



Developing Novel Solutions for
Women's Health and Cancer

Corporate Presentation

March 2012

OTC: BNVI.PK

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Bionovo's Discovery and Development History

**Developing novel, botanically derived therapeutics
that address large, unmet needs in women's health.**

Bionovo Background

- Founded 2002, initiated operations in 2005
- **Our focus** is developing botanically derived drugs for women's health indications
- **Bionovo products** address large markets with unmet needs
 - Post menopausal symptoms (hot flashes) – Phase 3
 - Breast cancer – Phase 2 ready
- **Unique advantages**
 - Botanically derived therapeutics with strong IP
 - Proven manufacturing capability of Phase 3 clinical product
 - Platform technology capable of generating many products
 - Strong scientific and development teams



A Value Opportunity

■ Fully owned products, no royalties

■ Menerba – Phase 3, post menopausal symptoms, hot flashes

- Revenue potential in billions of dollars
- Clinical and preclinical data show it is safe and effective
- Strong IP and know-how position
- Manufacturing process established for FDA
- Short time to market



■ Other pipeline products

- Bezielle – Phase 2 ready for breast cancer
- Seala – Phase 1 ready for vaginal dryness

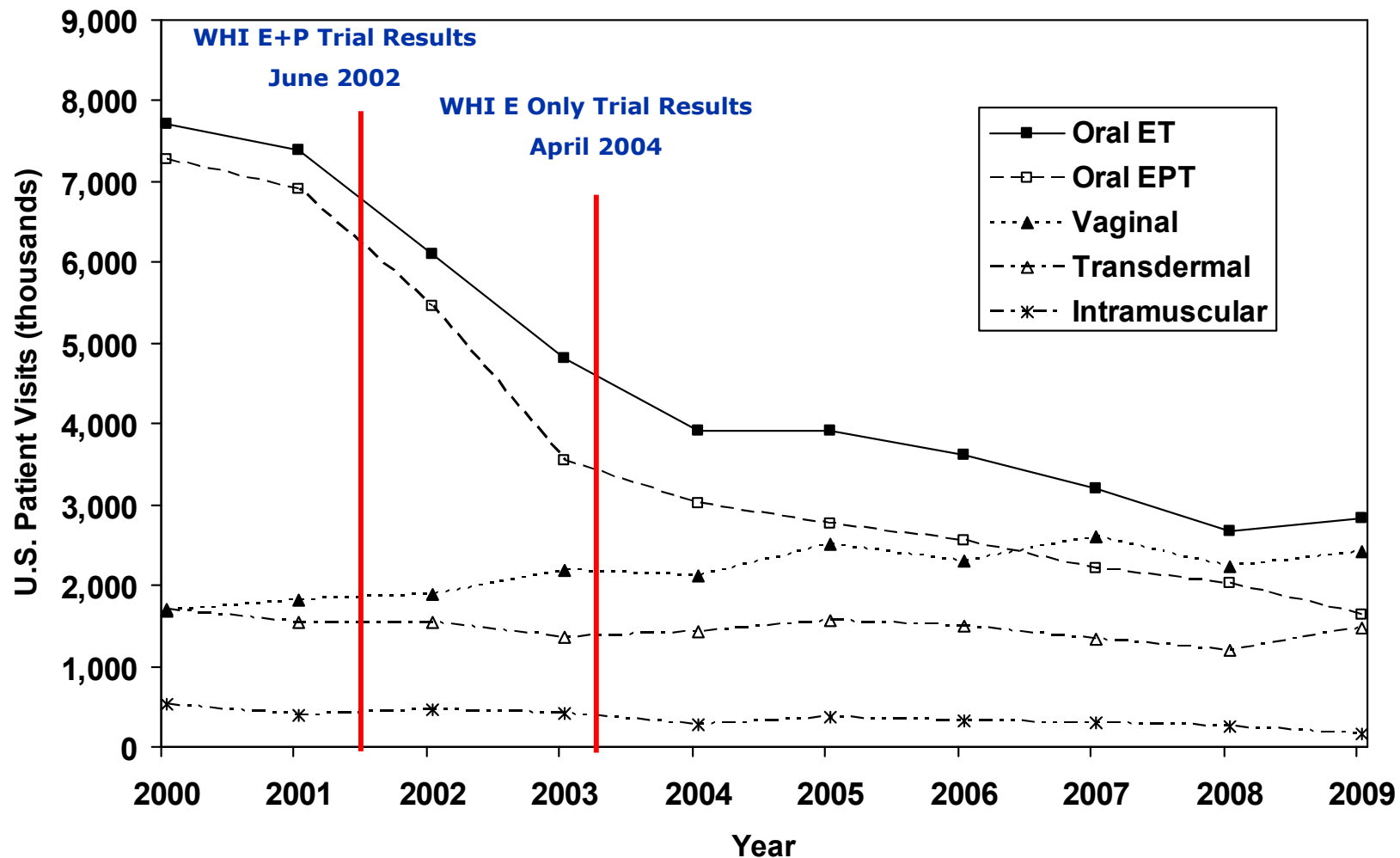


■ Platform technology – proof of concept

- Post menopausal female related obesity
- Solid tumors

Post WHI: Change in Landscape of Menopausal Treatment

- From 2001 to 2009, total reported menopausal hormone therapy (MHT) use decreased by 52%, from 17.5 million reported use to 8.3 million

