

## **ESSA Pharma Presents Therapeutic Potential of EPI-7386 at 2020 Virtual American Urological Association (AUA) Annual Meeting**

**Houston, Texas and Vancouver, Canada, May 15, 2020** – ESSA Pharma Inc. (Nasdaq: EPIX; TSX-V: EPI), a clinical-stage pharmaceutical company focused on developing novel therapies for the treatment of prostate cancer, today presented new preclinical data on ESSA's clinical candidate, EPI-7386, at the 2020 Virtual American Urological Association ("AUA") Annual Meeting.

In an oral poster presentation titled, "The preclinical characterization and development of EPI-7386, an N-terminal domain androgen receptor inhibitor for the treatment of prostate cancer", a more in-depth preclinical characterization of EPI-7386 including gene expression analyses and the toxicologic profile was presented. The studies highlight new information about EPI-7386 including:

- ***In vitro* cellular gene expression analyses demonstrate that EPI-7386:**
  - Inhibits androgen-induced genes with major similarities but some differences from enzalutamide in a cellular model sensitive to androgen receptor inhibitors.
  - In the same cellular model, the combination of enzalutamide and EPI-7386 inhibits androgen-induced gene expression more completely and broadly.
  - EPI-7386 shows superiority to enzalutamide in inhibiting androgen-induced genes in an androgen receptor resistant model, and in contrast to enzalutamide, also blocks genes induced by the AR-V7 androgen receptor splice variant.
  
- **Toxicology studies evaluating the safety profile of EPI-7386 demonstrate that:**
  - Very high plasma exposures of EPI-7386 were achieved across all studies.
  - The drug was well tolerated at both the low and middle doses, corresponding to drug plasma exposures 2-5 fold higher than the efficacious exposures achieved in mouse xenograft models.
  - The highest doses tested were characterized as the HNSTD (highest non-severely toxic dose) and only exhibited body weight loss and reduced food consumption. The drug plasma exposures achieved at this high dose were 7-10 fold higher than the efficacious exposures achieved in mouse xenograft models.
  
- **The starting clinical dose of EPI-7386 will be 200 mg given once-daily**

"The breadth of *in vitro* and *in vivo* studies utilized to profile EPI-7386 preclinically demonstrate an encouraging profile for EPI-7386 across a variety of antiandrogen sensitive and antiandrogen-resistant cellular models, xenograft and patient-derived xenograft mouse models, and gene expression analyses. The favorable toxicologic profile of EPI-7386 observed in our IND-enabling studies at very high exposures will permit initiation of the Phase 1 study at a dose of 200 mg per day, which should allow us to reach biologically relevant blood levels of EPI-7386 in patients quickly," said Dr. David R. Parkinson, President & Chief Executive Officer. "We look forward to beginning patient dosing soon in our initial phase 1 study of EPI-7386 in mCRPC patients whose tumors are progressing on current anti-androgens."

## **About ESSA Pharma Inc.**

ESSA is a clinical-stage pharmaceutical company focused on developing novel and proprietary therapies for the treatment of castration-resistant prostate cancer in patients whose disease is progressing despite treatment with current therapies. ESSA's proprietary "aniten" compounds bind to the N-terminal domain of the androgen receptor ("AR"), inhibiting AR driven transcription and the AR signaling pathway in a unique manner which bypasses the drug resistance mechanisms associated with current anti-androgens. The Company is currently conducting a phase 1 study of EPI-7386 in patients with metastatic castration-resistant prostate cancer ("mCRPC") who are failing current standard-of-care therapies. For more information, please visit [www.essapharma.com](http://www.essapharma.com) and follow us on Twitter under @ESSAPharma.

## **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, 2018). 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 six decades. Although tumors are often initially sensitive to medical or surgical therapies that decrease levels of testosterone, 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 five 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 who 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 animal 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 the Private Securities Litigation Reform Act of 1995 and/or 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, the timing and enrollment of a Phase 1 study of EPI-7386, future presentations with respect to EPI-7386 and the content thereof, and other statements regarding EPI-7386, including those surrounding the Company's clinical evaluation of EPI-7386.

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) the accuracy of ESSA's financial projections; (ii) obtaining positive results of clinical trials; (iii) obtaining necessary 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 Annual Report on Form 20-F dated December 19, 2019 under the heading "Risk Factors", a copy of which is available on ESSA's profile on the SEDAR website at [www.sedar.com](http://www.sedar.com), ESSA's profile on EDGAR at [www.sec.gov](http://www.sec.gov), 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 and United States securities laws. Readers are cautioned against attributing undue certainty to forward-looking statements.

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