ESSA Pharma Inc. Receives FDA Response on IND Application

Houston, Texas and Vancouver, Canada, May 4, 2015 -- ESSA Pharma Inc. ("ESSA" or the "Company") [TSX-V: EPI] announced today that it has received notification from the Food and Drug Administration ("FDA" or the "Agency") in the US that the Company’s IND application, filed March 31, 2015, has been placed on clinical hold pending receipt by the FDA of additional chemistry and pharmaceutical data related to the stability of the drug substance and drug product and a Certificate of Analysis on drug product.

The Company had sought approval of their IND application for the treatment of patients with metastatic castration-resistant prostate cancer who failed abiraterone and/or enzalutamide. The IND application is a complete description of the chemistry, non-clinical pharmacodynamics and pharmacokinetics, animal toxicology, manufacturing, and other relevant information related to EPI-506.

“We fully appreciate the Agency’s perspective." stated Bob Rieder, ESSA’s CEO. “We will submit the required data as soon as they are available for the Agency’s review. The delay caused by this circumstance is not expected to be significant, since the availability of those data had already been built in to the timelines prior to the IND submission. We have targeted Q3/2015 for first-patient-in, and that guidance remains valid”.

EPI-506 was designed to block a novel target on the androgen receptor, the N-terminal domain. Inhibition of the N-terminal domain of androgen receptor has the potential to block tumor growth after current hormone-therapy drugs have failed. That potential has been demonstrated in several well-accepted in vitro and in vivo studies showing that EPI-506 inhibits tumor growth in those prostate cancer models. The target patient population for EPI-506 – metastatic castration resistant prostate cancer ("mCRPC") patients who have failed current hormone therapies – represents the greatest unmet medical need in this therapeutic area.

In its upcoming Phase 1/2 clinical trial, ESSA intends to demonstrate the safety, tolerability, maximum tolerated-dose, pharmacokinetics, and efficacy of EPI-506 in metastatic CRPC patients who have failed abiraterone or enzalutamide or both.

Contact Information:

Bob Rieder
CEO, ESSA Pharma Inc.
T: 778-331-0962; 832-831-5958, (ext 108)
E: brieder@essapharma.com

Dr. Frank Perabo
Chief Medical Officer,
ESSA Pharma Inc.
T: 832-831-5958, (ext 103)
E: fperabo@essapharma.com

About Prostate Cancer

Prostate cancer is the second most commonly diagnosed cancer among men and the fifth most common cause of male cancer death worldwide (Globocan, 2012). Adenocarcinoma of the prostate is dependent on androgen for tumor progression and depleting or blocking androgen action has been a mainstay of hormonal treatment for over 6 decades. Although tumors are often initially sensitive to medical or surgical therapies that decrease levels of testosterone (i.e., ADT), disease progression despite castrate levels of testosterone generally represents a transition to the lethal variant of the disease (mCRPC) and most patients ultimately succumb to the illness. The treatment of mCRPC patients has evolved rapidly over the past 5 years; despite these advances, additional treatment options are needed to improve clinical outcomes in patients, particularly those who fail existing treatments including Abiraterone or Enzalutamide or those that have contraindications to receive those drugs. Over time, patients with mCRPC generally experience continued disease progression, worsening pain, leading to substantial morbidity and limited survival rates. In both in-vitro and in-vivo studies, ESSA’s novel approach...
to blocking the androgen pathway has been shown to be effective in blocking tumor growth when current therapies are no longer effective.

**Forward-Looking Statement Disclaimer**

This release contains certain information which, as presented, constitutes “forward-looking information” within the meaning of applicable Canadian securities laws. Forward-looking information involves statements that relate to future events and often addresses expected future business and financial performance, containing words such as “anticipate”, “believe”, “plan”, “estimate”, “expect”, and “intend”, statements that an action or event “may”, “might”, “could”, “should”, or “will” be taken or occur, or other similar expressions and includes, but is not limited to, statements about the IND application and review process; the Company’s intention to recruit patients into its proposed Phase 1/2 clinical trial in Q3 2015; the Company’s ability to advance product candidates into, and successfully complete, clinical trials; and the implementation of the Company’s business model and strategic plans.

Forward-looking statements and information are subject to various known and unknown risks and uncertainties, many of which are beyond the ability of ESSA to control or predict, and which may cause ESSA’s actual results, performance or achievements to be materially different from those expressed or implied thereby. Such statements reflect ESSA’s current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by ESSA as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. In making forward looking statements, ESSA may make various material assumptions, including but not limited to (i) timelines for the IND application and review process and proposed Phase 1/2 clinical trial; (ii) obtaining positive results of clinical trials; (iii) obtaining regulatory approvals; and (iv) general business, market and economic conditions.

Forward-looking information is developed based on assumptions about such risks, uncertainties and other factors set out herein and in ESSA’s prospectus dated December 5, 2014 under the heading “Risk Factors”, a copy of which is available on ESSA’s profile at the SEDAR website at [www.sedar.com](http://www.sedar.com), and as otherwise disclosed from time to time on ESSA’s SEDAR profile. Forward-looking statements are made based on management's beliefs, estimates and opinions on the date that statements are made and ESSA undertakes no obligation to update forward-looking statements if these beliefs, estimates and opinions or other circumstances should change, except as may be required by applicable Canadian securities laws. Readers are cautioned against attributing undue certainty to forward-looking statements.