Innocrin Pharmaceuticals, Inc. Appoints Edwina Baskin-Bey, MD as Chief Medical Officer and Expands the Ongoing Phase 2 Study of Seviteronel in Women with Estrogen Receptor-positive or Triple-negative Breast Cancer (TNBC)

- *Edwina Baskin-Bey, MD joins Innocrin as Chief Medical Officer, overseeing all aspects of seviteronel (VT-464) development. Seviteronel is currently in Phase 2 clinical studies for women with TNBC or estrogen receptor-positive (ER+) breast cancer (BCa) and in Phase 1 / 2 studies for men with castration-resistant prostate cancer (CRPC) whose disease has progressed following abiraterone or enzalutamide alone or both abiraterone and enzalutamide.*

- *Oral once-daily seviteronel has demonstrated therapeutic activity in Stage 1 of Phase 2 studies in women with TNBC or ER+ BCa. Due to this proof-of-concept achievement, full Phase 2 enrollment has commenced. Updated Phase 2 clinical results will be presented on December 8, 2016 at the San Antonio Breast Cancer Symposium.*

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Innocrin Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing the oral, dual-mechanism, selective CYP17 lyase and androgen receptor (AR) inhibitor, seviteronel, for the treatment of breast and prostate cancers resistant to recently-approved hormonal therapies, today announced the appointment of Edwina Baskin-Bey, MD as Chief Medical Officer, effective August 30, 2016.

William Moore, PhD, Innocrin Chief Executive Officer stated, “I’m very pleased to welcome Edwina to the senior management team. Her strong development experience with AR pathway-targeted therapies such as abiraterone, enzalutamide, and apalutamide will serve Innocrin well as we move into later-stage Phase 2 breast and prostate cancer clinical studies.”

Dr. Baskin-Bey has extensive oncology research and drug development experience. Immediately prior to joining Innocrin, she led several prostate cancer development programs at Janssen as Global Director of Oncology Development. Prior to Janssen, she was Global Director of Oncology Development at Astellas Pharma, with responsibility for the development of various (Phase 0-4) oncology products, including enzalutamide. Following receipt of a Doctorate in Medicine degree from Mount

Sinai/NYU, Dr. Baskin–Bey trained as a general surgeon at the Mayo Clinic, performing basic scientific and clinical research through the National Institutes of Health.

Said Dr. Baskin-Bey, "I am excited to join Innocrin as the company expands its Phase 2 breast and castration-resistant prostate cancer development programs. Seviteronel holds great promise for late-stage breast and prostate cancer patients whose disease has progressed while on currently available therapies."

Innocrin also announced that once-daily oral seviteronel has advanced to Stage 2 in both the ER+ and AR+ triple-negative breast cancer (TNBC) groups in its ongoing open-label Phase 2 study (NCT02580448). 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 the ER+ and TNBC populations based upon early signs of significant therapeutic activity.

Dr. Baskin-Bey commented, "It is encouraging to see early signs of single-agent seviteronel clinical benefit in these two breast cancer patient populations which are in need of new treatment options. The combined inhibition of CYP17 lyase and the AR is a novel approach for the treatment of TNBC and ER+ disease. Seviteronel potentially addresses an unmet medical need for women whose breast cancer has progressed despite treatment with traditional ER-targeting agents or chemotherapy."

Innocrin will present updated Phase 2 clinical study results from 7:30-9:00 AM on December 8, 2016 at the San Antonio Breast Cancer Symposium (poster P2-08-04).

About Seviteronel (VT-464) Seviteronel is a once-daily oral therapeutic that can be 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 blocks the growth of resistant ER+ and AR+ breast cancer cells more potently than enzalutamide.

A growing body of preclinical and clinical evidence shows that seviteronel blocks the growth of deadly, castration-resistant prostate cancer 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*).

About Breast Cancer Each year over 230,000 women are diagnosed with breast cancer 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 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. Innocrin wholly owns the patents that protect seviteronel and structurally related classes of CYP17 lyase-selective inhibitors. CYP17 lyase inhibitors may also have high commercial potential for the treatment of other cancers including ovarian, liver, bladder, and head and neck. In addition, Innocrin has interest in 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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