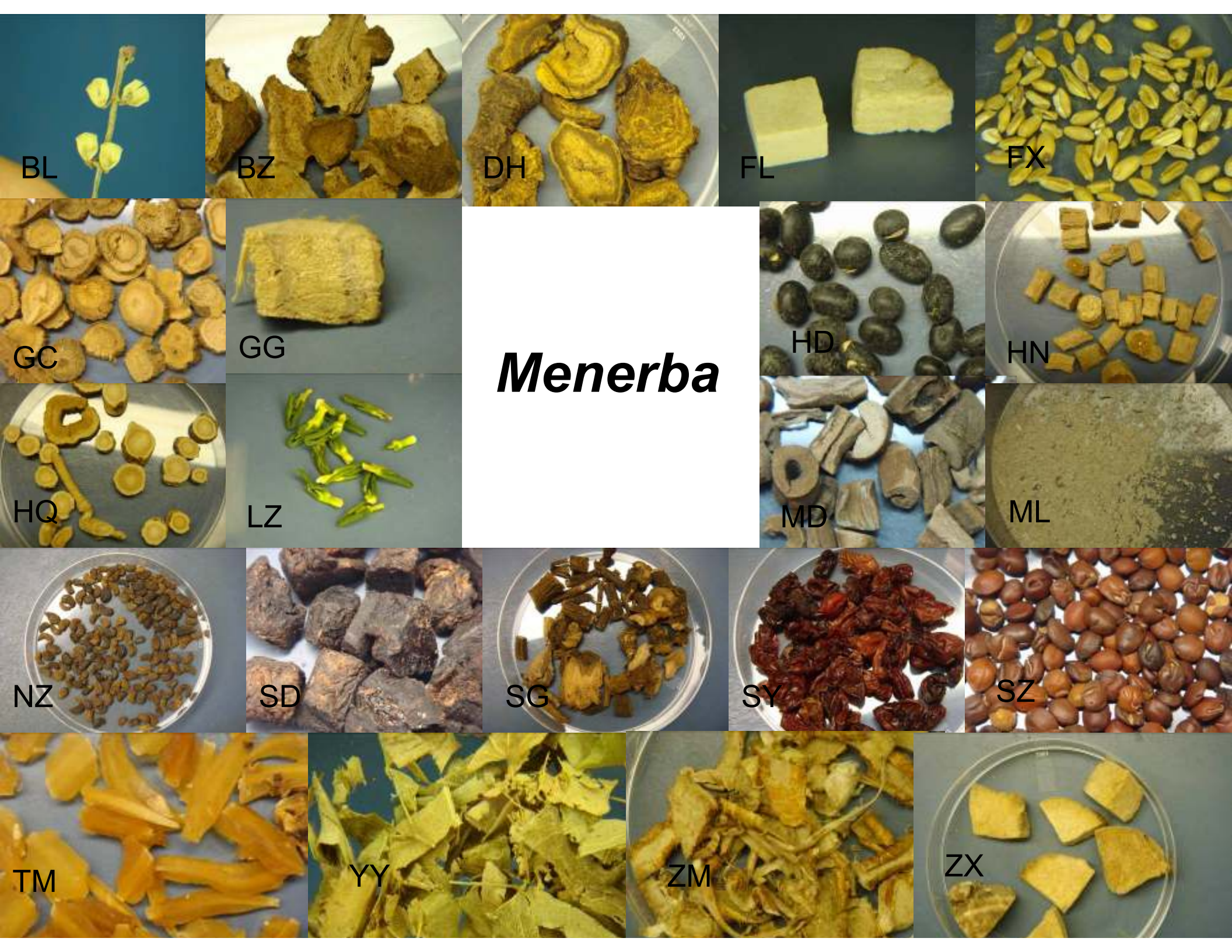


Tsai. Menopause 2011 18 (4)

Menerba – Post Menopausal Symptoms, Hot Flashes

- Estrogens have safety issues
 - WHI study in 2002, usage dramatically decreased
- Menerba is not an estrogen – targets estrogen receptor beta
 - Excellent safety profile
- Phase 3 pivotal clinical trial initiated
- Strong clinical and preclinical data package
- Strong IP and know-how position
 - Composition of matter patent coverage to 2026
 - 22 herb mixture almost impossible to duplicate
- Manufacturing process established for FDA
 - Consistent, reproducible results
 - Analytical methods in place
- Short time to market





