DARE

IN ENGLISH, IT MEANS "TO BE BOLD."

IN ITALIAN, IT MEANS "TO GIVE."

Transforming Women's Health

We founded Daré Bioscience with the ***sole focus*** of putting women's health first –

to **boldly address** existing therapeutic gaps and **give women** the novel treatment options they want and need.

Forward-Looking Statements; Disclaimers

This presentation is for informational purposes only and is not an offer to sell or a solicitation of an offer to buy any securities of Daré Bioscience, Inc. ("Daré" or the "Company"). This presentation includes certain information obtained from trade and statistical services, third-party publications, and other sources. Daré has not independently verified such information and there can be no assurance as to its accuracy.

All statements in this presentation, other than statements of historical fact, are forward-looking statements within the meaning of federal securities laws. In some cases, you can identify forward-looking statements by terms such as "may," "will," "expect," "plan," "anticipate," "strategy," "designed," "could," "intend," "believe," "estimate," "target," or "potential," or the negative of these terms and other similar expressions. Such statements include, but are not limited to, statements relating to the clinical and market potential of XACIATO™ (clindamycin phosphate) vaginal gel 2% and Daré's product candidates, clinical trial advancement, timing and data, regulatory approval and commercialization, potential collaborations, expectations regarding existing collaborations, pipeline expansion, and potential funding and financing transactions. As used in this presentation, "first-in-category" is a forward-looking statement relating to market potential of a product candidate if it were to receive regulatory approval for the indication(s) for which it is being developed. None of the product candidates presented herein are approved for use outside of clinical trials. The timing of clinical trials, clinical trial data, FDA review and approval, collaborations and other milestones and events relating to development and commercialization of XACIATO and Daré's product candidates, other than those having occurred prior to the date of this presentation, are forward-looking statements. Forward-looking statements reflect management's estimates and expectations based on current information and involve risks, uncertainties and assumptions that may cause Daré's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements, including, without limitation: Daré's reliance on third parties to commercialize XACIATO and to manufacture and conduct clinical trials of its product and product candidates; the degree of market acceptance that XACIATO and any future product achieves; the coverage, pricing and reimbursement that XACIATO and any future product obtains from third-party payors; risks and uncertainties inherent in Daré's ability to successfully develop, obtain regulatory approval for and monetize its product candidates; Daré's need for additional capital to fund operations and execute its business strategy; and those risks and uncertainties described under the heading "Risk Factors" in Daré's most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the Securities and Exchange Commission. All forward-looking statements are current only as of the date of this presentation. Daré does not undertake any obligation to update any forward-looking statement in this presentation to reflect new information, future developments or otherwise, except as required by law.

Women's Health
An Efficient Investment Thesis

Transforming women's health by advancing **high-impact, first-in-category** product candidates that have **already demonstrated proof of concept**.

Global R&D

- Approximately **1% of healthcare research spending** is invested in non-oncologic female conditions.[1]
- The global healthcare pipeline is comprised of **less than 2%** of non-oncologic women's health conditions.[2]

Commercial opportunity

We believe **investment** in women's health will be efficient and **disproportionately impactful**:

- Women's health products make up **27% of total blockbuster products** while contributing to 35% of total blockbuster sales.[3]
- **Women control 80% of U.S.** healthcare purchasing decisions.[1]

1 - McKinsey & Company, February 14, 2022, Unlocking Opportunities in Women's Healthcare

2 - GlobalData Drugs Database and McKinsey & Company

3 - IQVIA Monthly Global MIDAS $ Const-Exchng (MNF) 2013 – 2022

Blockbuster defined as $500 million dollar sales in a year Women's Health including conditions solely or disproportionately affecting women; excludes oncology conditions in women

The Daré value proposition

We leverage the insights and efficiencies of a deep vertical to mitigate risk and efficiently bring high-impact products to market with commercial collaborators

We deploy established active pharmaceutical ingredients (APIs) in first-in-category candidates…

APIs in select Daré candidates	Original FDA approval; established safety record
Clindamycin	1970
Tamoxifen	1977
Levonorgestrel	1982
Ritonavir	1996
Sildenafil	1998
Etonogestrel	2006

…and we have completed successful clinical trials with six assets in the portfolio, up to and including an FDA approval

	Number of successful completed trials
PHASE 1	4
PHASE 2	3
PHASE 3	1
Total	*8 (1 FDA approval)*

ORGANON

BAYER

We have established collaborations with two industry leaders, primed to commercialize Daré products at scale

Innovative treatments that women want and need

Our investigational products are some of the most potentially disruptive therapeutic candidates for women in decades

	ASSET	ADDRESSABLE MARKET (millions of women)
1	Gel to treat **bacterial vaginosis**	23
2	Monthly **hormone-free contraceptive**	35
3	Topical cream to improve **arousal** sensations	20
4	Monthly non-oral combination hormone therapy for **menopause symptoms**	45
5	Non-hormonal treatment for **sexual pain**; unmet need for women with breast cancer	25
6	Treatment for human papilloma virus (HPV) infection to **prevent cervical cancer**	1 (annually)
7	Two development candidates to prevent **pre-term birth**	1 in 10 infants

Innovative treatments that women want and need

Our investigational products are some of the most potentially disruptive therapeutic candidates for women in decades

ASSET	ADDRESSABLE MARKET (millions of women)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	REGULATORY SUBMISSION	FDA APPROVED
XACIATO™ ORGANON (clindamycin phosphate) vaginal gel 2%	23						✓ Launched 4Q-2023
Ovaprene® BAYER NIH Monthly **hormone-free contraceptive**	35				Pivotal Phase 3 commenced 4Q-2023		
Sildenafil Cream, 3.6% ^ Topical cream to improve **arousal**	20			Phase 2b study completed			
DARE-HRT1^ Monthly hormone therapy for **menopause symptoms**	45				IND and Phase 3 study preparations		
DARE-VVA1 ^ Hormone-free treatment for **sexual pain**	25			IND cleared; Phase 2 study preparation			
DARE-CIN (formerly R-131-2) ^ HPV therapy to **prevent cervical cancer**	1 (annually)			Phase 1 and proof of concept studies completed			

^505(b)(2) regulatory pathway anticipated.
Timelines represent anticipated timing.

XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years of age and older. See Full Prescribing Information for the safe and effective use of XACIATO.
See XACIATO selected safety information on slide 15. See slide 10 for earlier stage programs

XACIATO™ (Clindamycin Phosphate) Vaginal Gel 2%

Daré's first FDA-approved product

XACIATO [zah-she-AH-toe] (clindamycin phosphate) vaginal gel 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis (BV) in females 12 years of age and older*

In less than five years since licensing the technology, Daré advanced a **pivotal clinical trial**, gained **FDA approval**, and **ensured product supply** to support the U.S. launch of XACIATO

Commercialization Collaborator ORGANON

- **$12.8 million in upfront and milestone payments received to date**
- Eligible to receive **tiered double-digit royalties** and potential milestone payments of **up to $180 million**

*XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older. See Full Prescribing Information for the safe and effective use of XACIATO. See XACIATO selected safety information on slide 15. See slide 10 for earlier stage programs

Ovaprene®

Investigational intravaginal hormone-free, monthly contraceptive

Daré's potential first-in-category contraceptive product

Designed to be an easy-to-use monthly option with effectiveness approaching hormonal methods.

There are currently no FDA-approved monthly, hormone-free contraceptives.

Pivotal study collaboration with NICHD.

NIH National Institutes of Health

Based on our communications to date with the FDA, if successful, we believe **only this single registration study will be required to support a premarket approval** application submission with the FDA.

Commercialization Collaborator

BAYER

- Bayer received the right to obtain exclusive US rights to commercialize the product, **following completion of the pivotal clinical trial** if Bayer, in its sole discretion, pays Daré **$20 million**.
- Daré may receive up to **$310 million in commercial milestone payments, plus double-digit, tiered royalties on net sales.**

Sildenafil Cream, 3.6%

Investigational topical formulation of the active ingredient in Viagra®

Commercial Rights Not Yet Partnered

Daré's potential first-in-category treatment for female sexual arousal disorder (FSAD).

There are currently no FDA approved treatments for FSAD. FSAD is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.

Of the various types of female sexual dysfunction disorders, **FSAD is most analogous to erectile dysfunction (ED) in men.**

ED product **Viagra® peaked at $2.05 billion in sales in 2012.**[1]

Phase 2b Clinical Study:

The Phase 2b **was the first study specifically evaluating a potential therapy for the treatment of FSAD**.

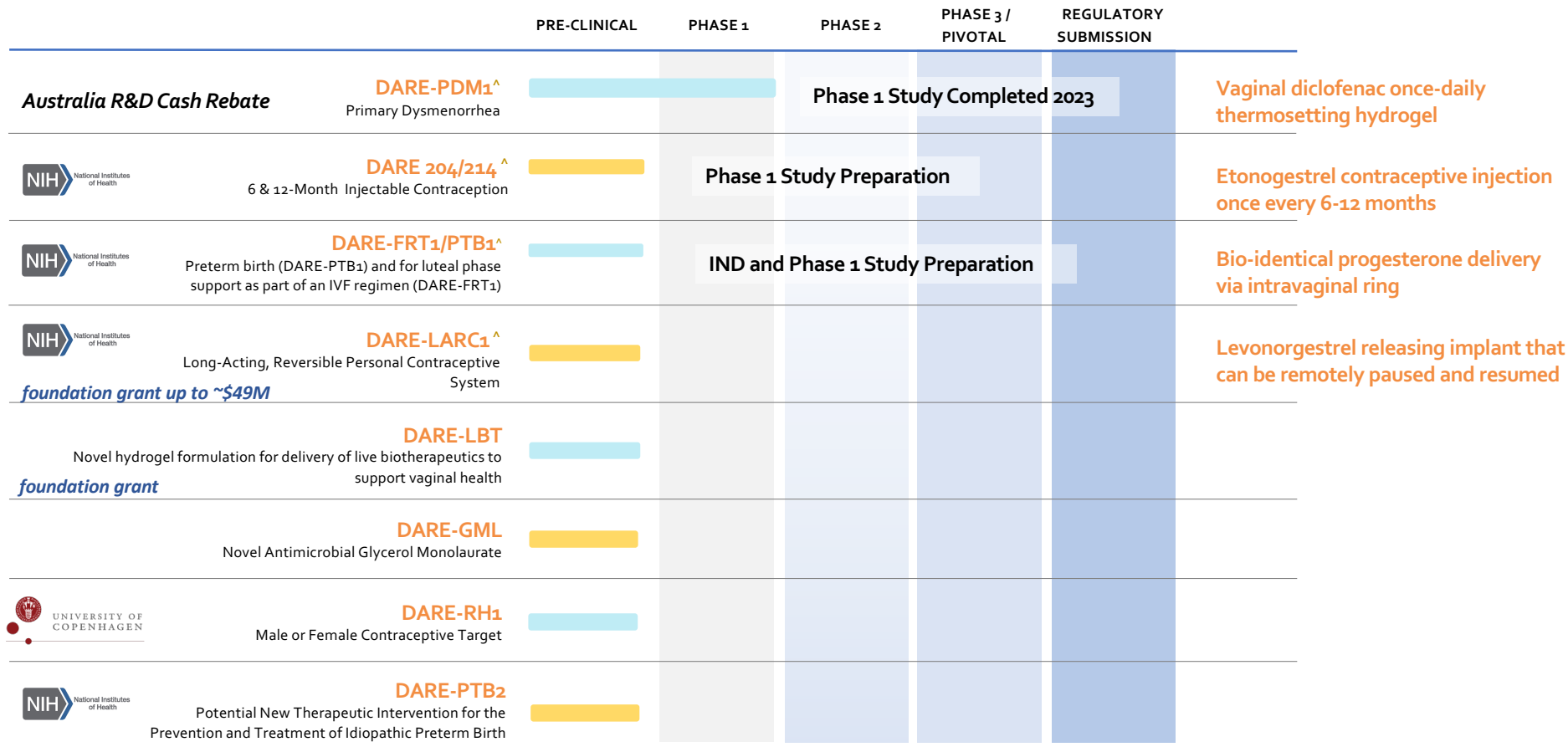
- Characterized **sexual response** impacted by the arousal dysfunction;
- Evaluated the **patient population** based on symptoms reported and concomitant diagnoses or medications;
- Identified **endpoints** to take forward into a Phase 3 program

Demonstrated statistically significant improvement in the proposed patient population to be studied in Phase 3.[2]

End of Phase 2 meeting with FDA held December 2023.

