

## **Monoclonal Antibody for a Prostate-Specific Tumor Suppressor Gene**

### **Background**

Relatively little is known about the molecular mechanisms involved in prostate carcinogenesis due to the lack of animal models that mimic human prostate carcinoma. Mutant mouse models lacking genes critical for prostate development could be utilized to understand the molecular pathways involved in prostate cancer initiation and progression.

Also, very few tumor suppressor genes have been definitively shown to be lost during prostate cancer progression. Thus, the identification of prostate-specific tumor suppressor genes would be extremely valuable in studying prostate carcinogenesis.

**The present invention relates to: (1) the identification of a prostate-specific tumor suppressor gene, (2) generation of monoclonal antibodies (mouse and human) to the tumor suppressor protein, and (3) mutant mouse models of prostate cancer.**

### **Summary of the Technology:**

Knockout mice lacking the functional homeobox gene Nkx3.1 and the lipid phosphatase Pten were generated to study the molecular factors involved in prostate carcinogenesis. These mutant mouse models have been demonstrated to model human prostate cancer. Studies with these mouse models clearly implicate a role for Nkx3.1 as a prostate-specific tumor suppressor gene. These studies also showed that the loss of Nkx3.1 protein expression is a hallmark of prostate cancer in mice and humans, and occurs also in early stages of the disease.

Monoclonal antibodies against human Nkx3.1 regulatory protein have been produced. A method for detecting the presence of Nkx3.1 in biopsy tissue samples has been developed.

### **Advantages:**

#### Mutant Mouse:

- Mouse models that mimic early stages of human prostate cancer are not currently available. The mutant mouse models lacking the homeobox gene Nkx3.1 and pten tumor suppressor would significantly advance prostate cancer research.

#### Nkx3.1 Monoclonal Antibody:

- Prostate-specific antigen (PSA) is a tumor marker currently used for early detection of prostate cancer. Elevated serum concentrations of PSA, however, is not always a useful indicator of prostate cancer because a variety of factors such as physical activity and age can affect the serum concentration of PSA. Measurement of serum

PSA concentrations is used to detect other prostate pathologies as well. Moreover, PSA testing does not detect small-volume histologic cancers. Thus, testing for Nkx3.1 protein could have useful clinical applications in prostate disease management.

File 00-05 Abate-Shen et al.

Alternatively, including both PSA and Nkx3.1 monoclonal antibody in any diagnostic program could improve cancer detection rates.

- There are very few markers that distinguish indolent versus aggressive prostate cancer. The Nkx3.1 could be used as a diagnostic marker to detect aggressive prostate diseases.

### **Applications:**

- Mouse anti-human and anti-mouse polyclonal as well as monoclonal antibodies with specificity for the tumor suppresser Nkx3.1 protein are available. These antibodies can be used:
  - As tumor marker for early detection of prostate cancer.
  - Pre-treatment staging of prostate cancer
  - Post-treatment monitoring of prostate cancer.
  - As a marker to distinguish between indolent versus aggressive prostate

cancer. -As a research tool to elucidate the molecular mechanisms involved in prostate cancer initiation and progression.

- The knockout mice can be used to study the molecular mechanisms involved in prostate cancer initiation and progression.

### **Patent Status:**

- US patent applications filed on the monoclonal antibody. (Application No.: 10/366,990)
- Application published on February 6, 2003. Publication No.: 2003-0027226 A1

### **Licensing Opportunity:**

- This technology is available for exclusive license.

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File 00-05 Abate-Shen et al.