Innocrin Pharmaceuticals, Inc. Granted SME Status Designation by the European Medicines Agency

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RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Innocrin Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company focused on the development of the oral, selective CYP17-lyase/androgen receptor (AR) inhibitor seviteronel for castration resistant prostate cancer (CRPC) and advanced breast cancer, announced today that it has been granted Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency's (EMA) Micro, SME office. The SME initiative promotes innovation from smaller companies like Innocrin, to ensure Europe continues to be a favorable environment for pre-clinical and clinical development of promising new therapeutic options like seviteronel.

SME status will provide Innocrin with significant financial incentives to progress clinical development for seviteronel in Europe, including a 90-100% fee reduction (depending upon orphan drug status) for scientific advice and quality inspections of facilities along with additional fee deferrals/waivers for selected EMA regulatory filings. Innocrin will be eligible for EMA certification of quality and manufacturing data prior to review of clinical data, and EMA-provided translation of regulatory documentation required for market authorization, further reducing the financial burden of the regulatory approval process.

"The granting of SME status is an important milestone for Innocrin, allowing us to work with the EMA in an efficient way to progress and expand our innovative development program for seviteronel in Europe," stated Dr. Eshelman, Innocrin Chief Executive Officer.

Edwina Baskin-Bey, M.D. Innocrin Chief Medical Officer stated, "Granting of the SME status by the EMA, following FDA Fast Track Designation for seviteronel in the treatment of breast and prostate cancer, continues to validate Innocrin and our clinical programs. The EMA decision, along with expansion of our Phase 2 clinical trials in Europe, will further grow our collaborative development program for seviteronel in AR-driven cancers."

About Seviteronel (VT-464)

Seviteronel is a once-daily therapeutic that selectively inhibits CYP17 lyase, an enzyme needed for the synthesis of androgens and estrogens, and also directly blocks the AR.

It is thought that the AR may stimulate disease progression of BCa tumors that no longer are ER+ (e.g., are triple-negative) or are ER+ but have become resistant to ER-directed therapies such as aromatase inhibitors or tamoxifen. Preclinical study results presented at the 2015 San Antonio Breast Cancer Symposium, confirmed that seviteronel, due to its multiple mechanisms of action, blocks the growth of resistant ER+ and AR+ BCa cells more potently than enzalutamide. Phase 2 enrollment of women and men with BCa is ongoing in the CLARITY-01 (CYP17 Lyase and Androgen Receptor Inhibitor Treatment with Seviteronel) study (NCT02580448).

A growing body of preclinical and clinical evidence shows that seviteronel blocks the growth of deadly CRPC that is resistant to abiraterone (a CYP17 hydroxylase inhibitor) or enzalutamide (an AR antagonist). 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, as well as the high cross-resistance between these agents (e.g., cancers that are resistant to abiraterone are typically resistant to enzalutamide and vice versa). Fast Track Designation was granted for seviteronel treatment of men with CRPC on 10 December 2015. Enrollment is ongoing in two Phase 2 studies (NCT02012920, NCT02445976).

About Breast Cancer

Each year over 464,000 women in the EU and 230,000 women in the United States (US) are diagnosed with BCa. 2,300 men are diagnosed with BCa in the US each year, with limited up-to-date statistics on male breast cancer incidence in Europe. In 2013, there were almost 93,500 deaths in Europe, 1,000 were male and the rest were female. In the US, there were almost 40,000 and 440 deaths (females and males respectively) attributable to the disease.

While estrogen deprivation is currently the standard of care for ER+ BCa, the majority of patients eventually develop resistance. ER+ patients comprise ~75% of all metastatic breast cancer cases, and TNBC accounts for ~15-20%. TNBC has a more aggressive course than ER+ BCa does but both have poor survival rates post-failure of endocrine and/or chemotherapy.

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. Prostate cancer afflicts nearly 240,000 men in the US and 343,000 in Europe each year. Approximately 36,000 men in the US and 71,000 in Europe die due to prostate cancer each year.

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

Innocrin discovers and develops novel oral inhibitors of CYP17 lyase and the AR. Innocrin wholly owns the patents that protect seviteronel and structurally related classes of CYP17 lyase-selective inhibitors. CYP17 lyase inhibitors may have high commercial potential for the treatment of a wide array of cancers including ovarian, liver, bladder, and head and neck. In addition, Innocrin has plans to develop CYP17 lyase inhibitors for the treatment of non-oncologic syndromes that are 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.

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