of cancer-related deaths and is associated with a poor prognosis; a diagnosis is frequently made in the more advanced stages of the disease since patients remain largely asymptomatic despite tumor growth.\(^\text{12}\) It is hoped that with the approval of the new vaccine, the survival rate of pancreatic cancer patients will improve.

Other vaccines in phase III clinical trials include those for the treatment of melanoma and non-small cell lung cancer. All of these vaccines work by boosting the patient’s natural immune system, either by targeting an antigen overexpressed in the tumor cells or by administering genetically modified tumor cells.\(^\text{13,14}\) In the earlier phases of clinical trials, treatment vaccine development is being made in various cancer types (Table 1) and has the potential to bring about more alternatives in cancer therapy management.

Vaccines for cancer treatment are now being studied in advanced-disease patient populations, thus not offering viable treatment options for patients in the preliminary stages of disease. Although there are few vaccines in the late stages of development, there are many in the pipeline that will hopefully prove to be beneficial treatment alternatives for different forms of cancer—and perhaps even offering a cure one day.

### Table 1

Areas of Cancer Treatment Vaccine Development

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References