1. https://qz.com/quartzy/1238783/its-the-20th-anniversary-of-viagra-heres-how-its-changed-the-world
2. Based on informal post-hoc analyses. See slide 32.

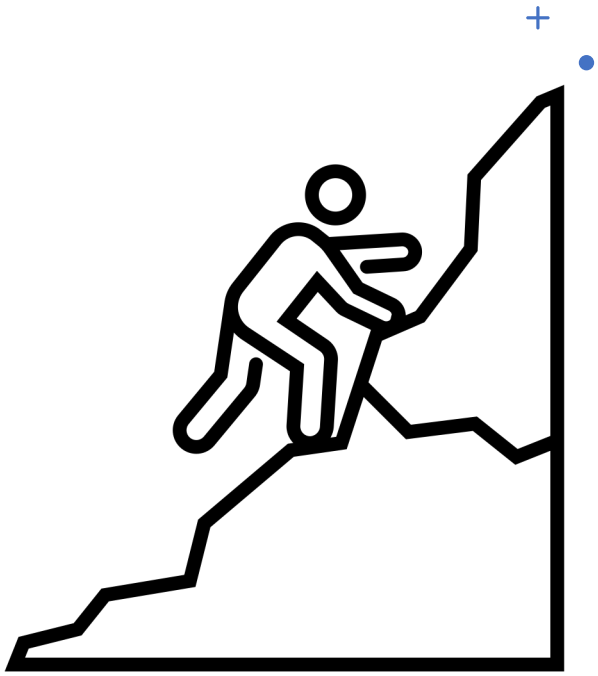
Earlier Stage Programs with Grant Funding Enhance the Pipeline



^505(b)(2) regulatory pathway anticipated.

Upcoming Milestones

- **XACIATO**™ (Clindamycin Phosphate) Vaginal Gel 2% – Quarterly sales and launch updates
- **Ovaprene®** – Phase 3 study recruitment and data updates
- **Sildenafil Cream, 3.6%** – End of Phase 2 meeting FDA feedback; Phase 3 design, development, and collaboration strategy updates



Appendix

XACIATO™

(Clindamycin Phosphate) Vaginal Gel 2%
One-time intravaginal administration

XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years of age and older.

See Full Prescribing Information for the safe and effective use of XACIATO.

See XACIATO selected safety information on slide 15.

ORGANON

Commercialization Collaborator

Bacterial Vaginosis

Daré Innovation: XACIATO™ (Clindamycin Phosphate) Vaginal Gel 2%*

Clinical Issue

- Recurring infection, difficult to treat effectively
- Most common vaginal condition in women ages 15-44
- Estimated to **affect ~23 million women in the US**[1]
- Bacterial Vaginosis increases health risks[2], including increased risk of preterm birth, sexually transmitted infections, post-surgical infection, and pelvic inflammatory disease that can increase the risk of infertility

Limitations with Rx standards of care

- Bacterial vaginosis is a disruption in the optimal vaginal microbiome and therefore recurrent in many women
- Women experiencing recurrence have three or more episodes in the same year, and may not prefer multiple doses of systemic antibiotics
- **Rx suboptimal:** clinical cure rates of 37-68% **(excluding XACIATO™)**[3]

Target Product Profile

- **Single self-administered dose**, any time of day
- Vaginal delivery of the antibiotic, with minimal systemic exposure
- Colorless, odorless gel
- Demonstrated equivalent cure rates in both women having her first occurrence of bacterial vaginosis as well as those with a history of multiple prior episodes
- Clear labeling for special populations such as pregnant and lactating women

1.https://www.cdc.gov/std/bv/stats.htm and https://www.census.gov/data/datasets/2017/demo/popproj/2017-popproj.html
2.https://www.mayoclinic.org/diseases-conditions/bacterial-vaginosis/symptoms-causes/syc-20352279
3. Bacterial vaginosis product data: http://www.clindesse.com/pdf/PI.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf; http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205223s000lbl.pdf

XACIATO Selected Safety Information

- XACIATO is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin.
- Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued.
- Polyurethane condoms are not recommended during treatment with XACIATO or for 7 days following treatment. During this time period, polyurethane condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases. Latex or polyisoprene condoms should be used.
- XACIATO may result in the overgrowth of Candida spp. in the vagina resulting in vulvovaginal candidiasis, which may require antifungal treatment.
- The most common adverse reactions reported in >2% of patients and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.
- XACIATO has not been studied in pregnant women. However, based on the low systemic absorption of XACIATO following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.
- There are no data on the effect of clindamycin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.
- Please see the Prescribing Information, Patient Information, and Instructions for Use.

Ovaprene®

Investigational potential first-in-category, hormone-free, monthly birth control

U.S. Commercialization Collaborator

Phase 3 Development Collaborator

Contraception: Market Opportunity

Women in the Reproductive Health & Contraception Market Segment
(over **60 million women**)

Population of women 15-44 years by age: US, 2020

Age (years)	US (Percent)	US (Count)
15-19 yrs	15.9	10,266,332
20-29 yrs	34.0	21,918,026
30-39 yrs	34.3	22,159,866
40-44 yrs	15.8	10,199,608
Total	100.0	64,543,832

Sources: US Census Bureau.
Population estimates based on bridged race categories released by the National Center for Health Statistics.
Retrieved June 15, 2023, from www.marchofdimes.org/peristats.

Successful Contraceptive Brands Peak Sales:

Mirena® Hormone IUD
(levonorgestrel-releasing intrauterine system) 52mg.

