

## Investor Presentation

February 2024

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### Regulatory disclaimer:

• Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill ESTELLE®, Mithra is now focusing on its second product DONESTA®, the next-generation hormone therapy. Mithra also offers partners a complete spectrum of solutions from early drug development, clinical batches and commercial manufacturing of complex polymeric products (vaginal ring, implants) and complex liquid injectables and biologicals (vials, pre-filled syringes or cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, is headquartered in Liège, Belgium.

#### General disclaimer:

- Mithra Pharmaceuticals is closely following the evolution of macroeconomic conditions, the geopolitical situation in Ukraine and the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt operations accordingly.
- Mithra Pharmaceuticals has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, limitations on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Mithra Pharmaceuticals will continue to update the market as needed and whenever possible.

#### Note

ESTELLE® and DONESTA® are registered trademarks of Mithra Pharmaceuticals or one of its affiliates.

## Achievements to date-- 2023

### May

• EUR 12.5 million in financing from Highbridge/Whitebox

### June

- EUR 10 million in cash from our sale of Mayne Pharma shares
- Positive preclinical data for CSF-1R tyrosine kinase inhibitors

### July

 EUR 17.05 million Canadian binding term sheet for DONESTA® with Searchlight Pharma

### August

- EUR 20 million equity private placement with Armistice Capital (with up to EUR 45 million more possible)
- API Supply agreement for Estetrol (E4) native estrogen with Gedeon Richter
- EUR 1.25 million milestone payment from Fuji Pharma, ESTELLE® Japan partner



### October

- EUR 1.5 million milestone payment from Searchlight for execution of Canadian agreement
- EUR 2.5 million milestone payment from Fuji Pharma, ESTELLE® Japan partner

### November

- FDA recommends DONESTA® for full US market authorization
- NEXTSTELLIS® (ESTELLE®) granted additional US patent until 2036

### December

- EUR 5.7 million initial milestones deal with Gedeon Richter for DONESTA® and ESTELLE® in China
- Mithra is eligible to receive a total of EUR 2.05 million sales-related milestones, along with tiered double-digit royalties on annual net sales

## Cash inflows from partnerships

Product	Regional marketing partners	Total upfront & milestone payments to date (EUR)	Total potential future milestones (EUR) <sup>1</sup>	Total royalty &/or supply cash in from inception to date (H1 2023) (EUR)
ESTELLE®	15	128 million	296 million	21 million
DONESTA®	2	55 million	32 million	0 million
MYRING <sup>®</sup>	20	12 million	0 million	9 million
Total		198 million	328 million	30 million

<sup>&</sup>lt;sup>1</sup> additional potential upside of high single-digit to low double-digit per annum royalties based on sales

## Strategic priorities

### **ESTELLE®**

- Support marketing partners to realize growth potential
- Continued clinical development to support product differentiation

### **DONESTA®**

- Complete NDA filing with FDA
- Establish optimal U.S. marketing agreement
- Perform additional clinical Phase 2 studies
- Hair
- Skin
- Sexual desire

### Estetrol (E4)

- New indications in women's health for fertility
- IVF implantation exploratory clinical studies on endo metrial thickening
- New pharmacoecenomic Phase 2 and Phase 4 studies
- Estetrol (ESTELLE® / DONESTA®) safety in breast cancer & blood clotting

### Additional imperatives

- Debt consolidation
- Better leverage CDMO
- Options for Novalon complex therapeutics business
- Acquire preclinical and/or clinical opportunities



