

# REPROS THERAPEUTICS



**Dedicated to Treating Male  
and Female Reproductive Disorders**

Corporate Presentation

June 2017

# Safe Harbor

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In this presentation, we rely on and refer to information and statistics regarding the pharmaceutical industry. We obtained this information and these statistics from third-party sources, which we have supplemented where necessary with information from publicly available sources and our own internal estimates. Industry publications and surveys generally state that they have obtained information from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified such data, and we make no any representation as to the accuracy of such information. Similarly, we believe our internal research is reliable, but it has not been verified by any independent sources.

# Company Overview and Recent Leadership Appointments

- Originally founded as Zonagen – an animal health company using technology from Baylor University
- IPO 1993
- Key recent developments
  - Patrick Fourteau named as Chairman of the Board
  - Larry Dillaha, M.D. named President and CEO
  - Important patent issuance with coverage until 2027
  - FDA meeting to discuss path forward for Proellex®
  - European filing for Enclomiphene

# Experienced Management Team

- **Larry Dillaha, M.D. – President and CEO (Feb 2017)**
  - *Sanofi, Sciele / Shionogi, Insys Therapeutics*
  - *History of clinical and regulatory success*
  
- **Kathi Anderson, CPA – CFO**
  - *Joined Repros in 2002*
  - *More than 15 years in biotech, life sciences*
  
- **Joe Wernicke, M.D., Ph.D. – Chief Medical Officer**
  - *30 years industry experience*
  - *Eli Lilly, Cyberonics*

# Proellex<sup>®</sup> (Telapristone Acetate) for the Treatment of Uterine Fibroids and Endometriosis

- Licensed from NIH, 1999
- Selective Progesterone Receptor Modulator (SPRM)
- No selectivity for glucocorticoid receptor need for chronic intermittent dosing
- Lead indications:
  - *Treatment of Uterine Fibroids*
  - *Treatment of Endometriosis expected to follow*
- Strong patent protection
  - *NCE related thru 2021*
  - *Off-Drug Interval thru 2027*

# Selective Progesterone Receptor Modulator (SPRM)

- Evolved from progesterone antagonists
  - *Mifepristone*
  - *Limited use because of high affinity for glucocorticoid receptor over progesterone receptor*
    - Recognizing need for more selective progesterone receptor activity; SPRMs developed
- Mixed agonist and antagonist activity at progesterone receptor
  - *Relative activity is tissue specific*
  - *Minimizing activity on other steroidal receptors*