- Physician inserted, long-acting. low/locally delivered hormone IUS
- **2020 worldwide sales: €1.2 billion (Bayer)**[1]

Lo Loestrin®
(norethindrone acetate and ethinyl estradiol, ethinyl estradiol tablets)

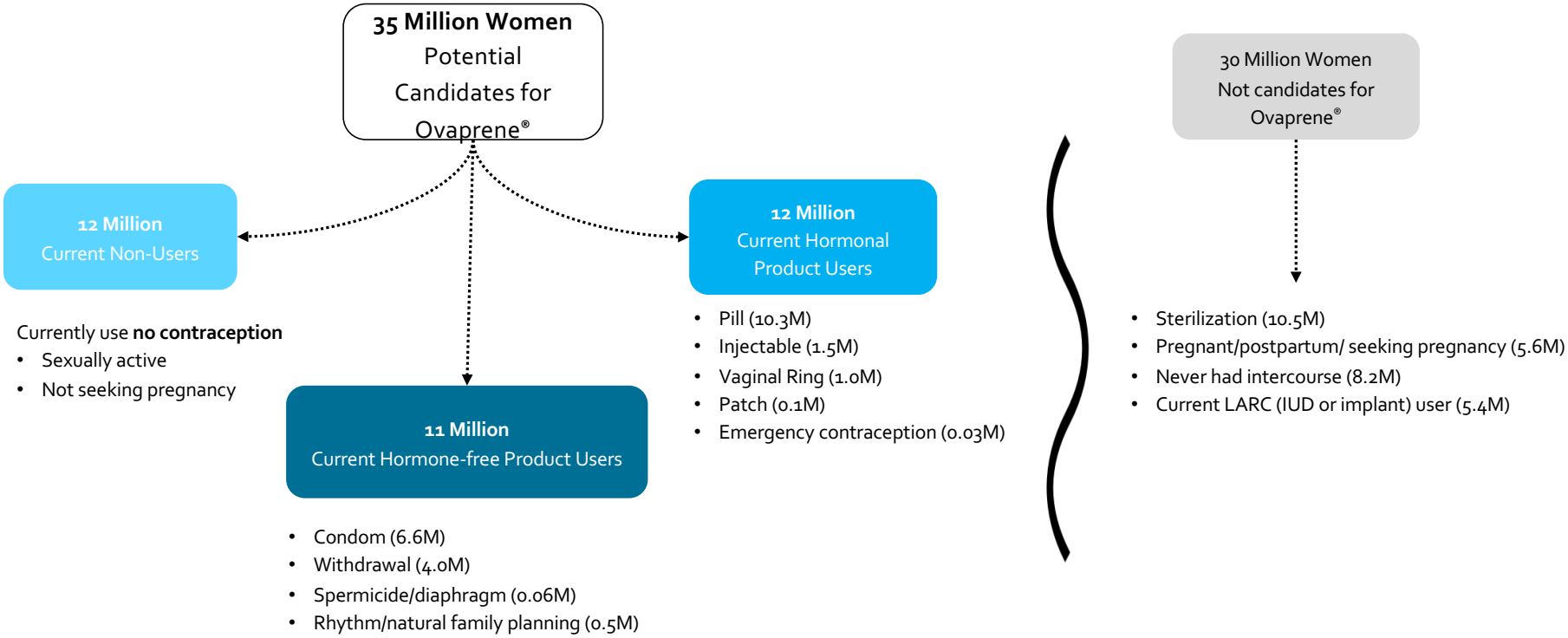
- Lowest amount of daily estrogen (10 micrograms) available in pill form
- **2019 US sales: $588 million (Allergan)**[2]

NuvaRing®
(etonogestrel/ethinyl estradiol vaginal ring)

- Monthly vaginal ring
- **2018 worldwide sales: $900 million (Merck)**[3]

1.https://www.bayer.com/en/bayer-ag-annual-report-2019.pdfx. Includes sales for Mirena®, Kyleena® and Jaydess® / Skyla®
2.https://www.prnewswire.com/news-releases/allergan-reports-fourth-quarter-and-full-year-2019-financial-results-301001646.html
3.https://www.sec.gov/Archives/edgar/data/0000310158/ 000031015819000014/mrk1231201810k.htm

Ovaprene® - Potential Market Opportunity[1,2]



1. Market research study conducted in 2019 for Daré Bioscience
2. Contraceptive use data applied to 2019 population data from US Census

Contraception:
What's Missing from Current Hormone-Free Options?

Hormone-free Options	Pregnancies Expected (per 100 women) [1,*]
Spermicides & Vaginal Gels [2]	>27
Condoms (male)	18
Diaphragms (with a spermicide)	12
Easy-to-use monthly option	**Effectiveness approaching hormonal methods**
Copper IUD	<1

Least Effective

Most Effective

1.U.S. Food and Drug Administration Birth Control Guide dated 6/14/2021: https://www.fda.gov/consumers/free-publications-women/birth-control-chart

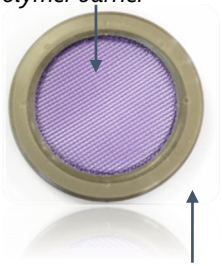
2.U.S. Food and Drug Administration Drug Data Prescribing information for a vaginal gel approved in 2020, Phexxi™ provides that in a multicenter, open-label, single-arm clinical trial in the U.S. (AMP002; NCT03243305), the 7-cycle cumulative pregnancy rate was 13.7% (95% CI: 10.0%, 17.5%), excluding cycles with back-up contraception, cycles <21 or > 35 days in length and cycles in which no intercourse was reported. The estimated Pearl Index, calculated based on data from the 7-cycle study, was 27.5 (95% CI: 22.4%, 33.5%). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208352s000lbl.pdf

* Pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011)."Contraceptive failure in the United States." Contraception 83(5):397-404.

Ovaprene® Investigational Hormone-Free, Monthly Contraceptive

Physical Barrier [6]

Three-dimensional, knitted polymer barrier



Spermiostatic Environment[6]

Contraceptive-loaded silicone ring releasing non-hormonal active Ferrous gluconate

Desired Features of Birth Control Products:[1-4]	Design Features of Ovaprene:[5-7]
+Efficacy	86% - 91% Expected Typical Use Effectiveness Approaching User-Controlled Hormone Contraception
+Hormone Free	No Hormones in the API Unique dual action MOA (spermiostatic & barrier)
+Convenience	Monthly Ring Form Women choose monthly intravaginal products for the convenience of a non-daily option
+Favorable Side Effect Profile	Safety Profile Similar to a Diaphragm No significant changes in vaginal flora and no serious adverse effects observed in studies to date
+Easily Manage Fertility	No Systemic/Long-term Activity Inserted and removed without a provider allowing for immediate return to fertility

1.https://www.urban.org/urban-wire/women-want-effective-birth-control

2.Lessard, L,Perspectives on Sexual and Reproductive Health, Volume 44, Number 3,9-2012

3.Hooper, DJ, Clin Drug Investig. 2010;30(11):74963

4.Ersek, J, Matern Child Health J (2011) 15:497–506

5.In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" contraceptive effectiveness of 86-91% in pivotal contraceptive studies evaluating pregnancy rates over six-month periods. Mauck C, Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437–444

6.Journal of Reproductive Medicine 2009; 54: 685-690

7.Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York, NY: Ardent Media, 2011.