## Strong Experienced Management



Chief Executive Officer
David Horn Solomon









Chief Scientific Officer Graham Dixon









Chief Operating Officer Xavier Paoli









Chief Commercial Officer
Jean Manuel Fontaine



Chief Financial Officer Christophe Maréchal





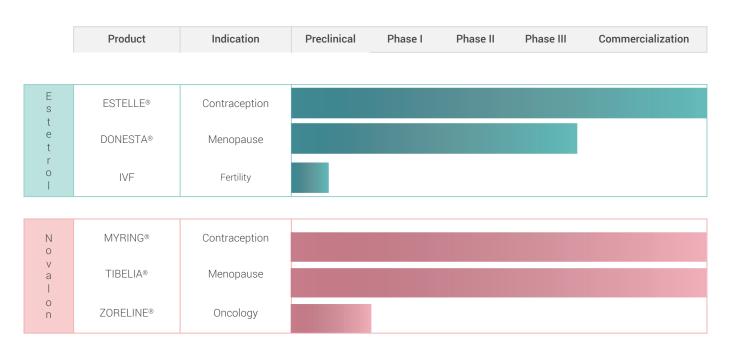


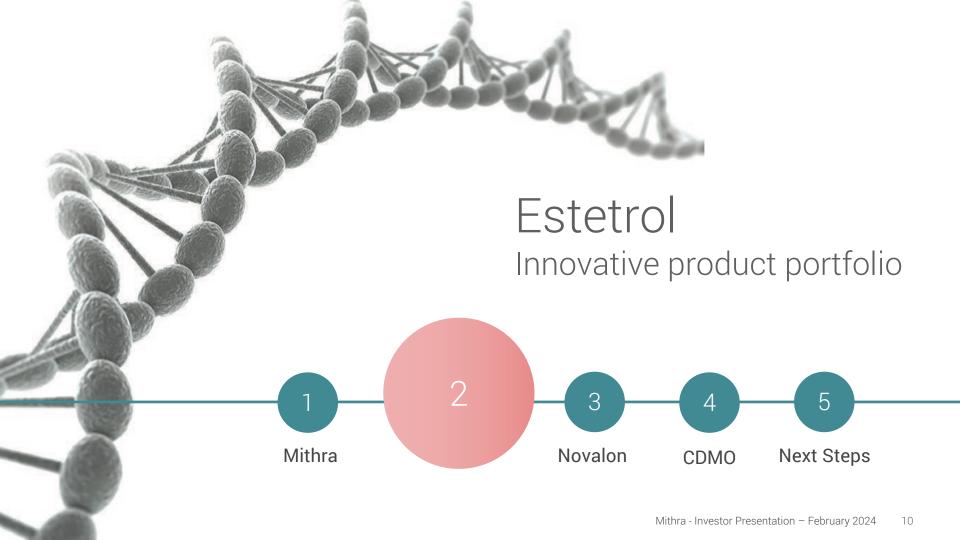






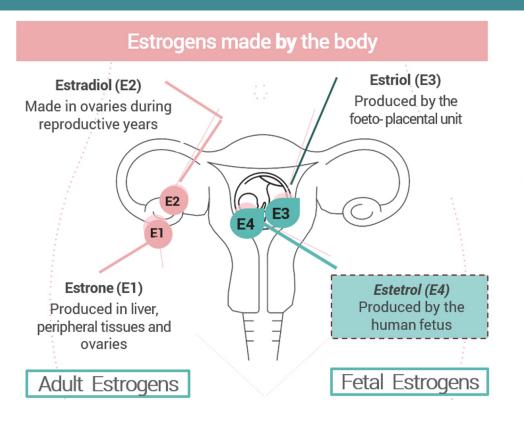
## Diversified pipeline offering multiple near-term catalysts





# Estetrol (E4) a new estrogen with a differentiated benefit/risk profile

## Estetrol: the early-life native estrogen



### Estrogens made outside the body

Synthetic Estrogens (e.g. Ethinyl Estradiol) Produced for medical use e.g. in birth control pills



Phytoestrogens

Found in plants, E1 e.g. in soybeans



Xenoestrogens

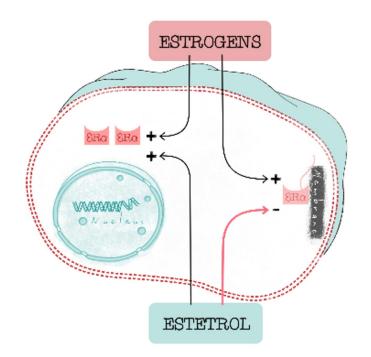
Endocrine disrupting agents coming from man-made products



