

PRESS RELEASE

Zeist, the Netherlands, December 12, 2019

THE PREGNANCY HORMONE ESTETROL HAS DUAL EFFICACY IN THE TREATMENT OF END-STAGE BREAST CANCER.

The pregnancy estrogen Estetrol (E4) has a DUAL effect when treating heavily-pre-treated women with advanced breast cancer who have no further treatment options. First, E4 has an anti-tumor effect and second, E4 improves wellbeing.

The Dutch biotech company Pantarhei Oncology presents on December 13, 2019 at the San Antonio Breast Cancer Symposium (SABCS) in the USA the results of the first clinical study with High Doses of the fetal estrogen Estetrol (HDE4) in women with advanced end-stage breast cancer. Nine women without further treatment options participated in the study and were treated with 20, 40 or 60 mg E4 per day for 12 weeks. Anti-tumor effects after 12 weeks treatment were confirmed in 5 of 9 women and strong improvement of wellbeing occurred in 7 of 9 patients.

Estetrol is a natural estrogenic hormone, synthesized exclusively in large quantities by the fetal liver during human pregnancy. Blood levels are high in the unborn child and high, but somewhat lower in the pregnant mother.

IMPROVEMENT OF QUALITY OF LIFE

Women with advanced, estrogen sensitive breast cancer (75% of all breast cancer patients) are generally treated first with anti-estrogen drugs such as tamoxifen, aromatase inhibitors and fulvestrant and more recently also with CDK4/6 inhibitors and everolimus. These treatments are effective for some time, but recurrence of tumor growth occurs in almost all cases, leaving only chemotherapy as the final treatment option. However, at that stage, the tumors may have become sensitive to High Dose Estrogen (HDE) treatment. In addition, due to previous anti-estrogen treatment, most of these patients have developed serious estrogen deficiency complaints such as extreme fatigue, frequent hot flashes, sleep disturbances, mood changes and depression, sexual problems, cognition and concentration disturbances and they may also lose bone mass and have an increased risk of fractures. These signs and symptoms of estrogen deficiency are influenced favorably by HDE4 treatment, with significant improvement of quality of life.

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THE DUAL EFFICACY OF ESTETROL

The principle investigator of the study at the University Hospital in Mainz, Germany, Prof Marcus Schmidt, says: “We were confident about the safety of Estetrol, but its dual efficacy, the anti-tumor effect and the positive effect on wellbeing, surprised us. This ‘feeling better phenomenon’ was described by one of my patients as ‘feeling less down and exhausted; instead feeling much more optimistic, powerful and positive on Estetrol’”. This patient had serious depression during earlier anti-estrogenic treatments. After completion of the 12-week study, she asked for continuation of E4 treatment and she has now been using HDE4 for almost two years.

Further larger studies are needed to confirm these findings, which requires an investment of €20 million. Pantarhei is looking for a pharmaceutical partner or other investors to continue the development of Estetrol and make this new DUAL efficacy treatment available for patients with end-stage advanced breast cancer as soon as possible.

FOR MORE INFORMATION

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