# PRESS RELEASE
# European Commission approves new oral contraceptive containing E4
## Dutch pill previously approved in the USA and Canada

**Zeist, the Netherlands, 21 May 2021 – Pantarhei Bioscience announced today that the European Commission has approved the new oral contraceptive Estelle®. This contraceptive pill contains Estetrol (E4), an estrogen developed by Pantarhei Bioscience since 2000. At the end of March, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) already gave a positive opinion for Estelle®.**

With the approval of Estelle® from Mithra Pharmaceuticals by the European Commission, this new contraceptive can be marketed in all EU member states. In Europe, Gedeon Richter will be responsible for the marketing and sales of the new pill under the brand name Drovelis®. Earlier this year, the American Food & Drug Administration (FDA) and the Canadian health authority Health Canada had already approved this contraceptive pill, which was largely developed in the Netherlands.

Estelle® is composed of 15 mg Estetrol (E4) and 3 mg of the progestogen drospirenone. E4 is a natural fetal estrogen, produced by the human fetal liver during pregnancy and is present in high concentrations in the blood of the child and mother. The E4 used in Estelle® is synthesised from plant sources.

Estetrol was identified as a fetal hormone by Egon Diczfalusy at the Karolinska Institute in Stockholm (Sweden) in 1965. In 2000, Herjan Coelingh Bennink founded the biotech company Pantarhei Bioscience to develop this fetal estrogen for oral contraception (OC) and for menopausal hormone therapy (MHT). The rationale behind the development of E4 for human therapeutic use is that an estrogen present in high concentrations during human pregnancy should be a safe drug for human use. Since 2001, Pantarhei Bioscience has performed preclinical and pharmacological studies with E4 followed by phase I and phase II clinical studies aimed at safety, efficacy and dose-finding in human. These studies showed that E4 has less effect on liver function and blood coagulation compared to other estrogens. In addition, Pantarhei has obtained several patents for E4 based on these studies. In 2015, 15 years after the start of the development, Pantarhei has sold its E4 portfolio to Mithra Pharmaceuticals for final phase III development of E4 for the OC and the MHT applications. Thereafter, Pantarhei Oncology was founded for the development of the oncological applications of E4, especially aimed at advanced breast and prostate cancer.

Herjan Coelingh Bennink, founder and president of Pantarhei Bioscience and the brains behind the development of E4: “We are very pleased that the European Commission has approved the marketing of this contraceptive pill containing E4, thereby recognizing the safety of E4 for young healthy women.”

Contraception experts such as Prof. Carolyn L. Westhoff, whom is Editor-in-Chief of the journal Contraception and Professor at Columbia University (USA), as well as Prof. Kristina Gemzell-Danielsson from the Karlinska University Hospital and WHO-Center in Stockholm (Sweden), have expressed their support for this new OC concept. “We are convinced that in the future E4 can also be used in the treatment of advanced breast and prostate cancer”, says Coelingh Bennink: “Current studies with high dose E4 (HDE4) for the treatment of breast and prostate cancer show promising results and have recently been published in leading scientific journals.”

**About Pantarhei**

Pantarhei Bioscience and Pantarhei Oncology are Dutch biopharmaceutical companies developing unique innovative treatment concepts in Women's Health (WH) and Reproductive Endocrine Oncology (REO). Since its foundation in 2000 by former Director R&D WH of Organon, Herjan Coelingh Bennink, both companies have now filed more than 220 patents worldwide. Pantarhei develops patent protected new treatment concepts for Women's Health and Reproductive Endocrine Oncology up until phase II "proof-of-concept" (PoC) in humans. All research and development activities are outsourced. At present PRO is focusing on the further oncological development of high dose E4 (HDE4) for the treatment of advanced breast and prostate cancer. For both indications PoC has been demonstrated and the projects are ready for further phase II (breast cancer) and phase III (prostate cancer) clinical development. In addition, PRO is developing a new 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). This project is in the final stage of preclinical development.

https://www.pantarheibio.com/
https://www.pantarheioncology.nl/

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**Note for response, not for publication**

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