Ovaprene® - Pre-Pivotal Study

The Pre-pivotal Postcoital Test (PCT) Clinical Study Met its Primary Endpoint

Ovaprene prevented the requisite number of sperm from reaching the cervix across all women and all cycles evaluated.

Specifically, in **100% of women and cycles, an average of less than five (< 5) progressively motile sperm** (PMS) per high-powered field (HPF) were present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.

	Mean *Progressively Motile Sperm*	Median *Progressively Motile Sperm*	Standard Deviation	Interquartile Range
Baseline PCT's	27.21	23.20	17.88	24.80
Ovaprene PCT's	0.48	0.00	1.18	0.10

In PCT studies of similar size, products (diaphragms) that demonstrated no motile sperm in the cervical mucus during PCT assessments later demonstrated "typical use" ***contraceptive effectiveness of 86-91%*** *in pivotal contraceptive studies evaluating pregnancy rates over six-month periods.*[1]

1.Mauck C., Vincent K. Biology of Reproduction, Volume 103, Issue 2, August 2020, Pages 437–444

Ovaprene® - Commercial License Agreement with Bayer

January 2020 - **Bayer**, which markets the $1 billion **Mirena contraceptive franchise**, and Daré announced the execution of a license agreement under which Bayer may commercialize Ovaprene investigational contraceptive in the US once approved by FDA[1].

Mirena® is the **#1 prescribed IUD** in the U.S.*

We believe the licensing agreement with Bayer is validation of our broader corporate strategy and confirmation of Ovaprene's market potential, if approved, as the first monthly non-hormonal contraceptive product in the US market.

Bayer received the right to obtain exclusive US rights to commercialize the product, **following completion of the pivotal clinical trial** if Bayer, in its sole discretion, pays Daré **$20 million**.

Daré may receive up to **$310 million in commercial milestone payments, plus double-digit, tiered royalties on net sales.**

Bayer supports the development and regulatory process by providing up to two full-time equivalents (internal experts) in an advisory capacity, which gives Daré access to their global manufacturing, regulatory, medical and commercial expertise.

* https://www.mirena-us.com/; supported by 2014-2016 SHS data.

1.https://ir.darebioscience.com/news-releases/news-release-details/bayer-and-dare-bioscience-announce-exclusive-licensing-agreement

Ovaprene® - Collaborative Research Agreement with NIH

"This collaboration between Daré and NICHD marks an important milestone in Women's Healthcare Innovation. Women are at the center of everything we do and we are so pleased to continue to partner with Daré in support of our mission We're For Her to provide women with education and access to contraceptive options," *said John Berrios, Bayer's Head of Women's Healthcare.*

Cooperative Research and Development Agreement (CRADA) for the Pivotal Phase 3 Study

July 2021 – Daré announced that funding and clinical operations support for the Phase 3 will be provided by the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under the CRADA[1]

The pivotal Phase 3 study will be **supported by the NICHD's Contraceptive Development Program** which oversees the Contraceptive Clinical Trials Network (CCTN) established in 1996 to conduct studies of investigational contraceptives. The Phase 3 study will be conducted within the CCTN with the NICHD's CRO.

Daré will be responsible for providing clinical supplies of Ovaprene® and coordinating interactions with and preparing and submitting supportive regulatory documentation to the FDA.

Under the CRADA, Daré also agreed to contribute **$5.5 million** toward the total estimated cost to conduct the pivotal Phase 3 study. Three payments totaling $5 million have been made. Daré and NICHD are in discussions regarding an amendment to the CRADA.

1. https://ir.darebioscience.com/news-releases/news-release-details/dare-announces-collaborative-research-agreement-crada-pivotal

Ovaprene® - U.S. Regulatory Strategy[1]

Premarket approval (PMA) strategy

The Center for Devices and Radiological Health (CDRH) as lead review division

Based on our communications to date with the FDA, if successful, we believe ***only this single registration study will be required to support a premarket approval*** *application submission with the FDA*

Pivotal study design:

This is a non-comparative study meaning all women will use Ovaprene – ***there is no placebo***

Target approximately 250 subjects to complete ~12 months (13 menstrual cycles), of use.

Primary objective:

typical use pregnancy rate over 13 menstrual cycles (estimated Pearl Index)

Secondary objectives:

13-cycle typical use cumulative pregnancy rate

Safety, acceptability, product fit/ease of use, vaginal health

1.Anticipated regulatory pathway and timelines.

Sildenafil Cream, 3.6%

Investigational topical formulation of the active ingredient in Viagra®

Potential First-In-Category treatment for Female Sexual Arousal Disorder (FSAD) – there are no FDA approved treatments for FSAD

Designed to increase local blood flow to promote improved genital arousal response.

Applied topically, avoiding hepatic first-pass metabolism response, resulting in lower systemic exposure potentially resulting in reduced side effects vs. oral sildenafil, including Viagra®.

