

REGULATED INFORMATION  
INSIDE INFORMATION



Mithra signs landmark contract for  
commercialization of Estelle® in Europe  
and Russia with Gedeon Richter

Conference call

Liege, 12-09-2018

**mithra**  
Women's Health

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# Agenda

1. Scope of agreement
2. Estelle<sup>®</sup> - Status
3. Market: Europe + Russia
4. Richter
5. Agreement Terms
6. Royalty Guidance
7. Summary

# 1. Scope of agreement

- 20-year Exclusive\* License for Estelle®
- Territories :
  - Western & Eastern Europe
  - Russia



## 2. Estelle<sup>®</sup> – Status

- Oral contraceptive product candidate composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).
- Recent positive top-line results for pivotal Phase III study in Europe and Russia\*
  - Excellent contraceptive efficacy
  - Outstanding bleeding profile, cycle control, quality of life and safety and tolerability
- Top-line results of the US/Canada Phase III study on track to report in Q1 2019

\* Cf Press release 8-08-2018 « Mithra announces positive top-line results of Estelle Phase III oral contraceptive study in EU/Russia »

# 3. Market: Europe + Russia

- The European market (including Russia) for contraceptives is valued at approximately **EUR 1.6 billion annually**, with combined oral contraceptives (COCs) accounting for over 69.1%.
- The territories under the agreement represent 21.6% in value of the worldwide oral contraceptive market (**EUR 5.2 billion**), making this a key region for the commercialization of Estelle®.

\*IMS Analytics Link Q3/2017. CAGR volume 2013-2027: -1.7%. IMS numbers based on the 30 most important countries of the 54 countries under the agreement.

## 4. Richter – An ideal partner for Estelle®

- Headquartered in Budapest, Hungary
- A significant player in international Women's Healthcare
- Major pharmaceutical company in Central & Eastern Europe, with an expanding direct presence in Western Europe, China and Latin America
- Market capitalization of EUR 3.5 billion; consolidated sales of approximately EUR 1.4 billion in 2017
- Richter product portfolio covers important therapeutic areas, including Women's Health, Central Nervous System and Cardiovascular
- Largest R&D unit in Central & Eastern Europe, original research activity focuses on CNS disorders, also active in biosimilar product development
- Gedeon Richter Plc. ([www.richter.hu](http://www.richter.hu))



**GEDEON RICHTER**

## 4. Richter – An ideal partner for Estelle®

- Women's Health sales amounted to **EUR 469.4 million in 2017** (40% of total sales for the company), with the oral contraceptive portfolio representing a turnover of **EUR 292.9 million**.
- Richter is a **market leader** in Russia & Eastern Europe
- **Rapidly growing presence** in Western Europe is an important driver of the Women's Health division
- The company has a clear strategy to further strengthen the franchise in Eastern and Western Europe, with the addition of innovative products such as Estelle®.



**GEDEON RICHTER**



# 5. Agreement Terms: license

- Milestones: 55 million downpayment
  - EUR 35 million upfront on contract signature
  - EUR 20 million related to market approvals
- Potential additional sales-related milestones
- Royalties
  - Tiered royalties from high single-digit to substantial double-digits in view of sales volumes

# 4. Agreement Terms : Supply

- Mithra to receive guaranteed annual recurring revenues (MAQ)
- Production options
  - Mithra to manufacture initial supplies of Estelle<sup>®</sup> for Richter at its CDMO\*.
  - Richter to evaluate the option to manufacture and supply Estelle<sup>®</sup> as well as key API's in territories under the agreement.
  - In view of the production forecasts of this contract and previously closed agreements, this option may offer Mithra a competitively priced future manufacturing source when the Mithra CDMO reaches full capacity.

# 6. Deal potential

- Annual partner (Gedeon Richter) revenue if Estelle reaches a market share of:
  - A. 5% in Europe and 7,5% in Russia = € 175 Million
  - B. 7,5% in Europe and 10% in Russia = € 260 Million
  - C. 10% in Europe and 15% in Russia = € 350 Million
  - D. 15% in Europe et 20% in Russia = € 520 Million

# 7. Summary

- Major endorsement of Estelle<sup>®</sup>'s potential as a next-generation COC with enhanced benefit / risk profile
- Significant partnership with Women's Health leader in world's second-largest market by value
- Potential for substantial royalties and revenues over lifetime of contract

Thank you for your attention  
Any questions?

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