



Innocrin Pharmaceuticals, Inc. Granted Fast Track Designation by FDA for VT-464 Treatment of Patients with Metastatic Castrate-resistant Prostate Cancer

- *Seviteronel (VT-464) to be presented in three sessions at the ASCO Genitourinary (ASCO GU) Cancer Symposium to be held in San Francisco, California January 7- 9, 2016*

January 06, 2016 10:54 AM Eastern Standard Time

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Innocrin Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing small-molecule CYP17 lyase-selective inhibitors for the treatment of hormonally-dependent breast and prostate cancers resistant to traditional anti-hormonal therapy, today announced that the FDA granted Fast Track Designation for seviteronel (VT-464) for the treatment of patients with metastatic castrate-resistant prostate cancer ("CRPC").

Established under the FDA Modernization Act of 1997, the Fast Track program is designed to facilitate the development and review of drugs intended to treat serious conditions and fill an unmet medical need. A drug development program with Fast Track designation is afforded greater access to FDA for the purpose of expediting the drug's development, review and potential approval.

"We believe that the award of Fast Track designation represents important recognition by FDA of seviteronel's potential to address a significant unmet need in the treatment of patients with CRPC," stated William Moore, Ph.D., Innocrin's Chief Executive Officer. "In addition, we are pleased to present new seviteronel clinical results in multiple sessions at ASCO GU. We believe that these presentations will raise the profile of a new agent that could make a tremendous impact for patients with very few other treatment options."

2016 ASCO GU - POSTER PRESENTATIONS

Title: Cardiovascular safety profile of VT-464 in patients with castrate-resistant prostate cancer (CRPC).

Presenter: Michael Kurman, M.D.

Date: Thursday, Jan. 7, 11:30 a.m. to 1:00 p.m. and 5:15 to 6:45 p.m. PST (*Poster Session A*)

Title: Objective response of the dual CYP17-Lyase (L) inhibitor / androgen receptor (AR) antagonist, VT-464, in patients with CRPC.

Presenter: Luke Nordquist, M.D.

Date: Thursday, Jan. 7, 11:30 a.m. to 1:00 p.m. and 5:15 to 6:45 p.m. PST (*Poster Session A*)

Title: Once-nightly (QD) dual CYP17-Lyase (L) inhibitor / androgen receptor (AR) antagonist VT-464-in patients with CRPC.

Presenter: Neal Shore, M.D.

Date: Friday, Jan. 8, 12:15 to 1:45 p.m. and 6:00 to 7:00 p.m. PST (*Poster Session B*)

About Seviteronel (VT-464)

Seviteronel is a once-daily oral therapeutic given without prednisone. Seviteronel selectively inhibits CYP17 lyase, a target of abiraterone, and has unique blocking effects on the androgen receptor (AR), the target of enzalutamide. There is a strong and growing body of preclinical and clinical evidence that shows that some abiraterone- or enzalutamide-resistant patients will respond to seviteronel treatment. Resistance following treatment with abiraterone, enzalutamide or both represents a major unmet medical need due to the widespread and growing use of these new agents, and to the high cross-resistance of cancers in patients exposed to these agents to approved drugs (e.g., patients who have been treated with either abiraterone or enzalutamide typically do not respond to the other).

Seviteronel may also have significant potential for the treatment of breast cancer due to its selective inhibition of CYP17 lyase, which results in the depletion of both androgens and estrogens, in addition to its AR antagonist activity. It is thought that the AR may stimulate disease progression in some patients whose tumors are triple-negative or are ER+ but have become resistant to ER-directed therapies such as aromatase inhibitors or tamoxifen. Recent preclinical study results, presented at the 2015 San Antonio Breast Cancer Symposium, have confirmed that seviteronel blocks the growth of ER+ and/or AR+ breast cancer cells more potently than enzalutamide.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in six will be diagnosed with prostate cancer in his lifetime. The American Cancer Society estimates that approximately 240,000 new cases of prostate cancer will be diagnosed and about 30,000 men will die of the disease this year, and that approximately two million men in the U.S. currently count themselves among prostate cancer survivors.

About Breast Cancer

Each year over 230,000 new cases of breast cancer are diagnosed in the United States, with almost 40,000 deaths attributable to the disease. While estrogen deprivation is currently the standard of care for postmenopausal women with hormone receptor-positive breast cancer, the majority of patients eventually develop resistance. Though patients with the ER+/AR+ subtype comprise ~75% of all metastatic BC cases, the most significant unmet need is the triple-negative subtype, a population that might respond well to anti-androgen therapies as evidenced by recent results from a Phase 2 study using enzalutamide.

About Innocrin Pharmaceuticals, Inc. (www.innocrinpharma.com)

Innocrin discovers and develops novel, best-in-class oral inhibitors of CYP17 lyase, a validated enzyme target for the treatment of castration-resistant prostate cancer (CRPC). Seviteronel and structurally-related classes of CYP17 inhibitors are wholly owned by Innocrin. CYP17 lyase inhibitors may also have high commercial potential for the treatment of breast cancer as well as non-oncologic syndromes that are due to hormonal excess including endometriosis, polycystic ovary syndrome and congenital adrenal hyperplasia. Innocrin's investors include the Novartis Venture Fund, Eshelman Ventures, Lilly Ventures, Hatteras Venture Partners, Intersouth Partners, Lurie Holdings, and Astellas Venture Management.

Contacts

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