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Innocrin Pharmaceuticals, Inc. Begins Phase 2 Study of Seviteronel in Women with Estrogen Receptor-positive or Triple-negative Breast Cancer and Expands Two Phase 2 Studies of Seviteronel in Men with Metastatic Castrate-resistant Prostate Cancer

- *Oral once-daily Seviteronel (VT-464) completed a Phase 1 Study in women with estrogen receptor-positive (ER+) or triple-negative (TN) breast cancer (BCa). The Phase 1 study results to be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting to be held in Chicago, Illinois June 3-7, 2016.*
- *Oral once-daily Seviteronel demonstrated therapeutic activity in Stage 1 of two Phase 2 studies in men with castrate-resistant prostate cancer (CRPC) whose disease progressed following enzalutamide alone or both enzalutamide and abiraterone. Patient enrollment has been expanded in Stage 2 of these separate Phase 2 studies.*

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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 breast and prostate cancers resistant to traditional anti-hormonal therapy, today announced that they have started dosing in a Phase 2 study of women with ER+ or TN BCa (NCT02580448). The Phase 1 portion of the seviteronel study has completed and a once-daily dose was selected for advancement into Phase 2 development.

William Moore, Ph.D., Innocrin's Chief Executive Officer stated, "The importance of the androgen receptor (AR) to the development of ER+ and TN BCa disease progression has become better recognized by the medical community. Seviteronel both reduces androgens and estrogens through its inhibition of CYP17 lyase and directly antagonizes the AR, so it has the potential to provide benefit for women with cancers that have not responded to traditional anti-estrogen therapies. We look forward to presenting the results from our Phase 1 study at the upcoming ASCO Annual Meeting."

2016 ASCO ANNUAL MEETING PRESENTATION

Title: Phase 1 study of oral seviteronel (VT-464), a dual CYP17-Lyase inhibitor and androgen receptor antagonist, in patients with advanced AR+ triple negative or estrogen positive breast cancer.

Presenter: Aditya Bardia, M.D.

Date: Sunday, June 5, 2016, 8:00 a.m. to 11:30 a.m. CDT

(Breast Cancer—Triple-Negative/Cytotoxics/Local Therapy Poster Session)

Innocrin also announced that once-daily seviteronel has advanced to Stage 2 in two separate Phase 2 CRPC studies. One is an open-label Phase 2 study funded by the National Cancer Institute (NCI), evaluating the efficacy and safety of seviteronel in men who have previously been treated with enzalutamide (NCT02130700). The second is an Innocrin-sponsored Phase 2 study of seviteronel in men who have been previously treated with both enzalutamide and abiraterone (NCT02012920). Phase 2 oncology studies typically employ early 'stopping rules' that prevent large numbers of patients from being exposed to inactive drugs. Seviteronel has advanced to Stage 2 in both studies based upon early signs of therapeutic activity in each population.

Dr. Moore further commented, "It is gratifying that seviteronel has demonstrated early signs of therapeutic benefit in both of these very important clinical studies. Novel therapies for men whose CRPC has progressed despite treatment with enzalutamide or with abiraterone represent a growing unmet medical need. Positive results from these studies will enable us to advance seviteronel as a therapeutic alternative to systemic radio- or chemo-therapy for these men. Correlative results from these studies, which include AR-v7 analyses, will help us identify the populations that will most benefit from seviteronel."

Innocrin anticipates presenting final results from these Phase 2 BCa and CRPC clinical trials at future medical conferences.

About Seviteronel (VT-464) Seviteronel is a once-daily oral therapeutic given without prednisone. Seviteronel selectively inhibits CYP17 lyase, a target of abiraterone, and also directly blocks the AR, the target of enzalutamide. A growing body of preclinical and clinical evidence shows that seviteronel is active in prostate cancers that have become resistant to abiraterone or enzalutamide. CRPC disease progression following treatment with abiraterone, enzalutamide or both represents a major unmet medical need due to the widespread and growing use of both agents, and to the high cross-resistance between these agents (e.g., cancers that are resistant to either abiraterone or enzalutamide typically are also resistant to the other).

Seviteronel may also have significant potential for the treatment of breast cancer due to its ability to down-regulate both AR and ER signaling through its selective inhibition of CYP17 lyase, which results in the depletion of both androgens and estrogens, and to its direct AR antagonist activity. It is thought that the AR may stimulate disease progression in tumors that are triple-negative or are ER+ and are resistant to ER-directed therapies such as aromatase inhibitors or tamoxifen. Recent preclinical study results, presented at the 2015 San Antonio Breast Cancer Symposium, confirmed that seviteronel blocks the growth of resistant ER+ and 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. 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. The largest target population is ER+/AR+ patients which comprise ~75% of all metastatic BCa cases. The most significant unmet need is triple-negative BCa, but the subset of patients that are AR+ (20-50%) should benefit from anti-androgen therapies as evidenced by recent results from a Phase 2 enzalutamide study.

About Innocrin Pharmaceuticals, Inc. (www.innocrinpharma.com) Innocrin discovers and develops novel 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 other hormonally-driven cancers including breast, ovarian, liver, bladder, and head and neck. In addition, Innocrin has interest in non-oncologic syndromes that are also due to hormone 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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