BL

BZ

DH

FL

FX

GC

GG

HD

HN

HQ

LZ

Menerba

MD

ML

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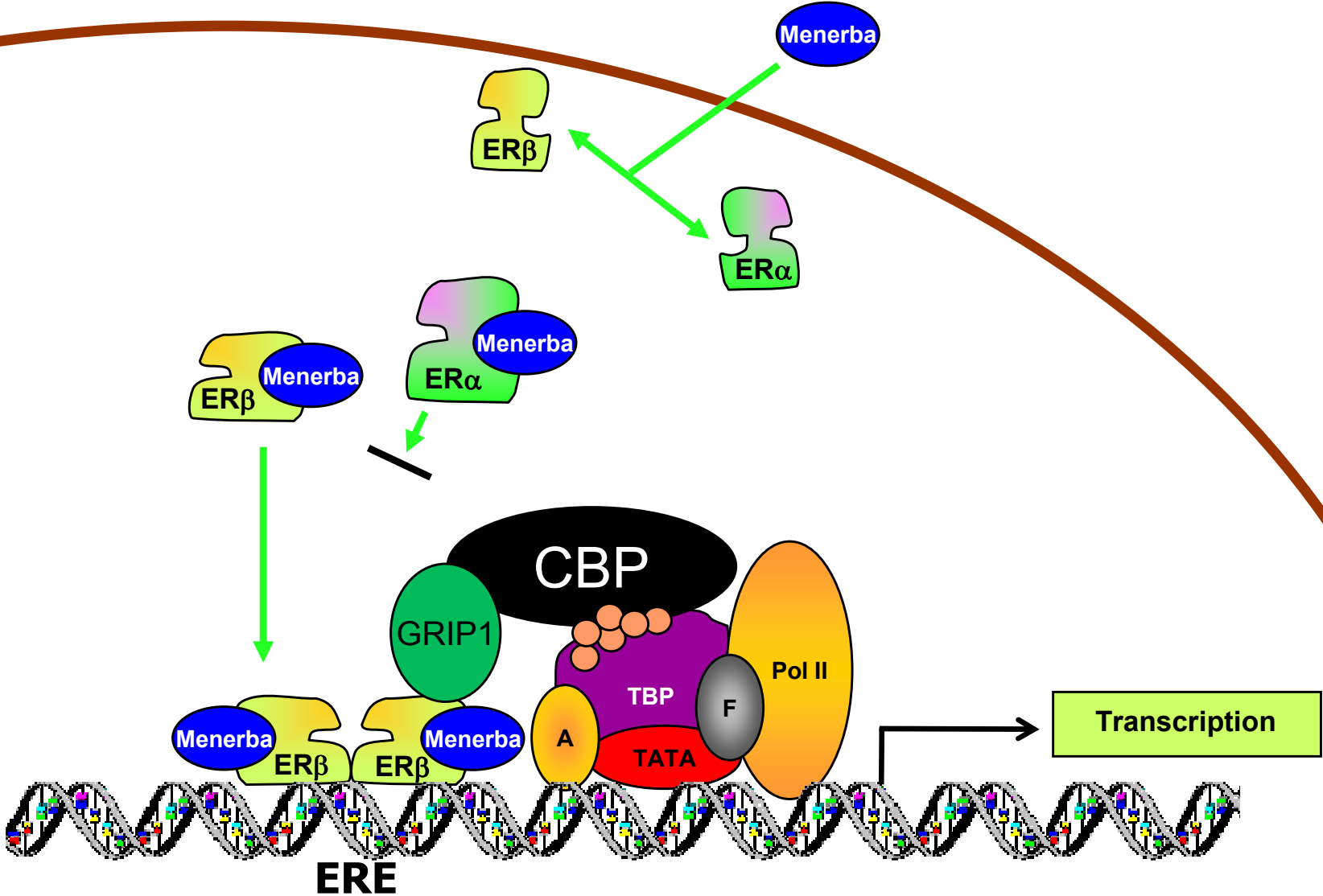
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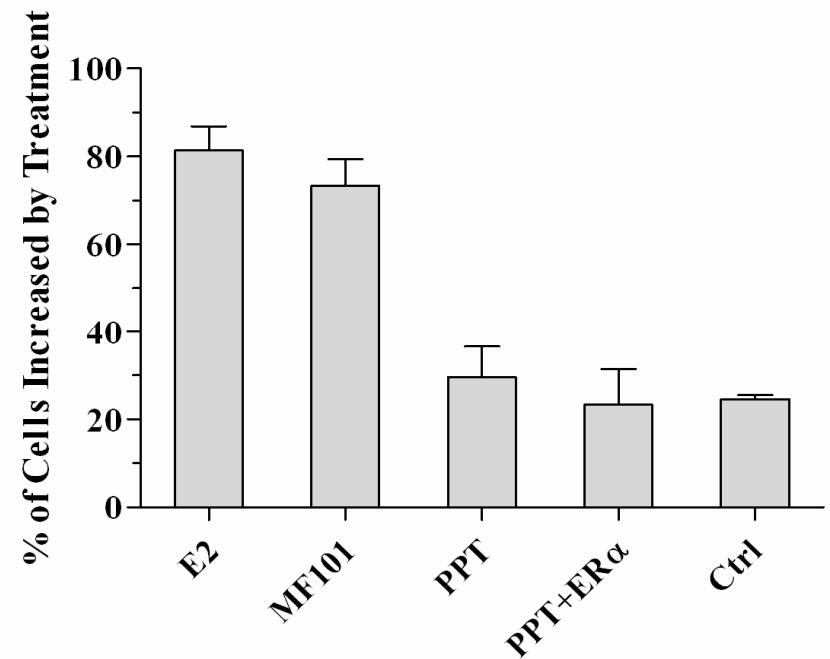
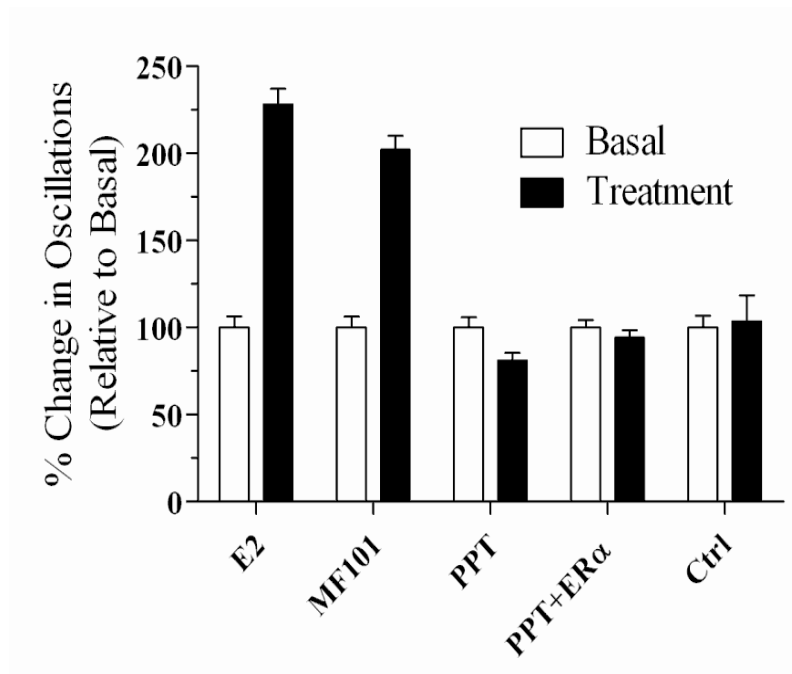
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Menerba Selectively Recruits ERβ and Coactivators to Target Genes



