FEMALE AROUSAL AND ORGASMIC COMPLAINTS IN A DIVERSE CANCER POPULATION TREATED WITH ZESTRA: A TOPICAL APPLIED BLEND OF BOTANICAL OILS

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Innovus Pharma’s Overview

Commercial Products:

- **Zestra®**: Superior topical product to increase arousal, desire and satisfaction in women
  - Only commercially available and clinically proven product in over 276 women with FSI/AD (a large & growing unmet market)
  - Zestra® is a superior female sexual satisfaction solution for consumers and health care professionals
  - Commercially available in the USA and Canada through large retailers, drug wholesalers and online

- **EjectDelay™**: Topical treatment for Premature Ejaculation (PE)
  - Launched in Q2 2014 online in the US
  - Extending availability to large retailers and drug wholesalers in H2 2014

- **Sensum+™**: Topical product to increase penile sensitivity
  - First partnership signed with Ovation Pharma for Morocco and expecting first commercial batch delivery in Q4 2014

- **Zestra Glide®**: Water based lubricant for women
  - Only water based lubricant with high viscosity to allow long lasting activity
Company Background

• Headquartered in La Jolla, California, is an emerging pharmaceuticals company that delivers innovative health solutions through its OTC medicines and consumer and health products

• Innovus is dedicated to providing solutions based on real science

• Products: Ejectdelay, Circum serum

• Mission:
  – Innovus Pharma's mission is to in-license, acquire or develop over-the-counter and consumer healthcare products designed for in-home treatment of medical conditions and ailments to help people take care of themselves and their families in order to live healthy lives
A Commercial High Value Asset

• Zestra®, acquired in end of 2013, is the only clinically-proven COMMERCIALY SOLD consumer care product with statistically significant clinical efficacy in women with FSI/AD, a disorder estimated to affect 10 million women.

• Over 11 MILLION DOSES of Zestra® have been sold.

• Zestra® is WOMEN APPROVED:
  • 92% of users said that they would recommend to a friend and 78% said they would use it again.
  • Zestra® is currently being sold in retailer such as Walmart and through distributors such as McKesson, and Cardinal Health.

• EXCELLENT SAFETY PROFILE: 2 in 1 million reported minor adverse events from over 11 million doses sold since launch.

• Zestra® PATENT PROTECTED until 2021.
Zestra

• Patented blend of:
  – Borage seed oil
  – Evening primrose oil
  – Angelica root extract
  – Coleus forskohlii extract

• Designed to increase sexual sensation, arousal and pleasure

• No drug/ drug interactions

• Topically applied: clitoris and outer genital areas

• Only AE in trials: skin irritation - greatest on mucous membrane
• Two clinical studies are in the published medical literature that support its use in clinical sexual medicine treatment paradigms.


Zestra® Induced a statistically significant increase in Desire and Arousal in women using the product as compared to placebo

*2003 & 2007 Zestra® Clinical studies; The Journal of Sex & Marital Therapy, 29(s):33-44, 2003 and January 2010
Zestra® Clinical Efficacy-Secondary Endpoint
Women’s Inventory of Treatment Satisfaction (WITS)

- Women using Zestra® were 6 times more satisfied with their treatment as compared to placebo
- Women using Zestra® were twice more sexually satisfied as compared to placebo

*p2003 & 2007 Zestra® Clinical studies; The Journal of Sex & Marital Therapy, 29(s):33-44, 2003 and January 2010*
Patient Experience

• Patients report importance of
  – All natural ingredients
  – Non hormonal nature of the product
  – No drug interaction
  – No concern with cancer treatment interaction
• Can be used on nipples as well for increased sensation
• Only mild genital burning is the only AE
• Topically applied to clitoris, mons, or outer vaginal area
Material and Methods

• We present a case series of 10 women who presented with self reported delayed arousal and poor orgasmic response and decreased orgasmic intensity.

• Patients were evaluated and assessed using a standardized protocol previously described by a sexual medicine gynecologist.
Results

- Patient demographics included median age of 55.4 years.
- Cancers: Breast, rectal, uterine, ovarian and lung.
- All women were diagnosed by strict criteria to have genital syndrome of menopause.
- Marital status
  - 1 single
  - 1 divorced
  - 8 married
- All women were sexually active with a functional partner.
• **Hormone Ranges**
  – 7/10 women had normal hormones
  – though the majority had testosterone in the lower one third.
  – All women had Estradiol levels in the menopausal

• **Local Products**
  – 10 on vaginal moisturizers
  – 10 on lubricants
  – 3 on Estradiol cream
  – 1 on DHEA suppositories.
• At 4 week follow up, all patients reported

Efficacy with improved

• Intensity of orgasmic response
• Decreased latency of time to achieve orgasms
• Improved sexual experience and satisfaction
Conclusions

• Treatment for malignancy impacts
  – genital arousal and orgasmic function

• Several OTC products that purport to improve sexual satisfaction for women.

• All women treated in this case series reported
  – increased intensity of orgasmic response
  – decreased latency to orgasm

• Further randomized clinical trial study with standardized screeners and questionnaires with set endpoints is necessary to establish the generalizability of these preliminary case findings are planned and underway