KELOWNA PROSTATE CANCER SUPPORT & AWARENESS GROUP

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We hope that all those who receive our newsletter are staying safe and are beginning to be in line for getting the vaccine for this pandemic that we have been going through for over a year. This pandemic has been extremely hard on everyone, with all of us keeping to ourselves self-isolating or else keeping in our small bubble of family and maybe a very few friends.

According to some new information recently released by Health Canada, Canada has now approved a fourth vaccine for COVID-19. We will now have available the Pfizer, Moderna, AstraZeneca and the Johnson & Johnson vaccines. If we get vaccinated when it is our turn, we may be able to have in person meetings again beginning in the fall of this year

If anyone has any questions or concerns that I may be able to help with, please feel free to contact me either by email or on our home phone at - 250-762-0607.

Just remember what Dr. Bonny Henry says – Be Kind, Be Calm and Be Safe.

ESSA Pharma Presents Favorable Initial Phase 1 Clinical Pharmacology Data of EPI-7386

The following is an excerpt of a news release dated February 11, 2021 that was sent to me by Dr. Marianne Sadar.

ESSA Pharma Inc., a clinical-stage pharmaceutical company focused on developing novel therapies for the treatment of prostate cancer, presented preclinical and clinical pharmacology data from ESSA's Phase 1 clinical trial of EPI-7386 for the treatment of patients with metastatic castration-resistant prostate cancer ("mCRPC") at the 2021 American Society of Clinical Oncology Genitourinary ("ASCO GU") Cancers Symposium.

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 in men with metastatic castration-resistant prostate cancer ("mCRPC") whose tumors have progressed on current standard-of-care therapies. The phase 1 clinical trial of EPI-7386 began in the 3rd. quarter of 2020 following FDA allowance of the IND and Health Canada acceptance. The FDA 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.

Data highlights compare preclinical projections of EPI-7386's clinical pharmacokinetic parameters to the pharmacokinetic, safety and preliminary clinical data from the initial 200 mg cohort of patients enrolled in ESSA's multi-center, open-label, ascending multiple-dose Phase 1 study of EPI-7386 to treat patients with mCRPC who have become resistant to standard of care treatments. Patients participating in this trial have progressed on two or more approved systemic therapies for mCRPC, including at least one second generation androgen therapy not necessarily in the metastatic disease setting. In this initial cohort of patients receiving the 200 mg once-daily dose, EPI-7386 was well tolerated with no serious adverse events (side effects) observed. The results from this cohort support ESSAs preclinical projections regarding the pharmacologic properties of EPI-7386 in patients. EPI-7386 was well absorbed, demonstrated high exposure levels and was confirmed to have a long half life of at least 24 hours. The predicted exposures of EPI-7386 in patients were similar to the modeled projections and were still below optimal exposures of EPI-7386 associated with anti-tumor activity in animal models. *Despite the suboptimal 200 mg dose, one of three patients who completed 12 weeks of therapy experienced a prostate specific antigen ("PSA") decline of more than 50 percent after three cycles of EPI-7386 (12 weeks) with ongoing continued PSA declines continuing through six cycles of therapy, despite previously having failed enzalutamide and abiraterone acetate.* ESSA recently competed the 28-day safety evaluation period for the 400 mg dose cohort and is currently dosing patients in the 600 mg cohort.

"The results from the initial clinical data suggest a favorable pharmacokinetic profile of EPI-7386 in patients," said Dr. David R. Parkinson, President and Chief Executive Officer of ESSA pharma Inc. "Additionally, the data demonstrate proof of concept suggesting that EPI-7386, through its novel mechanism of action of targeting the N-terminal domain, may bypass the resistant mechanism mCRPC may experience on current antiandrogen therapies. While early in our clinical study, we are encouraged to have seen early signs of biological activity and declining PSA levels in a multi-refractory patient at the initial 200 mg dose.