## Estetrol: unique mode of action vs other estrogens

## AGONIST on the nuclear ERa

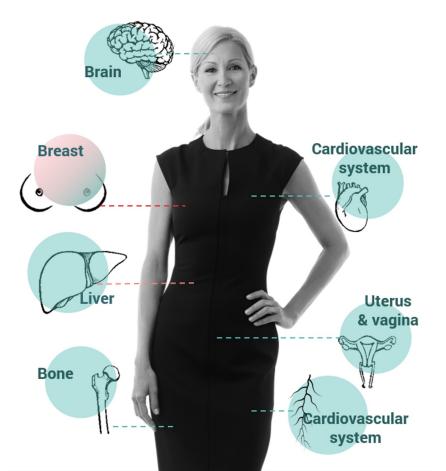
- Activates the nuclear estrogen receptor<sup>2-4</sup>
- Important estrogenic activity on the vagina, endometrium, bone and cardiovascular system to provide beneficial effects<sup>2-4</sup>



## ANTAGONIST on the membrane ERa

- Blocks the membrane estrogen receptor<sup>2-4</sup>
- Neutral effect on the liver unlike other estrogens<sup>2-4</sup>
- Low impact on breast tissue (normal and malignant)<sup>5-8</sup>

## A favorable safety profile



- Similar to other estrogens, estetrol has also a beneficial and positive impact on the cardiovascular system, brain, bone and endometrium
- Unlike other estrogens, estetrol has a limited impact on the liver and breast
- Breast: mixed activity on breast cell proliferation, migration and invasion<sup>1</sup>, limited impact on breast at therapeutic dose
- Liver:
- minimal impact on Sex Hormone Binding Globulin (SHBG) synthesis
- minimal impact on synthesis of coagulation factors (lower risk of VTE)
- limited lipid impact (including Triglycerides)

Visser et al. Climacteric 2008 | Mawet et al. Eur J Contracept Reprod Health Care 2015 | Gérard et al. J Endocrinol 2015 | Abot et al. EMBO Mol Med 2014 | Coelingh Bennink et al. Climacteric 2008 | Heegaard et al. Climacteric 2008 | Holinka et al. Biol Reprod. 1980 | Holinka et al. Climacteric 2008 | Pluchino et al. J Steroid Biochem Mol Biol 2014 | Tskitishvili et al. Exp Neurol 2014 | Guivarc'h et al. J Am Heart Assoc 2018 | Kluft et al. Contraception 2021 | Klipping et al. Contraception 2021

<sup>1.</sup> In presence of Estradiol (E2)



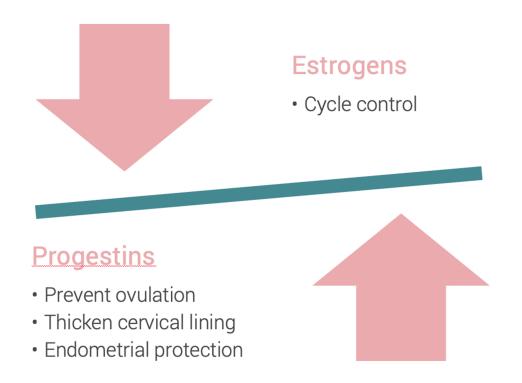
## ESTELLE®

(15mg estetrol / 3mg DRSP) A New Era in Combined Oral Contraception (COC)

### **OBJECTIVE**

Optimize women's physiological hormonal balance by combining the best progestin & estrogen according to their profile

## The role of female sex hormones in COCs



## ESTELLE® – addressing women's unmet need and improving women's contraceptive experience

### Improving contraceptive experience

Reliable contraceptive efficacy
Excellent cycle control<sup>1</sup>
Proven superiority in comparison to
Ethinylestradiol containing COCs
Improved quality of life & high user
satisfaction
Low risk of drug-drug interaction<sup>2</sup>

### Addressing unmet needs

### Favorable safety profile

Low impact on all markers of coagulation suggest low clotting risk Minimal increase of triglycerides Minimal impact on glucose metabolism Minimal impact on breast tissue expected based on preclinical data<sup>3</sup>

## Key partners for ESTELLE®'s commercialization



### GEDEON RICHTER

### Europe

Gedeon Richter Plc. is a major pharma. company which product portfolio covers many important therapeutic areas, including Women's Healthcare, Central Nervous System, and Cardiovascular areas

With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's healthcare field worldwide



