

PRESS RELEASE

Positive advice of the EMA for contraceptive pill with Estetrol after earlier approval by Health Canada

Zeist, 31 March 2021 – Pantarhei Bioscience announces that the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) has published a positive opinion for a novel combined oral contraceptive (OC) containing 15 mg estetrol (E4) and 3 mg drospirenone (DRSP), developed by Pantarhei Bioscience and Mithra Pharmaceuticals. Subject to approval by the European Commission, the marketing authorization valid for all European Union Member States is expected to be granted by the end of the second quarter 2021. The product will be marketed in Europe by the Hungarian company Gedeon Richter under the brand name Drovelis®.

Estetrol is a natural estrogen, synthesized by the human fetus during pregnancy only. Estetrol is present in high concentrations in the blood of the fetus and in 10-20 lower levels in the blood of pregnant woman. The E4 in drugs for human use is synthesized from soy plant estrogen precursors and does not contain other estrogens.

Estetrol has been identified in 1965 by Egon Diczfalusy at the Karolinska Institute in Stockholm, Sweden. In 2000, Herjan Coelingh Bennink has discovered E4 as a new and safer estrogen for human use and founded the biotech company Pantarhei Bioscience to develop this forgotten natural hormone for oral anticonception and for menopausal hormone therapy (MHT). In 2014 Pantarhei Oncology was founded for the development of high dose E4 (HDE4) for the treatment of advanced breast cancer (BC) and advanced prostate cancer (PC). The basic concept behind the development of E4 as an estrogenic drug for human use was, that an estrogen present in such high amounts during human pregnancy must be a safe hormone. This was confirmed by multiple preclinical and phase I and II clinical studies performed by Pantarhei Bioscience since 2001, demonstrating that E4 indeed had less effect on liver function and blood coagulation compared with other existing natural and synthetic estrogens. In 2015 Pantarhei Bioscience has sold her E4 portfolio to Mithra Pharmaceuticals for further development as an OC and for MHT, whereas Pantarhei Oncology focused on the oncological applications of HDE4 for advanced BC and PC.

Herjan Coelingh Bennink, President of Pantarhei Bioscience: “We are very pleased with the positive advice of the CHMP/EMA, confirming the safety of an E4 containing OC for young healthy women in need for safe and reliable oral contraception. Experts in hormonal contraception, including Prof Carolyn L. Westhoff (Columbia University, NY, USA and Editor-in-Chief of Contraception) and Prof Kristina Gemzell-Danielsson (the WHO-Collaborating Centre for Research in Human Reproduction, Karolinska Institutet and Karolinska University Hospital, Stockholm, Sweden), have expressed their scientific support for this new OC concept. At Pantarhei Oncology, we hope to be able to demonstrate the advantages of HDE4 for the treatment of advanced breast and prostate cancer in the near future. Clinical studies with HDE4 have already demonstrated “proof-of-concept” for both applications”.

About Pantarhei

Founded by the former Director R&D “Women’s Health” (WH) of Organon, Herjan Coelingh Bennink, Pantarhei Bioscience and Pantarhei Oncology are Dutch biopharmaceutical companies, developing unique and innovative, patent protected, new treatment concepts in the areas of WH and “Reproductive Endocrine Oncology” until “proof-of-concept” phase II in humans. All research and development activities are outsourced, creating almost virtual companies.

At present Pantarhei Oncology is focusing on the further oncological development of HDE4, preparing phase II (breast cancer) and phase III (prostate cancer) clinical studies. In addition, PRO is developing a new anti-cancer immunotherapy based on the natural ovarian antigen Zona Pellucida 3 (ZP3), for the treatment of tumors expressing ZP3 such as ovarian and non-small cell lung cancer (NSCLC).

<https://www.pantarheibio.com/>

<https://www.pantarheioncology.nl/>