FSAD– The Clinical Issue & Prevalence

Female Sexual Arousal Disorder (FSAD) is characterized primarily by inability to attain or maintain sufficient genital arousal during sexual activity.[1]

> **Of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction in men.**

FSAD should be distinguished from other sexual disorders characterized in the DSM, such as orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized as lack or absence of sexual fantasies and desire for sexual activity for some period of time.[2,3]

Meta-analysis of 95 studies from 2000-2014 indicated prevalence of Female Sexual Dysfunction in premenopausal women worldwide is 41%, and difficulty with arousal alone is 23%.[4]

Market research estimates:

33% of US women aged 21 to 60 (~ **20 million women**), experience symptoms of low or no sexual arousal.[5,6]

10 million women are considered distressed and actively seeking treatment.[5]

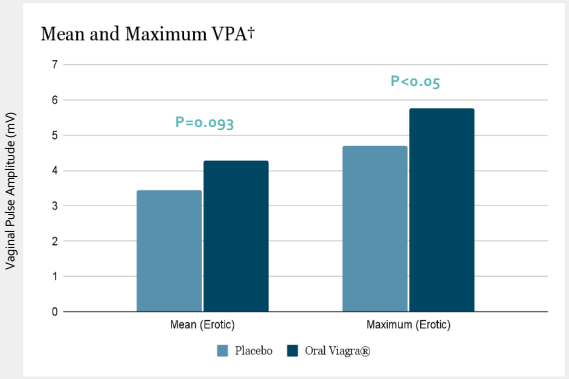
There are **no FDA-approved treatments** for FSAD

1. Diagnostic and Statistical Manual (DSM) 4th Edition Text Revision (DSM IV TR) defines FSAD as a persistent or recurrent inability to attain or to maintain until completion of the sexual activity, an adequate lubrication-swelling response of sexual excitement. The diagnostic criteria also state that the inability causes marked distress or interpersonal difficulty, is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.
2. https://labs.la.utexas.edu/mestonlab/female-sexual-interestarousal-disorders/, accessed 8 August 2023
3. https://my.clevelandclinic.org/health/diseases/24640-anorgasmia, accessed 8 August 2023
4. McCool et al. Sex Med Rev 2016;4:197-212. DOI: 10.1016/j.sxmr.2016.03.002
5. Ad Hoc Market Research: FSAD Prevalence Report (Oct 2015) conducted for SST LLC.
6. Based on US Census projections for 2016.

Oral Sildenafil provided a compelling proof of concept for FSAD

Statistically significant increases in Vaginal Pulse Amplitude (VPA)[1]

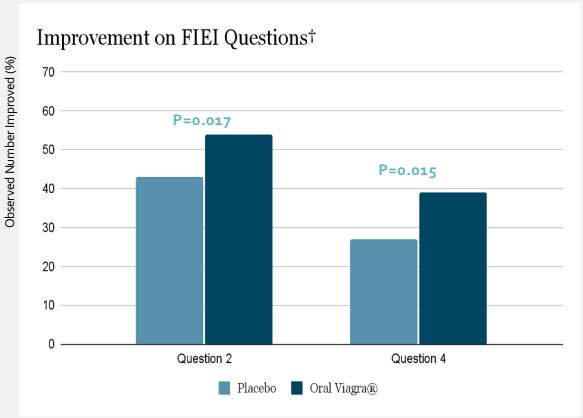
***Pfizer** VPA Clinical Lab Study – Oral Viagra*



† Twelve healthy premenopausal women were studied.

Statistically significant improvement in genital stimulation (FIEI)[2]

***Pfizer** Clinical Field Study – Oral Viagra*



† Question #2 – "After taking study medication, the sensation/feeling in my genital (vaginal, labia, clitoris) area during intercourse or stimulation (foreplay) seemed to be: (a) more than before, (b) less than before, or (c) unchanged".

Question #4 – "After taking the study medication, intercourse and/or foreplay was: (a) pleasant and satisfying; better than before taking the study medication, (b) unpleasant; worse than before taking study medication, (c) unchanged; no difference, or (d) pleasant; but still not like it used to be or I would like it to be."

202 postmenopausal women with FSAD who had protocol specified estradiol and free testosterone concentrations, and/or were receiving estrogen and/or androgen replacement therapy were studied.

Key Takeaways of Viagra® studies:

- Increased blood flow and clinical efficacy observed with oral sildenafil (Viagra®) in women.
- The side effect profile of the oral formulation was not optimal for women - leading to the exploration of alternative delivery options including a topical route of administration.

1.The Enhancement of Vaginal Vasocongestion by Sildenafil in Healthy Premenopausal Women. Journal of Women's Health & Gender-Based Medicine. Vol. 11, No. 4. 2002
2.Safety and Efficacy of Sildenafil Citrate for the Treatment of FSAD: A Double-Blind, Placebo Controlled Study. The Journal of Urology. Vol 170, 2333-2338, December 2003.

Sildenafil Cream, 3.6% - Phase 1 and Phase 2a Study Results

Phase 1 Study of SST-6007 (Sildenafil Cream, 3.6%)[1]

Normal healthy postmenopausal women were dosed with escalating doses of Sildenafil Cream, 3.6%, using a cross-over study design.

Sildenafil Cream had significantly lower systemic exposure compared to a 50 mg oral sildenafil dose:

- AUC – 3-6%
- Cmax – 1-2%

Sildenafil Cream was safe and well tolerated at clinically relevant doses (1-2g):

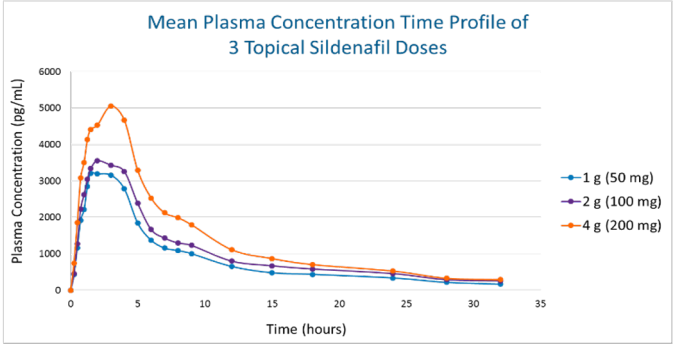
- Favorable product characteristics as self-reported by subjects
- Easy to use
- Readily absorbed

Phase 2a Study of SST-6007(Sildenafil Cream, 3.6%)[1]

Demonstrated increased blood flow in the genital tissue compared to placebo (mean change in VPA analysis) in 31 women (pre and postmenopausal) ~30 minutes post dosing.