An accurate assessment of the full safety and tolerability profile as well as the potential clinical benefits to therapy with EPI-7386 will require longer observation of more patients treated at higher doses. We look forward to continuing to conduct Phase 1 dose escalation study and anticipate providing more clinical data on the progress of the study in the second half of 2021."

About ESSA Pharma Inc.

ESSA is a clinical-stage pharmaceutical company focused on developing novel and propriety therapies for the treatment of patients with prostate cancer.

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 the 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 had 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.

EDITOR'S NOTE:

EPI-7386 has been a long time coming. *Dr. Marianne Sadar* started work in her lab at the BC Cancer Research facility in Vancouver close to 25 years ago, with the goal of finding something to treat men with mCRPC. EPI-7386 has gone through many changes during its years of development. EPI-7386 is the latest version of a drug that was originally synthesized and developed from a very specific sea sponge found in the South Pacific Ocean.

WITT'S WIT (ON THE LIGHTER SIDE) –

We Love Children
Ketchup

A woman was trying to get the ketchup out of the jar. During her struggle the phone rang so sheasked her four-year-old daughter to answer the phone. It was the minister calling. 'Mommy can't come to the phone to talk to you right now. She's hitting the bottle.'

Enzalutamide Plus ADT Effective in Metastatic Prostate Cancer –

The following is an excerpt of a report from Medial Dialogues and originated in the *Journal Urology* –

Researchers from *Duke Cancer Institute Center for Prostate & Urological Cancers*, Durham, North Carolina have recently noted that treatment with enzalutamide plus ADT provides improvements in men with bone and/or lymph node metastases but

may be less effective in men with visceral patterns of spread, according to the study published in the *Journal Urology.*

Enzalutamide plus ADT has previously been shown to improve clinical outcomes in men with metastatic hormone sensitive prostate cancer. Hence, Andrew J. Armstrong and colleagues conducted the study to assess if and how the pattern of metastatic spread impacts efficacy of enzalutamide plus ADT in men enrolled in ARCHES.

Men with metastatic hormone sensitive prostate cancer were randomized 1:1 to enzalutamide (160mg.day) plus ADT or placebo plus ADT, stratified by disease volume and prior docetaxel treatment. The primary endpoint was radiographic progression-free survival. Secondary endpoints included time to prostate specific antigen progression, initiation of a new therapy, first symptomatic skeletal event and castration resistance. Post hoc analyses were performed by pattern of metastatic spread based on study entry imaging.

The following results were observed –

a, Of the overall population with metastases identified at enrollment (1,146), the largest patient subgroups were those with bone metastases only (513), and those with bone plus lymph node metastases (351); there were fewer men with lymph node metastases only (154) and men with visceral + bone or lymph node metastases (128).

b, Enzalutamide plus ADT reduced the risk of radiographic progression versus placebo plus ADT in men with bone metastases only and bone plus lymph node metastases.

c. Similar improvements in secondary end points were also observed in those subgroups.

Therefore, the investigators concluded that "treatment with enzalutamide plus ADT provides improvements in men with bone and/or lymph node metastases but may be less effective in men with visceral patterns of spread."

The Kelowna Prostate Cancer Support & Awareness group does not recommend treatment modalities or physicians: However, all information is fully shared and is confidential. The information contained in this newsletter is not intended to replace the services of your health professionals regarding matters of your personal health.

The Kelowna Prostate Cancer Support & Awareness Group would like to thank Janssen - and TerSera for their support and their educational grants towards our newsletters and our support group.

UP COMING MEETING DATES FOR 2020 –

Due to the COVID-19 virus we are still NOT holding monthly Support group Meetings.

NOTE: I will be in touch with everyone whenever it is safe to get back to holding regular meetings.

NOTE: Many of our past newsletters are available for viewing and printing through our website. – www.kelownaprosate.com

- A big *Thank You to Doris at Affordable Web Design for all her work on our website.*