# Uterine Fibroids

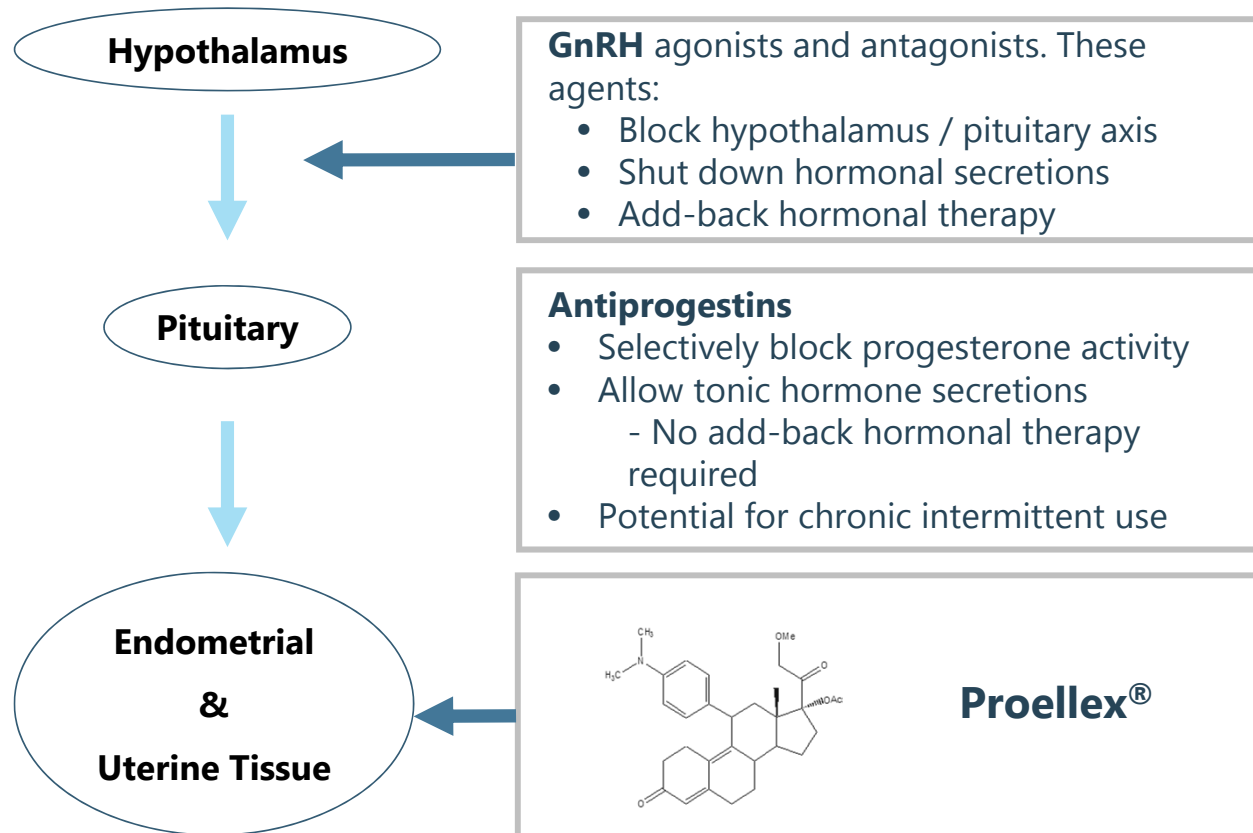
- Benign smooth muscle tumors of uterus (leiomyomas)
- Most common tumor of female reproductive tract
  - 20-77% of women aged 35-55
- Quality of Life often impacted
  - Heavy menstrual bleeding
  - Discomfort and pain
- Current Therapy
  - Medications
    - NSAIDs, OCPs, GnRH agonists, Progestin releasing IUDs
  - Minimally Invasive Procedures
    - Uterine artery embolization, myomectomy, ablation
  - Surgery
    - Hysterectomy – most common reason for hysterectomy – over half of the 600,000 done annually

# Endometriosis

- Endometrial tissue growing outside the uterus
  - *Infertility – pain, including pelvic pain*
  - *Dyspareunia*
  - *Dysmenorrhea*
  - *11% of women aged 15-44*
  - *25-40% of all cases of infertility*
  - *71-87% of women with chronic pelvic pain*
  - *53% teenagers with dysmenorrhea*
- Impact on QoL
- Current Therapy
  - *Medication*
    - NSAIDs, opioids, OCPs, Lupron, danazol
  - *Surgery*
    - Laparoscopic procedures – high rates of recurrence



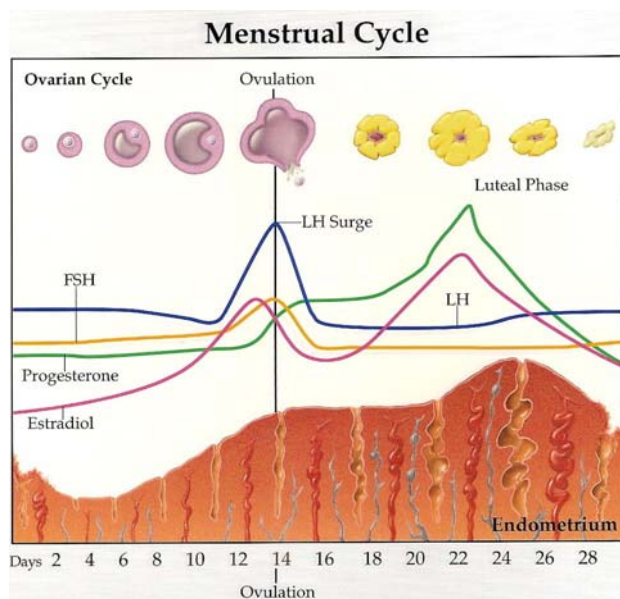
# How Antiprogestins Like Proellex<sup>®</sup> Work