Phase 1 Study

Parameter	Treatment Level		
	1 g cream (36mg sildenafil), n=20	2 g cream (71mg sildenafil), n=20	4 g cream (142mg sildenafil), n=19
Cmax (ng/mL)	3.61	4.10	5.65
AUCo-t(h*ng/mL)	27.45	33.32	45.33
Tmax (hr)	2.56	2.60	2.42



1. Data on file. Sildenafil Cream, 3.6% was previously known as SST-6007.

Sildenafil Cream, 3.6% - Thermography Study Results*

Demonstrated **time to effect (11-15 minutes)**

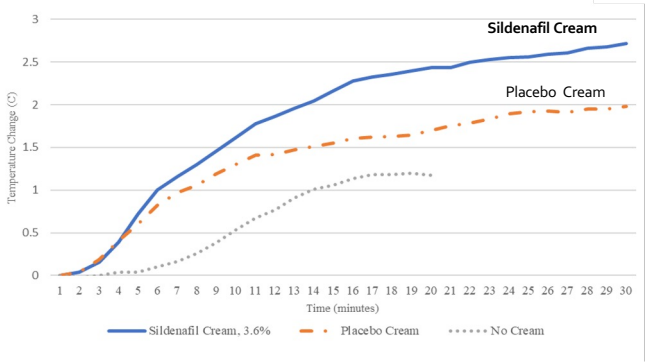
Positive cognitive arousal responses were noted.

Significantly **greater increases in genital temperature** after application of Sildenafil Cream compared to placebo cream.

Significantly **greater self-reported arousal** responses reported during Sildenafil Cream visits compared to placebo cream visits.

Statistically significant greater linear slope during minutes 11-15 of the sexually explicit stimuli as compared to the placebo cream for the vestibule.

Figure 1. Clitoral temperature change during the sexually explicit film



Thermography Study Design & Methodology (N=6)[1]

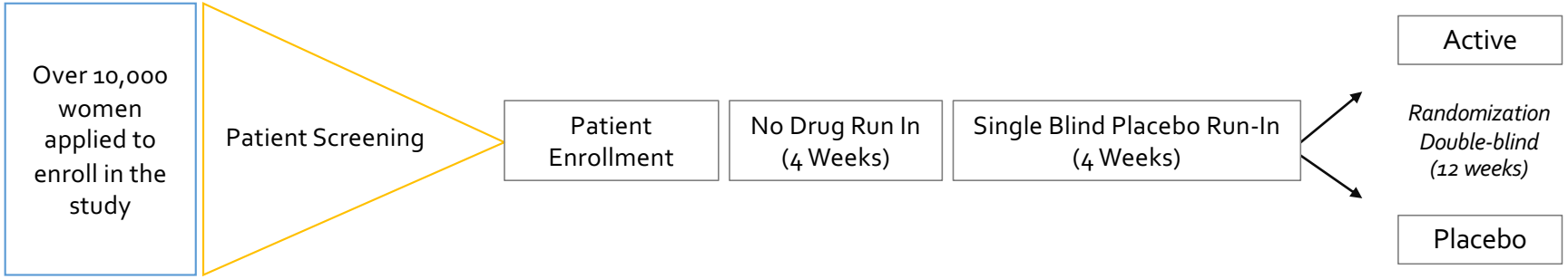
Phase 1, single-dose, double-blind, placebo-controlled, 2-way crossover study evaluating the feasibility of using thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women. The study required 3 visits and a follow up contact: Visit 1 (screening), Visits 2-3 (double-blind dosing) and a phone call (safety follow-up).

1. Data on file.

* Thermography utilizes sensitive cameras capable of detecting and recording temperature variations over time. Genital temperature changes are a surrogate for genital blood flow.

Overview of Phase 2b Study

Phase 2b, Exploratory, Randomized, Placebo-Controlled, Trial of Sildenafil Cream 3.6% for the Treatment of Female Sexual Arousal Disorder in Healthy Premenopausal Women (#NCT04948151) – N=200 Randomized, 101 Sildenafil Cream vs 99 Placebo



Co-Primary Endpoints: Change from baseline (BL) in SFQ28 Arousal Sensation (AS) Domain and FSDS-DAO Question 14

Secondary Endpoints: Change from BL in number & proportion of satisfactory sexual experiences (SSEs)

Several Exploratory Endpoints: Including SFQ28 Desire, Orgasm Domains, and FSDS-DAO Questions

Exit Interviews (EIs): EIs were performed better understand qualitatively what constitutes a meaningful change on the SFQ28-AS domain, Arousal Diary AS domain, FSDS-DAO Question 14, Patient Benefit Evaluation (PBE), and what constitutes meaningful improvement on the Patient Global Impression of Change (PGI-C), the PGI-C in Satisfactory Sexual Events (PGI-C SSE), and Patient Global Impression of Severity (PGI-S).

Evaluation of Recall Period: At the end of the No-drug Run-in and at the end of the Single-blind Placebo Run-in, the correlation between the 24-hour recall period and the 4-week recall period was evaluated for all patients who completed both the Arousal Diary, the FSDS-DAO, and the SFQ28. Additionally, at the same intervals, a subset of patients was selected randomly via interactive response technology (IRT), who completed the FSDS-DAO and the SFQ28 but did not complete the Arousal Diary, were evaluated to investigate whether completion of the diary questions influences how the patient answers question #14 of the FSDS-DAO and the SFQ28 AS domain scores. These patients completed the entire study but did not complete the Arousal Diary throughout the study. These patients did not affect the primary study objectives as they were not included in the analysis of the coprimary endpoints.

Establish Partner Safety: The sexual partners were enrolled in the study such that partner safety could be established.