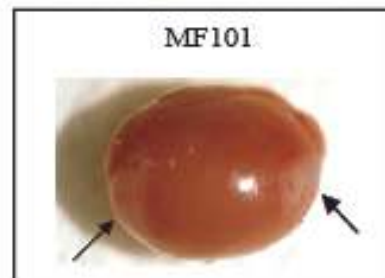
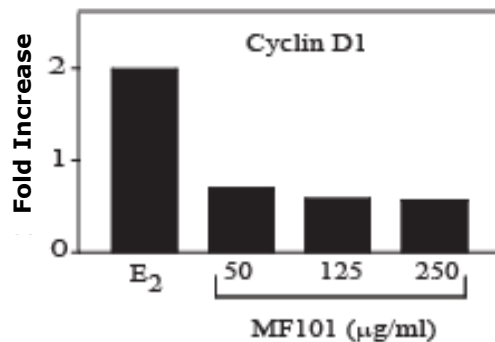
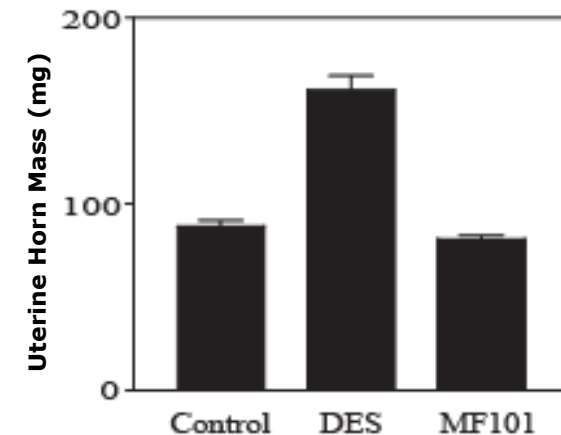
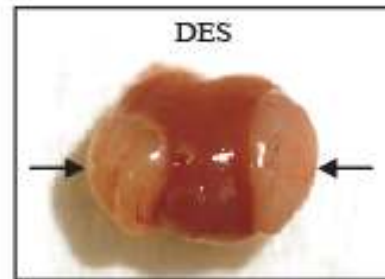
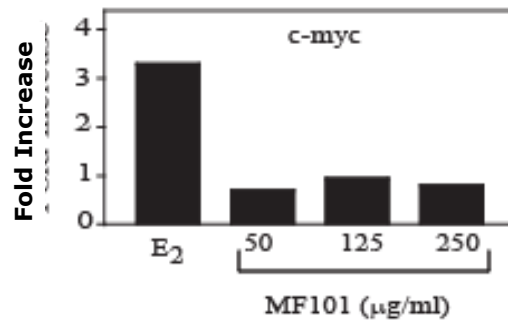
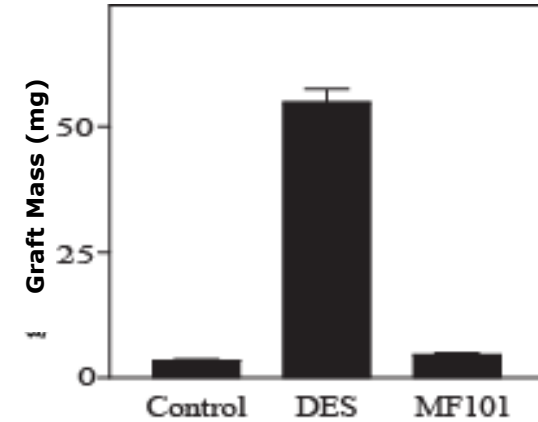
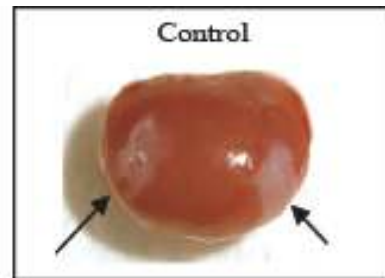
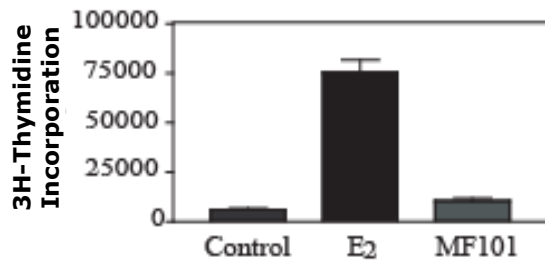
Thermal Regulation is Mediated by Menerba via ER β

- Hot Flashes are centrally regulated in the thermoregulatory zone in the hypothalamus
- Primary neurons differentiated from embryonic stem cells expressing both estrogen receptors were tested
- Estradiol and Menerba regulate calcium oscillations in primary neurons
- PPT, an ER α selective agonist, does not regulate calcium oscillations in primary neurons
- These results support that thermal regulation in neurons is mediated by Menerba via ER β



Menerba Does NOT Stimulate Cell Proliferation

- In contrast to estrogens, Menerba:
 - Does not activate oncogenes related to estrogen mediated proliferation
 - Does not increase uterine proliferation
 - Prevents breast cancer tumor formation in animal models



