

# ESSA Pharma Announces Clinical Collaboration Agreement with Bayer to Evaluate the Combination of EPI-7386 and Darolutamide in Patients with Metastatic Castration-Resistant Prostate Cancer

Houston, Texas and Vancouver, Canada, April 28, 2021 – ESSA Pharma Inc. (Nasdaq: EPIX) ("ESSA" or the "Company"), a clinical-stage pharmaceutical company focused on developing novel therapies for the treatment of prostate cancer, today announced that the Company has entered into a clinical trial collaboration and supply agreement with Bayer to evaluate ESSA's lead product candidate, EPI-7386, a first-in-class N-terminal domain androgen receptor inhibitor, in combination with Bayer's androgen receptor inhibitor, darolutamide, in patients with metastatic castration-resistant prostate cancer ("mCRPC").

Under the terms of the agreement, Bayer may sponsor and conduct a Phase 1/2 study to evaluate the safety, pharmacokinetics and efficacy of the combination of EPI-7386 and darolutamide in mCRPC patients. ESSA will supply EPI-7386 for the trial and will retain all rights to EPI-7386. The clinical study is expected to start in 2021.

"We are delighted to collaborate with Bayer to explore the potential clinical role of EPI-7386 in combination with Bayer's darolutamide in patients with metastatic castration-resistant prostate cancer, who have progressed on androgen deprivation therapy," said Dr. David. R. Parkinson, Chief Executive Officer, ESSA Pharma Inc. "Combining our two therapies will simultaneously target both ends of the androgen receptor, and potentially allow for a more potent approach to suppressing androgen activity. We look forward to investigating the combination of these therapies and their potential role together in the treatment of prostate cancer."

#### About EPI-7386

EPI-7386 is an investigational, highly-selective, oral, small molecule inhibitor of the N-terminal domain of the androgen receptor. EPI-7386 is currently being studied in a Phase 1 clinical trial (NCT04421222) in men with metastatic castration-resistant prostate cancer ("mCRPC") whose tumors have progressed on current standard-of-care therapies. The Phase I clinical trial of EPI-7386 began in Q3 of 2020 following FDA allowance of the IND and Health Canada acceptance. The U.S. FDA has granted Fast Track designation to EPI-7386 for the treatment of adult male patients with mCRPC resistant to standard-of-care treatment. ESSA retains all rights to EPI-7386 worldwide.

#### **About ESSA Pharma Inc.**

ESSA is a clinical-stage pharmaceutical company focused on developing novel and proprietary therapies for the treatment of patients with prostate cancer. 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 can lead to metastatic castration-resistant prostate cancer ("mCRPC"). The treatment of mCRPC patients has evolved rapidly over

the past ten years. Despite these advances, many patients with mCRPC fail or develop resistance to existing treatments, leading to continued disease progression and limited survival rates.

## 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, statements regarding the sponsorship by Bayer of a Phase 1/2 combination study, the anticipated start date in 2021 of the clinical study, the potential results of the study 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 10-K dated December 15, 2021 under the heading "Risk Factors", a copy of which is available on ESSA's profile on EDGAR at <a href="https://www.sec.gov">www.sec.gov</a>, and as otherwise disclosed from time to time on ESSA's SEDAR profile www.sedar.com.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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