Phase 2b Study Objectives Overview

- The Phase 2b was not only the first at-home study with Sildenafil Cream, 3.6%, **it was the first study specifically evaluating a potential therapy for FSAD as an indication**.
- As such, the objectives included:
  - Characterization of **sexual response** impacted by the arousal dysfunction;
  - Evaluation of the **patient population** based on symptoms reported and concomitant diagnoses or medications;
  - Identification of **endpoints** to take forward into a Phase 3 program
- These objectives were met – **the dosing regimen studied achieved a meaningful within patient change and statistically significant improvement in the patient population proposed to be studied in Phase 3 using the patient-related outcome measure studied in Phase 2b.**

Phase 2b
Post-Hoc Analyses

- Informal post-hoc analyses were conducted on enrollment FSD diagnosis category so that **efficacy could be evaluated in the study sub-populations based on concomitant diagnoses, such that the patient population most likely to benefit from the mechanism of action of Sildenafil Cream, 3.6% could be determined for the Phase 3 program.**
- In the ITT population, although not statistically significant, the Sildenafil Cream, 3.6% group (N=69) demonstrated greater improvement than the Placebo Cream group (N=59) in change from Baseline to end of study in SFQ28 (AS) domain (1.1 versus 0.8 respectively, p=0.6).
- When this SFQ28 (AS) domain efficacy assessment was performed excluding study participants with inability to orgasm and subjects suffering from vaginal pain, both indications that could have other underlying causes beyond the arousal dysfunction, **the improvement in the Sildenafil Cream, 3.6% group was above the recommended meaningful within patient change and statistically significant compared to the minimal improvement in the Placebo cream group.**

Variable and Subset Population	Sildenafil Cream 3.6% (N=29)	Placebo Cream (N=23)	P value
	Least Squares change (Standard Error) from BL at Week 12	Least Squares change (Standard Error) from BL at Week 12	
Proposed Phase 3 population – FSAD, including women with decreased desire as a result			
SFQ28 Arousal Sensation Domain	2.03 (0.62)	0.08 (0.71)	0.04
SFQ28 Desire Domain	1.27 (0.76)	-0.89 (0.86)	0.06
SFQ28 Orgasm Domain	1.12 (0.49)	0.186 (0.52)	0.19
FSDS-DAO – Item 3 Guilt	-0.64 (0.18)	-0.09 (0.20)	0.04
FSDS-DAO – Item 5 Stressed	-0.54 (0.17)	0.02 (0.19)	0.03
FSDS-DAO – Item 10 Embarrassed	-0.59 (0.17)	0.01 (0.19)	0.03

DARE-HRT1^

Investigational monthly menopausal hormone therapy

Potential first-in-category vaginal combination hormone delivery for treatment of vasomotor symptoms due to menopause

Self-administered 28-day IVR

Intravaginal ring (IVR) designed to release bio-identical estradiol and bio-identical progesterone over 28 days.

There are **no FDA-approved options** with both hormones in one monthly IVR.

Potential to be the first convenient monthly format product with both hormones.

Phase 1 / 2 Study Completed; IND Related Activities to Support Phase 3 Study Underway

^505(b)(2) regulatory pathway anticipated.

Vasomotor Symptoms of Menopause

Daré Innovation: DARE-HRT1 Monthly Vaginal Ring

Clinical Issue

- In the US, over 45M women are estimated to be in or approaching menopause; symptoms can last up to 10 years[1]
- ~75% of menopausal women experience hot flashes[2]
- 3 in 5 menopausal women felt that they were adversely affected by symptoms while at work[3]
- 35% of menopausal women reported that they had experienced 4+ symptoms of menopause, but only 44% said they had discussed their symptoms with a doctor[4]

Limitations with current standards of care

- Hormone therapy is the most effective treatment for VMS and other symptoms of menopause according to the The Menopause Society[5].
- The Menopause Society recommends delivering both estrogen and progesterone, simultaneously, for women with an intact uteri and The Menopause Society states that non-oral routes of administration may offer potential advantages.
- There are no FDA-approved products that combine both estradiol and progesterone in a non-oral monthly form.
- Many treatments do not offer bioidentical hormones to most closely mimic the natural hormones in a woman's body.

Target Product Profile

- A single, non-oral, non-daily, monthly product that can deliver both bioidentical estradiol and progesterone.
- Non-oral routes of administration bypass the liver[5] and may reduce the risk of blood clots[6].
- A vaginal ring is a preferred form factor, due to the convenience, discrete administration, and ease of use [7]. According to a survey of women who switched from an oral contraceptive to an intravaginal ring (IVR), 71% of reported they would continue to use the IVR after the study[8].

[1] https://my.clevelandclinic.org/health/diseases/21841-menopause
[2] https://www.hopkinsmedicine.org/health/conditions-and-diseases/introduction-to-menopause
[3] OPINIUM RESEARCH https://www.vodafone.com/sites/default/files/2021-10/menopause-global-research-report-2021.pdf
[4] https://www.healthyagingpoll.org/reports-more/report/womens-health-sex-intimacy-and-menopause
[5] https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf
[6] https://www.reuters.com/article/us-blood-clot/study-finds-no-blood-clot-risk-with-hormone-patch-idINTRE6BU1ZJ20101231
[7] Source: Internal Qualitative Market Research, Mar-Apr 2017
[8] Creinin MD, Multicenter comparison of the contraceptive ring and patch: a randomized controlled trial. Obstet Gynecol. 2008;111(2 Pt 1): 267-77.

DARE-VVA1^

Investigational hormone-free vaginal insert for dyspareunia

Potential first-in-category hormone-free intravaginal treatment for painful intercourse (dyspareunia) associated with vulvar and vaginal atrophy (VVA).

Proprietary formulation of tamoxifen for vaginal administration.

There are currently no FDA-approved vaginal hormone-free treatments for VVA.

Phase 1 / 2 Study Completed; IND cleared

Activities to Support Phase 2 Study Underway

^505(b)(2) regulatory pathway anticipated.

DARE-CIN^

Investigational anti-viral vaginal insert for HPV infection and cervical intraepithelial neoplasia (CIN)

Potential first-in-category, non-surgical, pharmaceutical intervention for the treatment of CIN and other HPV-related pathologies.

Proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert.

There are currently **no FDA-approved, non-surgical pharmaceutical interventions** to treat **CIN2+.**

There are **no FDA-approved treatments for HPV infection.**

Phase 1 and Proof-of-Concept Studies Completed; Activities to support IND filing to enable progression to Phase 2 clinical development underway.

^505(b)(2) regulatory pathway anticipated.

DARE

IN ENGLISH, IT MEANS "TO BE BOLD."

IN ITALIAN, IT MEANS "TO GIVE."

Transforming Women's Health

We founded Daré Bioscience with the ***sole focus*** of putting women's health first –

to **boldly address** existing therapeutic gaps and **give women** the novel treatment options they want and need.