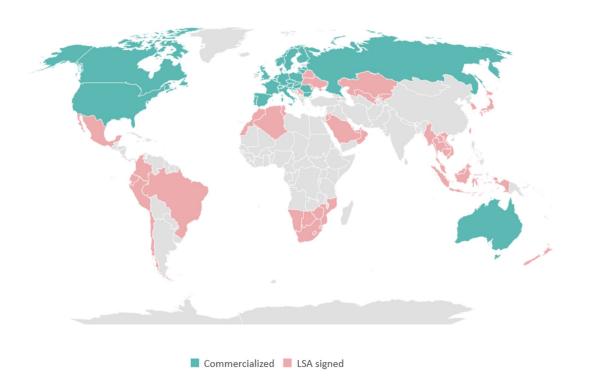
### U.S. and Australia

Mayne Pharma is an ASX-listed specialty pharma. company focused on commercializing novel and generic pharmaceuticals, offering patients better, safe and more accessible medicines

It has a 40-year track record of innovation and success in developing new oral drug delivery systems

Mithra holds 4.96% of the outstanding shares

## ESTELLE®: Global commercialization progress



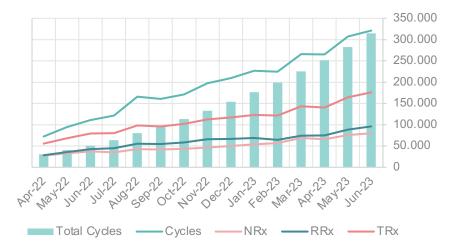
Commercialization started in 2021

### In 2023 – First launches in:

- Latin America
- Asia
- Middle East
- Ex CIS countries

## ESTELLE® in the US: NEXTSTELLIS® highlights

## NEXSTELLIS® monthly performance metrics from 2Q-2022 to 2Q-2023

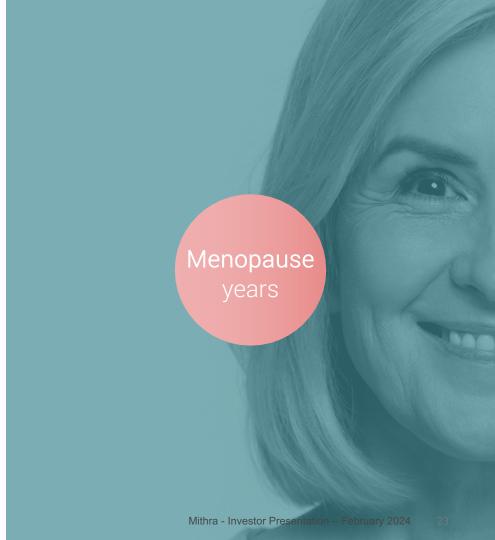


NEXTSTELLIS® growth is accelerating thanks to new commercial strategy implemented by Mayne in December 2022

- NEXTSTELLIS® has continued to achieve solid growth during 1H-2023 to date driven by access improvements (Co-Pay) and new targeting strategy implemented by Mayne in December 2022
- > 314,000 cycles dispensed since launch in June 2021
  - > 161,000 cycles dispensed in 6 months since January 2023
  - > 7,500 weekly cycles from now
- Growth 2Q-2023 vs 1Q-2023 of NRx +19% and TRx +19%
   RRx expected to improve following patient retargeting initiative in December 2022
- Experienced WH sales team of 94 (up from 86) able to reach target customers
- Net selling price returning to normal levels
- **Direct-to-Consumer campaign** launched in July 2022 with **GoodRx and TV campaign** launched in February 2023 with other marketing avenues being explored

## DONESTA®

(estetrol only)
A new era in
Hormone Therapy (HT)



## Hormone Therapy (HT)

Treatment recommended to address **long-term biological changes**, including common symptoms of menopause, that result from declining levels of the natural hormones (estrogen and progesterone) during and after menopause.

HT also helps **to balance estrogen and progesterone** in women around the time of menopause.

**Collapsing** of HT's use worldwide after the announcement of the first results of the **Women's Health Initiative (WHI) in 2002**, which indicated that HT could have more detrimental than beneficial effects.

