ESSA Pharma Announces Fast Track Designation Granted by the FDA to EPI-7386 for the Treatment of Metastatic Castration-Resistant Prostate Cancer

Houston, Texas and Vancouver, Canada, September 14, 2020 – ESSA Pharma Inc. (Nasdaq: EPIX; TSX-V: EPI) ("ESSA" or the "Company"), a clinical-stage pharmaceutical company focused on developing novel therapies for the treatment of prostate cancer today announced that the U.S. Food and Drug Administration ("**FDA**") granted Fast Track Designation to EPI-7386, its oral and highly-selective N-terminal domain inhibitor of the androgen receptor, for the treatment of adult male patients with metastatic castration-resistant prostate cancer ("**mCRPC**") resistant to standard-of-care treatment.

"We are pleased with the FDA's decision to grant Fast Track designation for development of EPI-7386 to treat mCRPC patients resistant to standard-of-care treatments," said Dr. David R. Parkinson, Chief Executive Officer of ESSA Pharma. "This designation signifies recognition of the unmet medical need for new and effective treatments for this patient population. EPI-7386 may represent a promising novel treatment option for these patients and the designation offers the opportunity to interact more closely with the FDA during the development of EPI-7386."

Fast Track is a designation granted by the FDA that is intended to facilitate development and expedite review of drugs to address an unmet medical need in the treatment of a serious life-threatening condition, and for which nonclinical or clinical data has demonstrated the potential of the drug to address this medical need.

A drug that receives Fast track Designation is eligible for some, or all, of the following:

- Eligibility for accelerated approval and priority review, if relevant criteria are met
- Rolling review, enabling ESSA Pharma to submit completed sections of its New Drug Application ("**NDA**") for review by the FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed (NDA review usually does not begin until the Company has submitted the entire NDA to the FDA)
- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data to support drug approval
- More frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers

About EPI-7386 Phase 1 Study

The Phase 1 clinical trial (NCT04421222) expects to enroll approximately 18 mCRPC patients in the dose escalation part of the study at selected clinical sites in the United States and Canada, with an additional ten patients planned to be enrolled in a dose expansion cohort involving additional clinical sites. The study will evaluate the safety and tolerability of EPI-7386 while additionally characterizing the pharmacokinetic, biological and anti-tumor effects of therapy.

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. The Company filed an IND with the U.S.

Food and Drug Administration for EPI-7386 in the first calendar quarter of 2020 and clearance was received April 30,2020. A Clinical Trial Application was filed with Health Canada in April 2020 and authorization was received June 3rd, 2020. For more information, please visit 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 belief that EPI-7386 may represent a promising novel new treatment option, the potential benefits of the Fast Track designation including eligibility for accelerated approval and priority FDA review, planned enrollment of a Phase 1 study of EPI-7386, and other statements 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, ESSA's profile on EDGAR at 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.

Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

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