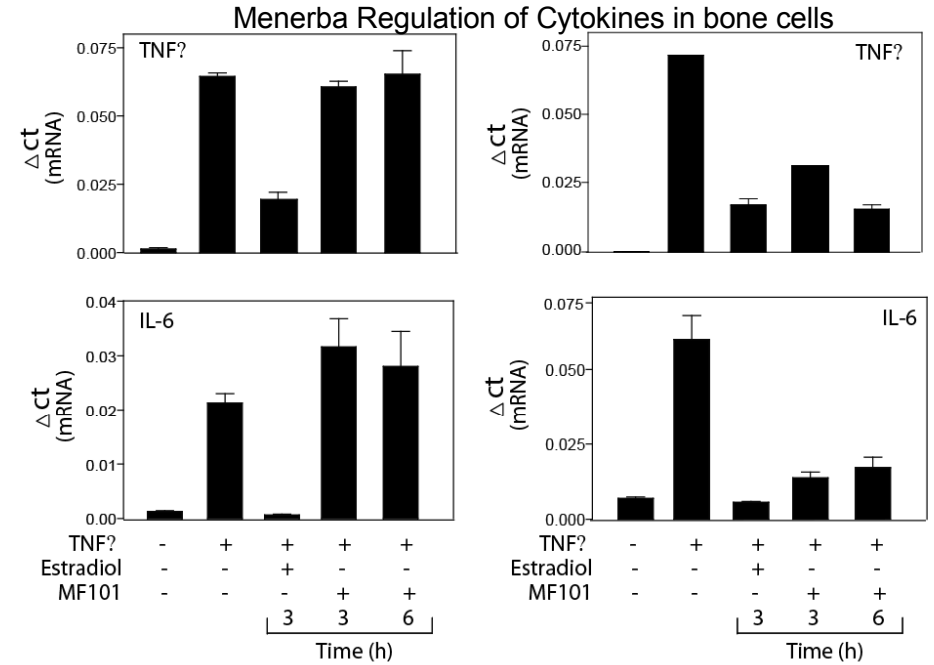
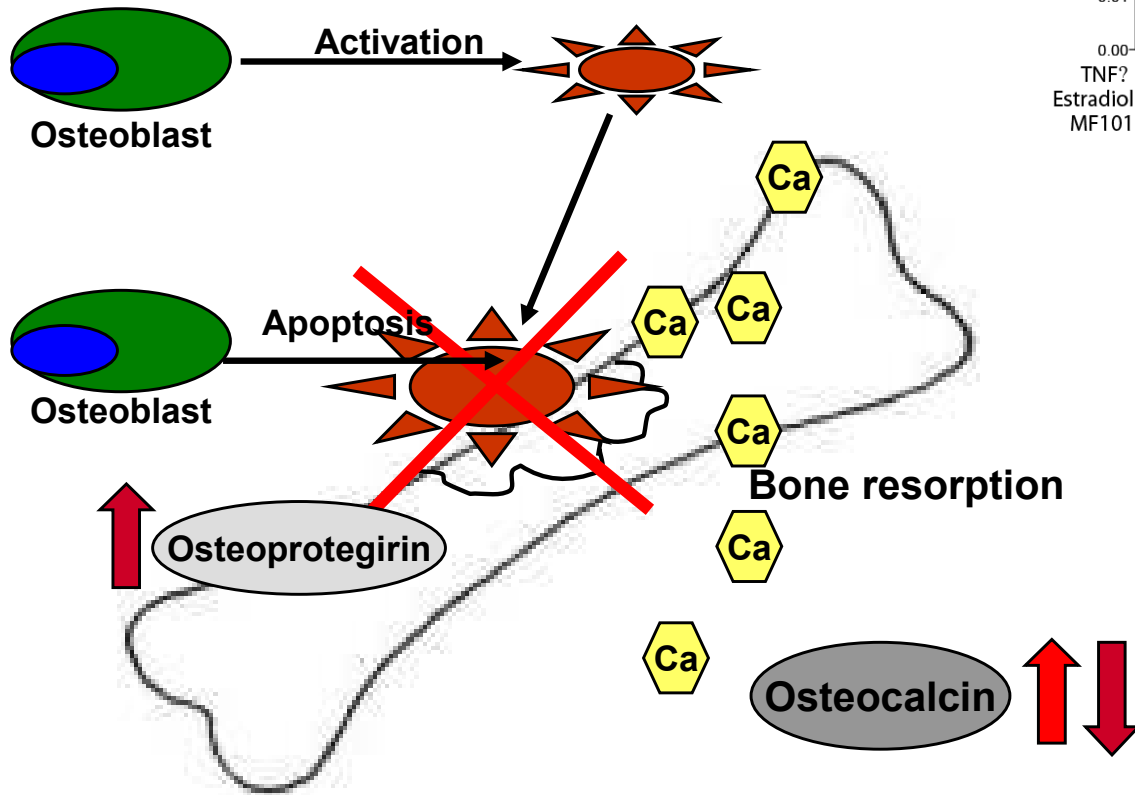
Source: Cvoro A, Endocrinology. November 9, 2006.

Menerba Effect on Inflammation and Bone

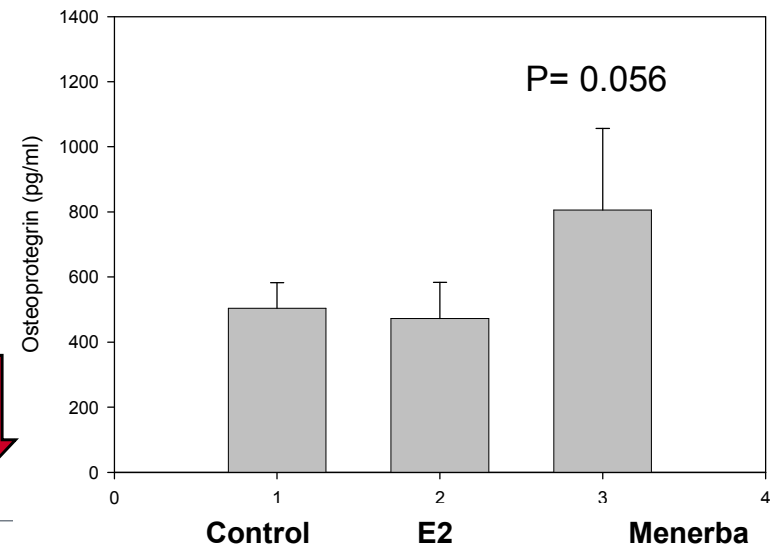
Menopause



Hormone Therapy



Osteoprotegerin Levels in OVX mice after 32 days of Treatment



Menerba – Historical Development Summary

■ Preclinical – completed

- Toxicology studies clean to highest feasible dose after 26 weeks

■ Phase I safety – completed

- Dose ranging from 1.25g to 15g
- Excellent safety

■ Phase II placebo controlled – completed

- 5 and 10g / day, placebo
- 12 week treatment
- Excellent safety, some loose stools
- Statistically significant efficacy