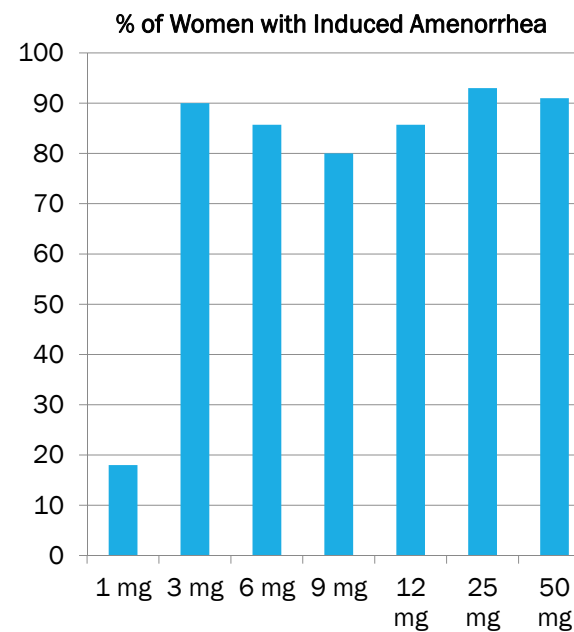
# Proellex<sup>®</sup> Effectiveness in Patients

## AN EFFECTIVE DOSE OF PROELLEX<sup>®</sup> STOPS MENSTRUATION (AMENORRHEA) IN MAJORITY OF WOMEN

Induction of amenorrhea relieves key symptoms of uterine fibroids and endometriosis

