

## 2. NON-TECHNICAL ABSTRACT

While the majority of patients with prostate cancer are diagnosed with "localized" disease (disease that has not yet spread beyond the prostate), between 30 and 40% of these patients will eventually have their PSA rise following either surgery (radical prostatectomy) or radiation therapy. For patients with disease that has spread to lymph nodes or bone (that can be seen on imaging studies such as X-rays), hormonal therapy can be used. However the vast majority of patients eventually have progressive disease. Chemotherapy has been shown to improve survival in patients in whom hormonal therapy is no longer controlling the disease; however, there is no therapy that has been shown to prolong life after chemotherapy.

This trial would enroll patients who have disease progression after chemotherapy but who have no significant symptoms. This trial seeks to use a vaccine, designed to teach a body's immune system to recognize and kill tumor cells that make PSA (prostate cancer cells). Similar trials have shown that this vaccine can generate an immune response (immune cells that can recognize and kill cancer cells) when given as an injection under the skin. Here, we seek to give the same vaccine except that with the boosting vaccines (all vaccines given after the initial priming vaccination) an antibody, anti-CTLA-4 will also be given. This is designed to release the "brakes" normally in place in the immune system to allow further generation of an effective immune response. The use of the combination of vaccine and anti-CTLA-4 antibody has been shown to be significantly more effective against tumors in mice than vaccine or antibody alone. Because there can be serious side effects with the anti-CTLA-4 antibody, we will start with a low dose of the antibody in combination with the vaccine and then if this is well tolerated, [we will] give the next group of patients a higher dose of the anti-CTLA-4 antibody for up to 4 different dose levels. Upon determination of a "safe" dose of anti-CTLA-4 antibody, we will look at a larger group of patients to determine clinical responses of the vaccine with anti-CTLA-4.