■ Formulation bridging/safety studies – completed

- Fiber removed (decreases loose stools), improved taste
- New 5 and 10 g doses now twice as potent
- 4 week treatment
- Good efficacy. similar to estrogens



Phase 2 Clinical Trial Results

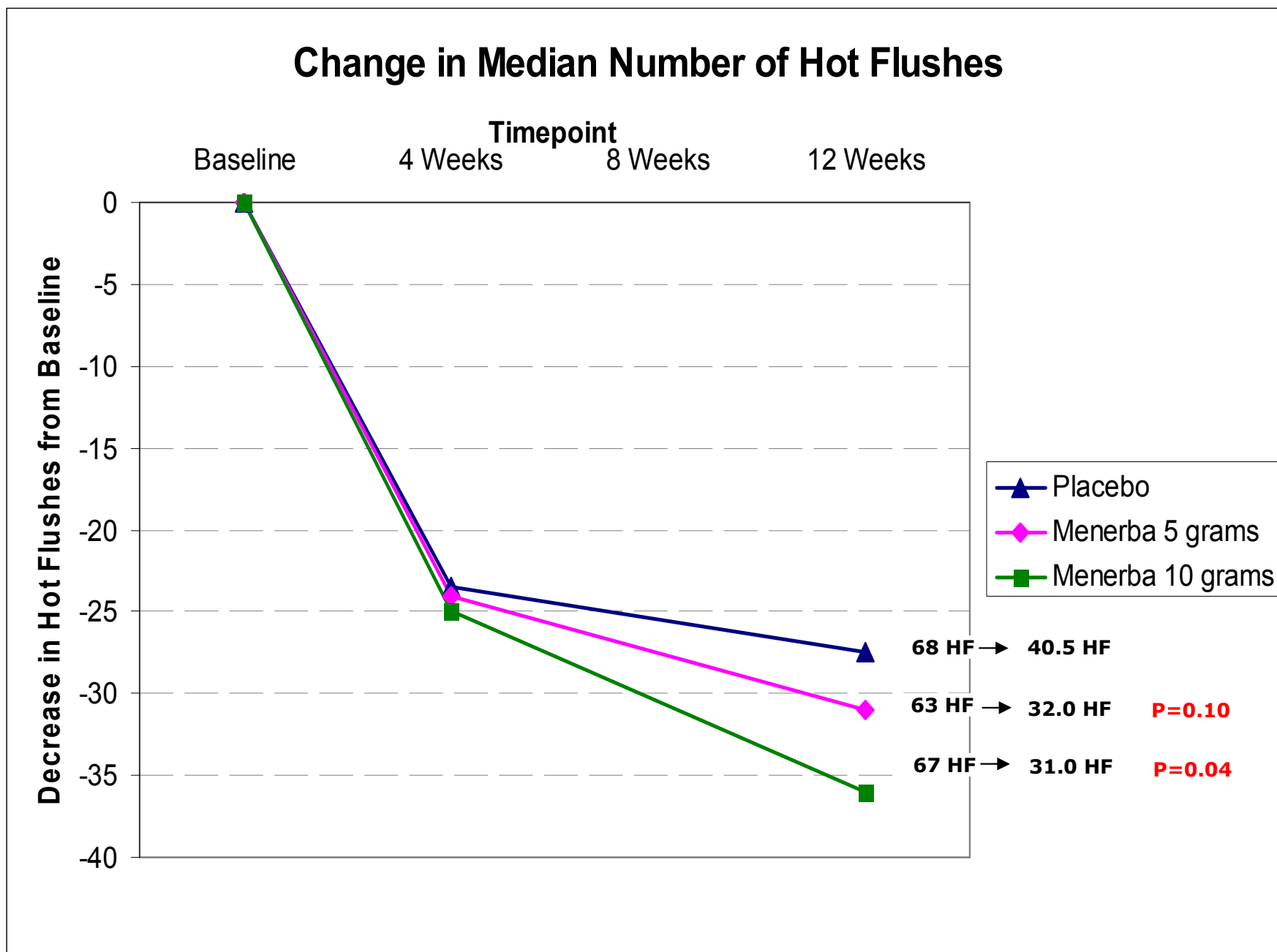
Efficacy

- Menerba demonstrated statistically significant ($p=0.04$) results in the high dose group
- 62% reduction in moderate to severe hot flashes
- Odds ratio of 60% reduction on Menerba vs. placebo was 2.4 ($p=0.02$)
- Menerba exhibits a clear dose response curve
- Higher dose (2x) to be included in Phase 3 trial

Safety

- No difference in the number of uterine bleeding episodes between treatment and placebo
- No cases of endometrial hyperplasia
- “Transient loose stools” was the only side effect (12.0% vs. 3.0% for placebo)
 - Benefit from reduced constipation on Menerba vs. placebo (1.3% vs. 4.0%)
- Statistically significant reduction in weight ($p=0.04$) and BMI ($p=0.05$) on Menerba versus placebo
- 91.0% of participants used greater than 75.0% of study medication during the 12 week period
 - Low drop out rate (2.0%)

