

ONCOPHAGE®

(vitespen)

INVESTIGATIONAL THERAPEUTIC CANCER VACCINE



ONCOPHAGE® (VITESPEN; FORMERLY HSPPC-96) IS A PATIENT-SPECIFIC THERAPEUTIC CANCER VACCINE CURRENTLY BEING STUDIED IN CLINICAL TRIALS TO DETERMINE ITS ACTIVITY IN DESTROYING CANCER CELLS AND PREVENTING FURTHER DISEASE PROGRESSION. PHASE 3 RESEARCH EVALUATING ONCOPHAGE INCLUDES CLINICAL TRIALS IN NONMETASTATIC RENAL CELL CARCINOMA AND METASTATIC MELANOMA. ONCOPHAGE HAS BEEN GRANTED FAST TRACK AND ORPHAN DRUG DESIGNATIONS FROM THE US FOOD AND DRUG ADMINISTRATION (FDA) FOR BOTH INDICATIONS. ONCOPHAGE HAS ALSO RECEIVED AN ORPHAN DRUG DESIGNATION FOR RENAL CELL CARCINOMA IN EUROPE.

BASED ON PATENTED HEAT SHOCK PROTEIN (HSP) TECHNOLOGY, ONCOPHAGE CONSISTS OF THE PARTICULAR CANCER'S 'ANTIGENIC FINGERPRINT.' THIS FINGERPRINT IS DESIGNED TO TRAIN THE IMMUNE SYSTEM TO FIGHT THAT PARTICULAR PATIENT'S CANCER – NOT HEALTHY NORMAL CELLS. AS A RESULT, ONCOPHAGE IS DESIGNED TO LIMIT THE TOXICITIES ASSOCIATED WITH BROADER-ACTING TRADITIONAL CANCER TREATMENTS.

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Product Profile: Oncophage®

CLINICAL RESULTS Since 1997, Oncophage has been studied in more than a dozen clinical trials in more than 750 patients, many of whom had advanced disease. Data from Antigenics' Phase 3 trial of Oncophage in nonmetastatic renal cell carcinoma (RCC, the most common type of kidney cancer) showed a 44-percent improvement in recurrence-free survival associated with Oncophage in a well-defined subgroup of earlier-stage (better-prognosis) patients. In a Phase 3 study of Oncophage in metastatic melanoma, overall median survival was 29 percent longer in patients who received at least 10 injections of Oncophage compared with physician's choice regimen. Preliminary findings from an investigator-sponsored, Phase 1/2 study evaluating Oncophage as a treatment for recurrent glioma, being conducted at the University of California, San Francisco, showed tumor-specific immune response in all treated patients, which may be associated with clinical benefit in this patient population.

HSP technology has been independently validated by more than 25 laboratories worldwide and documented in more than 150 publications. Oncophage has been evaluated in more than nine cancer indications, and can potentially be used to treat all cancer types.

CLINICAL TRIALS The Brain Tumor Research Center at the University of California, San Francisco, is currently evaluating Oncophage in an investigator-sponsored, Phase 1/2 study as a treatment for recurrent glioma. Clinical research involving Oncophage includes studies in several cancer types, such as renal cell carcinoma, metastatic melanoma, non-small cell lung cancer, lymphoma, and colorectal, pancreatic and gastric cancers. Antigenics also plans to investigate Oncophage in clinical trials for combination treatment.

ONCOPHAGE MANUFACTURE Following removal of the patient's tumor, the tumor is shipped overnight to Antigenics' manufacturing facility in Massachusetts. Using a proprietary, standardized, quality-controlled procedure, the heat shock protein gp96 and its associated peptides are isolated from the tumor. The gp96 complexes are purified, sterile-filtered, vialled, and shipped frozen back to the hospital pharmacy for use when the patient has recovered from surgery. The entire manufacturing process takes about 10 hours to complete.

HOW IT IS USED In clinical studies with Oncophage, the vaccine is administered once a week for the first month, then once every other week until the supply is depleted. Oncophage is designed to be administered during an office visit as a simple, subcutaneous (beneath-the-skin) injection.

ADVERSE EVENTS Oncophage has been studied in more than a dozen clinical trials and has been found to be well tolerated. The most common side effects reported in clinical studies with Oncophage were injection-site reactions and constitutional symptoms, including headache, back pain and fatigue. These events have generally been reported as mild to moderate and transient in nature.

REGULATORY DESIGNATIONS The US Food and Drug Administration has granted Oncophage fast track and orphan drug designations for both renal cell carcinoma and metastatic melanoma. Oncophage has also received an orphan drug designation for renal cell carcinoma in Europe.