ESSA PHARMA PRESENTS DATA FROM PHASE 1 TRIAL OF EPI-506 AT 2017 ASCO ANNUAL MEETING

- Well tolerated to date with an acceptable safety profile
- Signs of clinical activity at the higher dose range
- Enrollment continues in additional cohorts at higher dose levels

Houston and Vancouver, Canada, June 5, 2017 – ESSA Pharma Inc. (TSX: EPI; NASDAQ: EPIX) (“ESSA” or the “Company”), a clinical-stage pharmaceutical company focused on the development of novel small molecule drugs for the treatment of prostate cancer, announced that early data from the Phase 1 portion of the ongoing Phase 1/2 clinical trial of its product candidate, EPI-506, were featured in a poster presentation during the 2017 American Society for Clinical Oncology (“ASCO”) Annual Meeting held in Chicago.

Prostate cancer specialist, Kim N. Chi, M.D., at the BC Cancer Agency in Vancouver, presented the poster entitled, “Efficacy, safety, tolerability and pharmacokinetics of EPI-506 (ralaniten acetate), a novel androgen receptor (“AR”) N-terminal domain (“NTD”) inhibitor, in men with metastatic castration-resistant prostate cancer ("mCRPC") progressing after enzalutamide and/or abiraterone.”

The data presented were from the Phase 1 portion of the ongoing Phase 1/2 clinical trial of EPI-506. The open-label, single-arm, dose-escalation study is evaluating the safety, pharmacokinetics, maximum tolerated dose ("MTD"), and anti-tumor activity of EPI-506 in men with end-stage mCRPC who have progressed after prior enzalutamide and/or abiraterone treatment, and may have received one prior line of chemotherapy. Twenty-one patients were available for analysis as of the May 12, 2017 ASCO data cut-off and each patient had received four or more prior therapies for prostate cancer at the time of study entry.

The 21 patients self-administered oral doses of EPI-506 ranging from 80 mg to 2400 mg, with mean drug exposure of 87 days (range of 21 to 427 days). Seventeen patients discontinued treatment, primarily due to progressive disease, and four remain on study. Three patients have undergone prolonged treatment (median of 286 days; range 219 – not reached), after intrapatient dose escalation. Prostate-specific antigen (“PSA”) declines ranging from 4% to 29% have been observed in four patients at higher doses (≥1280 mg). An analysis of human drug exposures (AUC) compared to exposure levels derived from a xenograft model of castration resistant prostate cancer (“CRPC”) showed that EPI-506 doses of ≥2400 mg were beginning to reach the anticipated target range for significant tumor growth inhibition as indicated by the model. Additional Phase 1 cohorts continue to be enrolled to evaluate a 3600 mg dose (either once-daily or 1800 mg twice-daily).

EPI-506 was well tolerated and demonstrated an acceptable safety profile in doses up to 2400 mg. No treatment-related serious adverse events were reported. The most common adverse events ("AEs") were diarrhea (8/21) and nausea (6/21), either Grade 1 or 2. Anemia was the only AE ≥Grade 3 observed in more than one patient (3/21) but was considered by investigators to be unrelated to EPI-506. Other AEs ≥Grade 3 considered potentially related to EPI-506 included a single case of elevated AST reported as possibly related, and a single case of elevated amylase deemed probably related ("DLT").
“To see some indication of PSA responses in such a heavily treated patient population is encouraging. Given the acceptable safety and tolerability seen to date, we look forward to additional data that will be forthcoming from patients receiving higher doses of EPI-506,” said Dr. Chi. “Prostate cancer is the second most common cancer in men. Despite the therapeutic advances made in recent years, prostate cancer patients eventually progress on these treatments, so finding new options to complement or follow these therapies is absolutely essential.”

“EPI-506 represents a novel approach to blocking the androgen pathway, and we are very pleased to have our first clinical data presented at ASCO,” said David R. Parkinson, M.D., President and Chief Executive Officer of ESSA. “We have observed signs of clinical activity at the higher doses in this analysis, which correlates with our preclinical modeling, and are continuing to enroll patients in dose cohorts higher than those reported here.”

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 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.

About ESSA Pharma Inc.
ESSA is a clinical-stage pharmaceutical company focused on developing novel and proprietary therapies for the treatment of CRPC in patients whose disease is progressing despite treatment with current therapies. ESSA believes that its product candidate, EPI-506, can significantly expand the interval of time in which patients suffering from CRPC can benefit from hormone-based therapies. Specifically, EPI-506 acts by disrupting the AR signaling pathway, which is the primary pathway that drives prostate cancer growth. EPI-002, the primary metabolite of EPI-506, prevents AR transcriptional activity by binding selectively to the NTD of the AR. A functional NTD is essential for transactivation of the AR. In preclinical studies, blocking the NTD has demonstrated the capability to overcome the known AR-dependent mechanisms of CRPC. ESSA was founded in 2009.

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 about the Company’s Phase 1 clinical trial, including data and results thereof, and the Company’s planned announcement of such data and results; expectations regarding the initiation of the Phase 2 dose expansion study, including statements about the dose levels and expected timing thereof; 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) the accuracy of ESSA’s financial projections; (ii) the Phase 1 portion of the Phase 1/2 clinical trial proceeding as expected; (iii) obtaining positive results of clinical trials; (iv) obtaining necessary regulatory approvals; and (v) 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 14, 2016 under the heading “Risk Factors”, a copy of which is available on ESSA’s profile at 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.

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