## Richter and Pantarhei signed a license and supply agreement for commercialisation of a novel combined oral contraceptive

Gedeon Richter Plc. and Pantarhei Bioscience BV today announced that they have entered into a license and supply agreement to commercialise Pantarhei's combined oral contraceptive (COC), containing 30 µg ethinyl estradiol, 150 µg levonorgestrel and 50 mg dehydroepiandrosterone (DHEA). The product is under development with successfully completed Phase II trials and is ready for further clinical studies to obtain marketing approval. The geographic scope of the agreement covers Europe, Russia, Latin America and Australia.

Under the terms of the agreement Richter shall make an upfront payment upon signature of the contract, and further milestone payments shall be made depending on the progress of the development and the commercialization of the product. In addition, further sales related royalties will become payable to Pantarhei subsequent to the launch of the product. According to the agreement Richter is responsible for the financing of all expenses related to the required clinical and post approval studies.

"The addition of this combined oral contraceptive to our currently available products provides Richter the opportunity to further enhance our existing branded female healthcare franchise, being a paramount strategic initiative for our Company," stated Gábor Orbán, Chief Executive Officer of Gedeon Richter Plc.

"Gedeon Richter is the perfect partner for Pantarhei Bioscience to bring this new oral contraceptive concept Androgen Restored Contraception (ARC) to the market. The extensive and long term experience of Richter in producing and selling hormonal products guarantees for Pantarhei a successful future for this first choice new contraceptive pill," stated Herjan Coelingh Bennink, President of Pantarhei Bioscience and inventor of the ARC concept.

**About the combined ARC oral contraceptive**

The product under development is a combined oral contraceptive containing 30 µg ethinyl estradiol, 150 µg levonorgestrel and 50 mg DHEA in each tablet. ARC is a novel concept of oral contraception developed and patent protected by Pantarhei with the aim to restore sexual function with a special focus on sexual desire and arousal and to prevent mood disturbances. This is achieved by adding DHEA to the contraceptive pill. DHEA is a natural human adrenal androgen that is metabolised partially to testosterone after oral intake, which hormone level is suppressed when fertile women use a contraceptive pill. By adding 50 mg DHEA to the pill, the testosterone levels are normalised. The longstanding safety track record of DHEA in the human at the low dose level used in this application implies safety when DHEA is added to the pill.

**About Richter**

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China and in Latin America. Having reached a market capitalisation of EUR 4.1 billion (USD 4.9 billion) by the end of 2017, Richter's consolidated sales were approximately EUR 1.4 billion (USD 1.6 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System, and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's healthcare field worldwide. Richter is also active in biosimilar product development.

**About Pantarhei**

Pantarhei Bioscience B.V. (www.pantarheibio.com), headquartered in Zeist, the Netherlands, is a privately owned Dutch biopharmaceutical company developing safe and innovative new drugs for Women's Health applications and endocrine treatment of cancer based on existing compounds. Pantarhei develops the patent protected new treatment concepts up to proof-of-concept in the human (phase II). After successful proof-of-concept, the new product is licensed out to a pharmaceutical partner for final development (phase III), regulatory approval, marketing and sales.

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