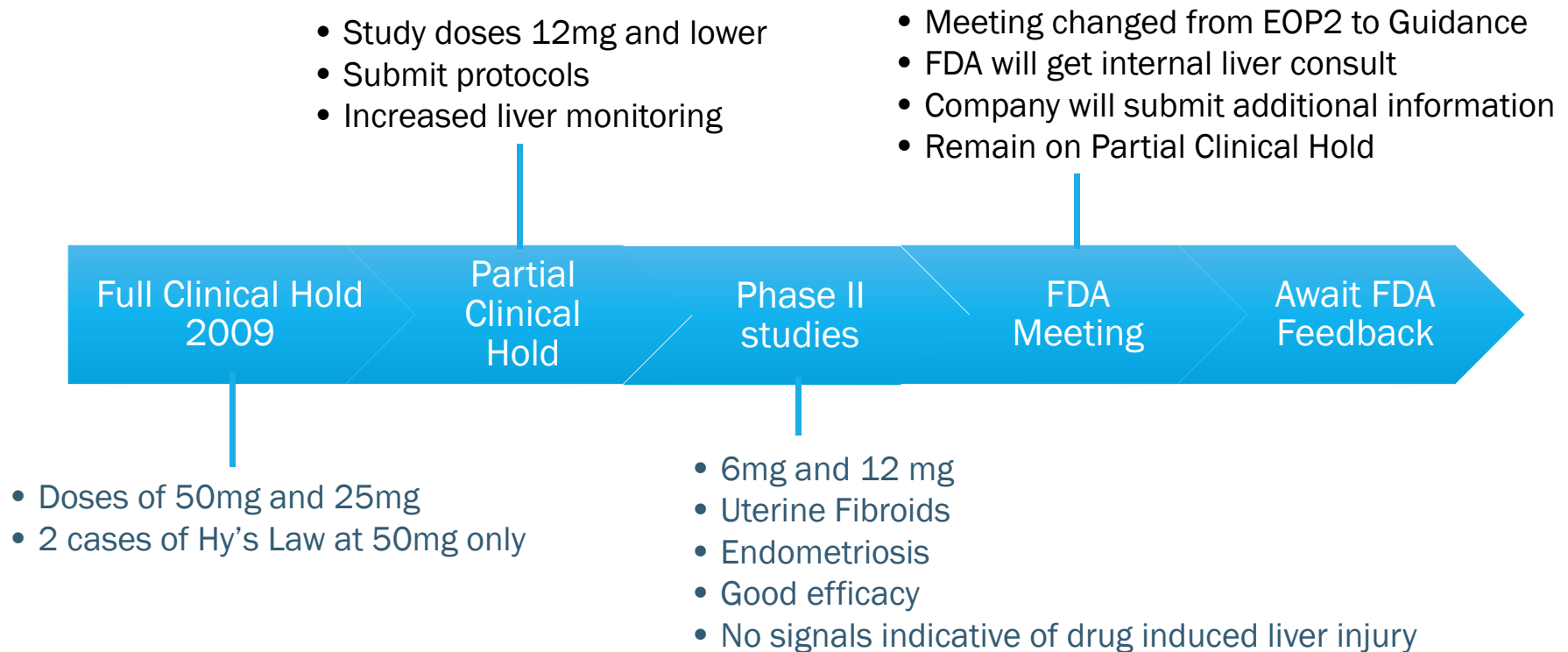


- Proellex<sup>®</sup> induced amenorrhea (no ovulation)
- Mimics early follicular phase without progesterone while maintaining tonic estrogen levels



Efficacy shown thru wide range of doses

# Regulatory / Development History



# Broad Patent Position on Proellex<sup>®</sup>

## ■ Off-Drug Interval

- Recent issuance of patent '074 – expires 2027
- Relates to the use of Selective Progesterone Receptor Modulators (SPRM), in particular Telapristone Acetate (Proellex<sup>®</sup>) or Ulipristal Acetate, with an Off-Drug Interval (ODI) for the treatment of estrogen-dependent hyperproliferative uterine conditions, such as uterine fibroids and endometriosis

## ■ NIH NCE patents

- *Coverage until 2021*

# Expected Regulatory Path Forward for Proellex<sup>®</sup>

- Repros empaneled a group of liver experts to review data and provided opinion to the FDA in May 2017
- Reached agreement with division to accept additional information from Repros, including opinion from company's liver experts, for submission to FDA internal liver panel
- Submit clinical protocol along with supplemental information
- FDA feedback may take 2-3 months

# Significant Market Opportunity and Investment in this Therapeutic Area

- Ulipristal Acetate
  - *Gedeon Richter product partnered with Allergan for US market*
  - *On market in EU*
    - *Esmya 5 mg for Tx of UF*
  - *Recently completed phase III*
    - *Venus II trial*
  - *Publicly stated intent to file NDA in 2H17*
  - *\$520 mil by 2020*
- Vilaprisan
  - *Bayer asset*
  - *Recently completed phase II program*
  - *Projected 1 billion euros per year*
- GnRH Agonists / Antagonists

# Enclomiphene for the Treatment of Secondary Hypogonadism

- NDA submitted January 2015
- Complete response letter received November 2015
- EMA filing currently under review in EU market
- Opinion date is anticipated in 1Q18
- Actively seeking partnering opportunities outside of the US

# Repros: Next steps and Milestones

- Continue discussions with FDA and obtain feedback to determine future clinical trial program for Proellex<sup>®</sup> for Uterine Fibroids and Endometriosis
- Submit Proellex<sup>®</sup> trial design to FDA
- EMA filing under review for Enclomiphene for secondary hypogonadism
- New management has experience and successful track record to achieve favorable results with the FDA
- Actively seeking partnering opportunities for Proellex<sup>®</sup> in the US, global or regional markets
- Actively seeking partnering opportunities for Enclomiphene outside of the US
- Maximize value from patent position