Innocrin Pharmaceuticals Appoints Fred Eshelman, PharmD as CEO and is Granted Fast Track Designation by FDA for Seviteronel Treatment of Women with Triple-negative Breast Cancer and Women or Men with Estrogen Receptor-positive Breast Cancer

- *Enrollment is complete for the female estrogen receptor-positive (ER+) cohort in its Phase 2 seviteronel breast cancer study, with enrollment in the female triple-negative and male ER+ cohorts ongoing.*
- *Phase 2 seviteronel castration-resistant prostate cancer (CRPC) study enrollment is ongoing.*
- *New non-clinical pharmacology data of seviteronel in breast and prostate cancer models was presented at the American Association of Cancer Research (AACR) annual meeting and will be presented at the American Urological Association (AUA) annual meeting.*

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RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Innocrin Pharmaceuticals, Inc., a clinical-stage company focused on the development of the oral, selective CYP17-lyase/androgen receptor (AR) inhibitor, seviteronel, announced today the appointment of Fred Eshelman, PharmD, of Eshelman Ventures® as Chief Executive Officer, effective March 15, 2017.

“We believe that the award of a second Fast Track designation for seviteronel, in addition to men with castration resistant prostate cancer (CRPC), is continued FDA recognition of the compound’s potential to address significant unmet medical need in hormone-dependent cancers”

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Douglas Reed, MD, Innocrin Chairman of the Board stated, “I am pleased to have Fred lead the Innocrin team as the company enters mid-stage clinical development for breast and prostate cancer. His transactional and drug development expertise will serve Innocrin well as the company and its clinical programs continue to mature.”

Fred Eshelman is the founder of Eshelman Ventures LLC, an investment company primarily interested in private healthcare companies. Previously he founded and served as CEO and Executive Chairman of Pharmaceutical Product Development (NASDAQ: PPD). After PPD he served as Founding Chairman and largest shareholder of Furiex Pharmaceuticals (NASDAQ: FURX), which was sold to Forest Labs/Actavis in July, 2014. His career has also included positions as senior vice president of development and board member of the former Glaxo, Inc., as well as various management positions with Beecham Laboratories and Boehringer Mannheim Pharmaceuticals.

“As the lead investor of Innocrin’s last round of financing, I am fully committed to the success of the seviteronel clinical development programs, since the drug provides novel treatment options for breast

and prostate cancer sub-types where patients have failed other therapies. I am not only investing in seviteronel, but also betting on members of the development team as I join the company's day-to-day leadership," said Dr. Eshelman.

Innocrin also announced that the FDA granted a second Fast Track Designation for seviteronel (VT-464). The new designation is for the treatment of women with advanced AR+ triple-negative breast cancer (TNBC) and women or men with advanced estrogen receptor-positive (ER+) breast cancer.

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 a second Fast Track designation for seviteronel, in addition to men with castration resistant prostate cancer (CRPC), is continued FDA recognition of the compound's potential to address significant unmet medical need in hormone-dependent cancers," stated Dr. Eshelman.

Edwina Baskin-Bey, M.D. Innocrin Chief Medical Officer stated, "Granting of the FDA Fast Track Designation for seviteronel treatment of women and men with advanced breast cancer helps to accelerate our already aggressive clinical development programs. Increased FDA collaborations and rolling reviews for both CRPC and breast cancer will allow for us to continue our momentum of bringing seviteronel to patients in need of new treatment options."

Innocrin also announced that it recently completed enrollment of women with ER+ breast cancer in the Phase 2 CLARITY (**C**YP17**L**yase and **A**ndrogen **R**eceptor **I**nhibitor **T**reatment with Seviteronel) study (INO-VT-464-006; NCT02580448) and enrollment of women with TNBC and men with ER+ breast cancer is ongoing. Phase 2 enrollment in its prostate cancer studies are also ongoing in men who have progressed following abiraterone, enzalutamide or both.

Innocrin also announced presentations at the American Association of Cancer Research (AACR) annual meeting (1-5 April 2017) and the upcoming American Urological Association (AUA) annual meeting (12-16 May 2017) describing new combination and single-agent seviteronel results in breast and prostate models resistant to approved therapies. Updated Phase 2 breast cancer clinical results will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting (2-6 June 2017).

About Seviteronel (VT-464)

Seviteronel is a once-daily oral therapeutic given without prednisone. Seviteronel 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 breast cancer 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+ breast cancer cells more potently than enzalutamide. Phase 2 enrollment of women and men with breast cancer is ongoing in the CLARITY-01 (**C**YP17 **L**yase and **A**ndrogen **R**eceptor **I**nhibitor **T**reatment 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 10 December 2015. Enrollment is ongoing in two Phase 2 studies (NCT02012920, NCT02445976).

About Breast Cancer

Each year over 230,000 women and 2,300 men are diagnosed with breast cancer in the United States, with almost 40,000 and 440 deaths 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 each year in the US and approximately 36,000 men die due to metastatic CRPC.

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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