Ph2 POC trials to launched in 2023 in skin quality, hair quality and FSAD



## DONESTA®: potentially beyond VMS

Clinical Phase	Primary Endpoint	Secondary Endpoint
Phase 3	Estetrol effect on reducing Vaso-Motor Symptom frequency / severity, H & NH* women	Effect on lipids, glucose metabolism, hemostasis parameters, breast density endometrial safety, health-related quality of life, treatment satisfaction and vulvar and vulvo-vaginal atrophy
Phase 2	Estetrol effect on various aspects of Female Sexual and Urogenital Functions	Effect of estetrol on quality of life
Phase 2	Effect of estetrol on skin health, quality and appearance	Effect of estetrol on quality of life and various skin-related endpoints
Phase 2	Effect of estetrol on hair texture, quality and appearance	Effect of estetrol on quality of life and various hair-related endpoints

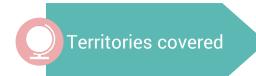
## DONESTA®: Gedeon Richter partnership



Seeking for the highest long-term added value for Mithra and Gedeon Richter Strengthening our long-term partnership



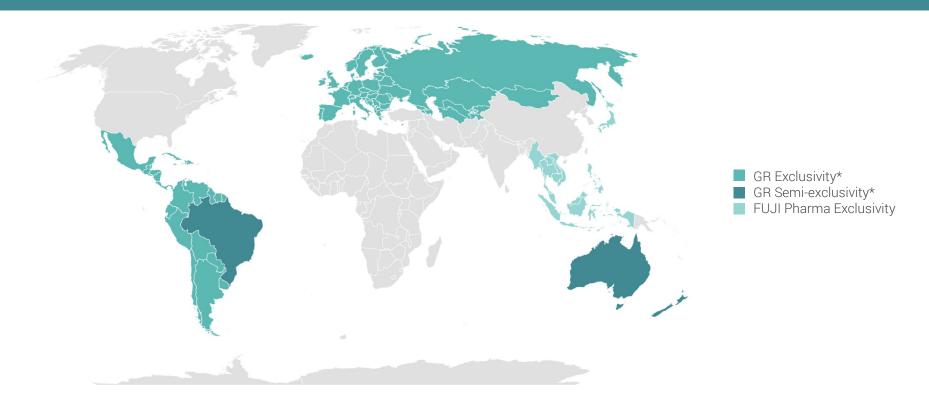
Upfront payment 55m EUR Regulatory milestones 15m EUR Double-digit royalties tiered or net sales

