

February 28, 2020  
Fuji Pharma Co., Ltd.

## Development status of estetrol/drospirenone in Europe

We have signed the partnership agreement with Mithra Pharmaceuticals (Belgium, "Mithra") in 2016, for an exclusive license and distribution right of estetrol/drospirenone (the "Product", Company development Code: FSN-013) in Japan and ASEAN.

Mithra announced on February 27th, 2020 that European Medicines Agency ("EMA") accepted the regulatory submission for the Product submitted by Gedeon Richter Plc (Hungary, "Richter"), which retains a development and distribution right in Europe, Russia and other CIS countries for this Product (the "Mithra Release").

We have been developing the Product with a Dysmenorrhea indication and conducting Phase II study for an approval in Japan. We have also been developing the Product as an oral contraceptive drug for ASEAN countries, primarily based on the European and American clinical test data. We believe that the development progress of the Product in Europe will help our development activities in Japan and ASEAN.

The Mithra Release summary is as follows (see <https://www.mithra.com/en/ema-accepts-richters-marketing-authorization-application-maa-for-estelle-a-novel-combined-oral-contraceptive> for details):

- EMA has accepted Richter's regulatory submission for a combined oral contraceptive;
- In two phase III clinical studies conducted in 3,725 women, the Product showed positive top-line results against primary efficacy and safety endpoints; and
- The same studies achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability.

Mithra also announced on January 10, 2020, that Environmental Risk Assessment study demonstrated absence of environmental risk for the Product, its endocrine disruptive effects on the environment were insignificant in comparison to currently marketed estrogens commonly found in the aquatic environment, and it will contribute to preserving intact ground and surface waters and ecosystems in line with UN 2030 sustainable development goals (SDGs). See <https://www.mithra.com/en/e4-paves-the-road-towards-a-revolutionary-era-of-environmental-friendly-medicines> for details.

Our company has stated in our Strategy Growth towards 2030 ("Vision for 2030") that we are "Contributing to

well-being of women in the world”, and “Integrating the world’s happiest company and social contribution”. The Product will be a strong engine for us to achieve our “Vison for 2030”.

### **About Mithra**

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women’s Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra’s goal is to develop products offering better efficacy, safety and convenience, meeting women’s needs throughout their life span. Its three lead development candidates are built on Mithra’s unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment for perimenopause and Donesta®, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 85 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)

### **About Richter**

Gedeon Richter Plc. 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 capitalization of EUR 3.6 billion (USD 4.1 billion) by the end of 2019, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.7 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.

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