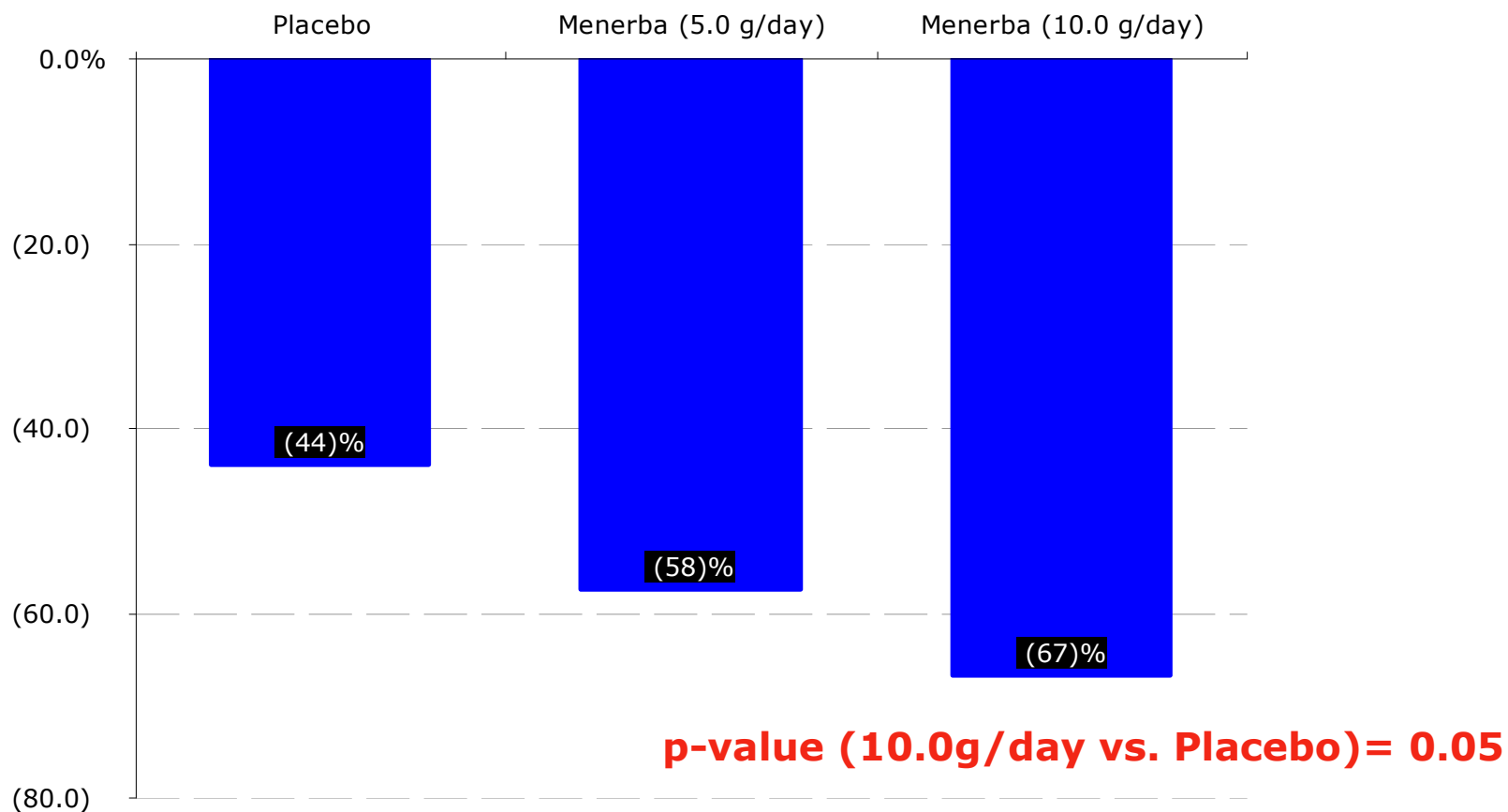
Phase 2 Efficacy Data



Phase 2 Reduction in Nighttime Awakenings

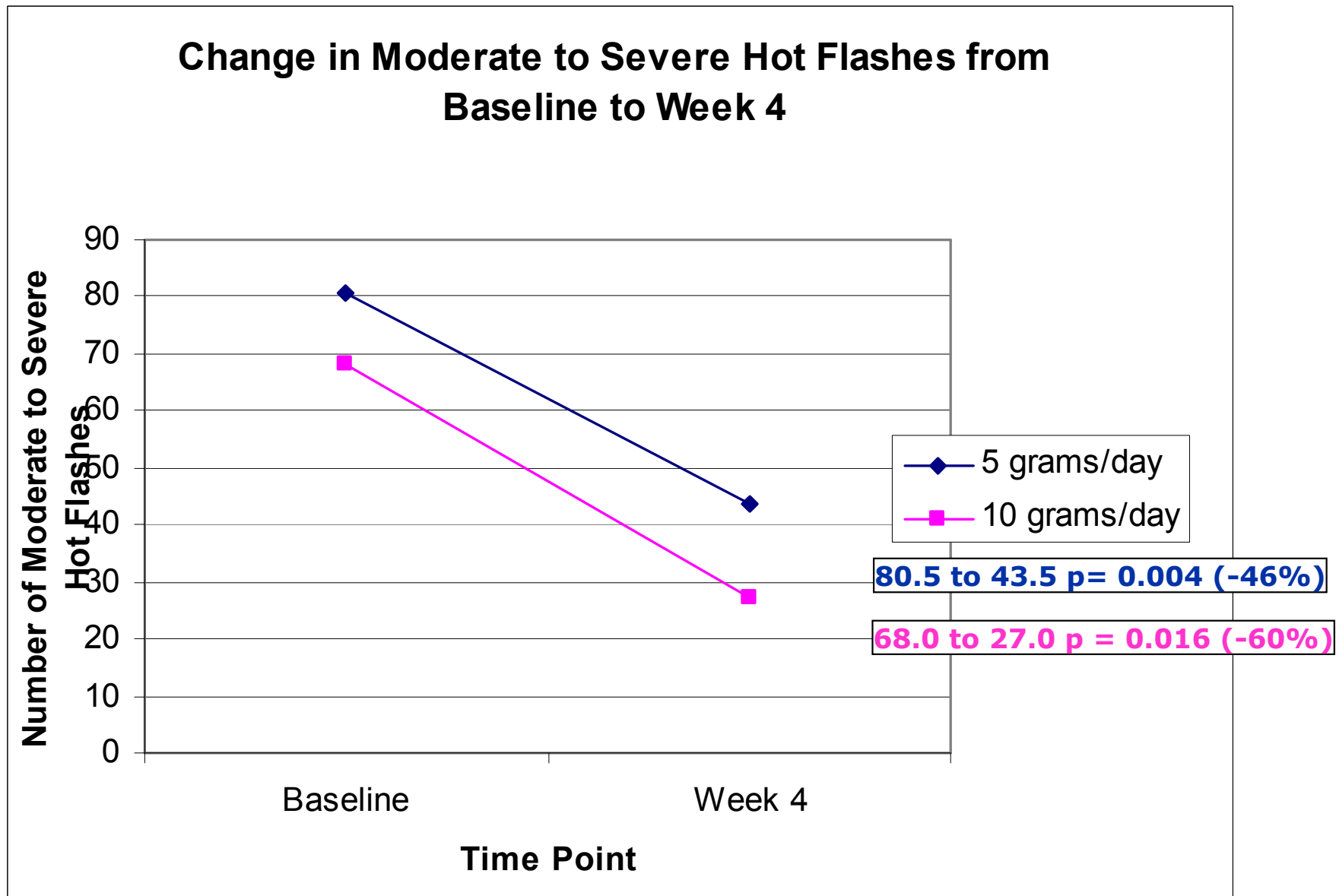
Menerba demonstrated a significant reduction in nighttime awakenings, a common issue with hot flashes compared to placebo group