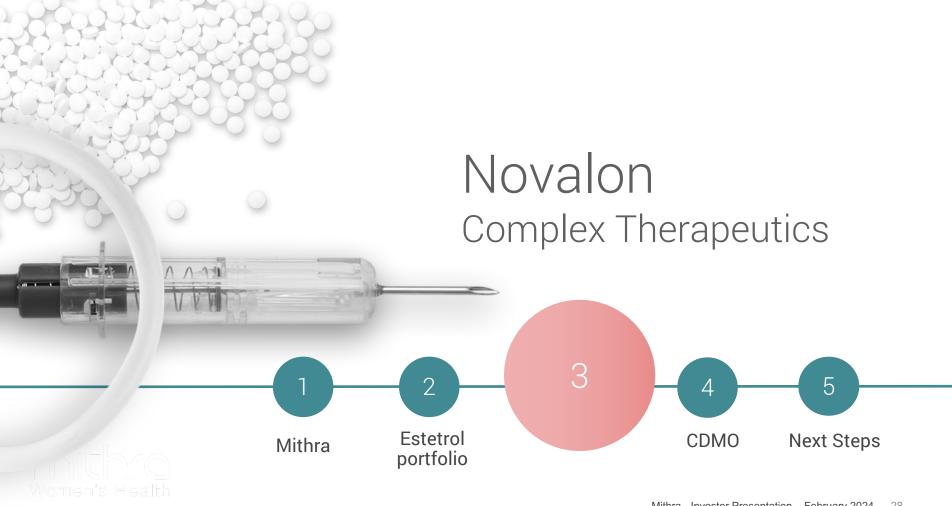


Exclusivity: Europe, Russia, CIS countries, Central & Latin America

Semi-Exclusivity: Brazil, Australia, New Zealand

## DONESTA®: Territories already covered

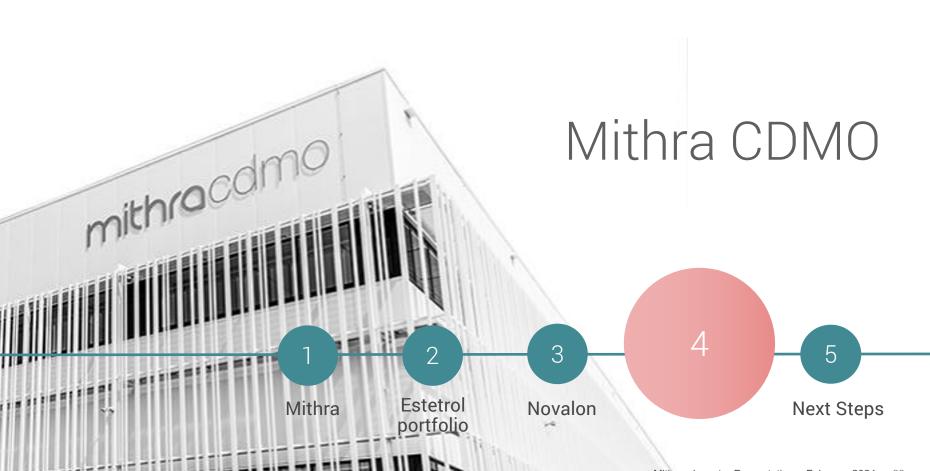




## Advancing our complex therapeutics business

Products	Description	Indication	Opportunity	Status
MYRING®	Contraceptive vaginal ring (based on etonogestrel/ EE/polymers)	Contraception	Circa \$580m*  Original product:  NUVARING® from Merck	Commercialized
ZORELINE®	Biodegradable SQ implant (goserelin)	Prostate & breast cancer and benign gynecological indications	Circa \$963m**  Original product: ZOLADEX® from AstraZeneca	New formulations assessed via animal PK/PD comparative study for 1 month and 3 months implant
TIBELIA®	Therapeutic solution for HT composed of tibolone (synthetic steroid)	Menopause	Circa \$117m**  Original product:  LIVIAL® from Merck	Commercialized

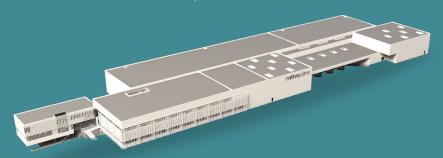
<sup>\*</sup> According to IQVIA, sales are for the 12 months ended June 2022 \*\* Source: IOVIA quantitative market research, 02 2022

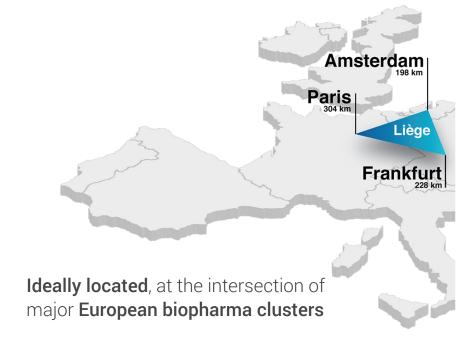


## An integrated R&D and manufacturing platform

## Specialized pharmaceutical ecosystem, to take products from POC to market

- 15,000 m² state-of-the art facilities
- Dedicated R&D and production areas
- Ability to handle high potent and complex developments
- Pilot, clinical & commercial batches
- GMP Standards compliance





Strategy for the CDMO is to leverage our unique expertise in polymers (long-acting, implants, vaginal rings) and injectables for high value-added commercial projects and products



## Next steps

### **DONESTA®**

- Support NDA filing with FDA
- Additional Phase 2 studies to support differentiation for treatment of menopause symptoms
  - Hair
  - Skin
  - Sexual desire

### **ESTETROL**

- New indications in women's health
  - IVF implantation exploratory clinical studies on endometrial thickening
- New pharmacoecenomic Phase 2 and Phase 4 studies to establish safety of Estetrol (ESTELLE®/DONESTA®) in breast cancer & blood clotting

### **ZORELINE®**

1-month & 3-month formulation studies

### Contact us

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