(Median % Reduction at 12 Weeks)

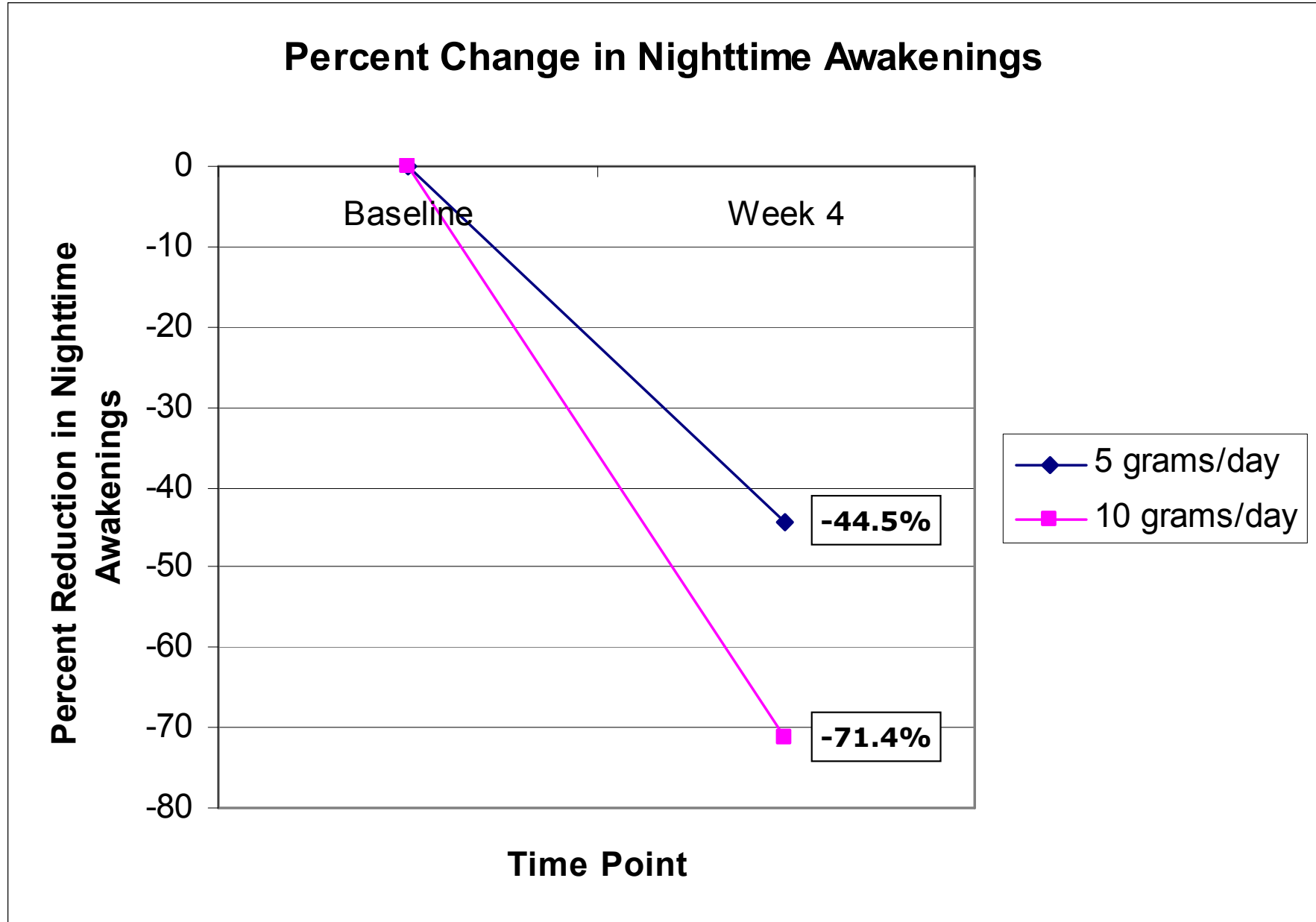


Source: Data from Phase 2 clinical trial of Menerba.

MF101-009 Reduction in Moderate to Severe Hot Flashes



MF101-009 Percent Change in Nighttime Awakenings



Menerba – Data Summary

■ Preclinical and Phase 1 showed excellent safety profile

■ Phase 2

- Statistically significant $p=0.04$ results in high dose group
- **62% reduction in moderate to severe hot flashes**
- **Clear dose response curve**
- **Excellent safety**

- Some loose stools primary side effect

■ Formulation bridging/safety studies (MF101-009)

■ **Efficacy similar to estrogens**

- 46% to 60% reduction in moderate-to-severe hot flashes at 4 weeks
- 44% to 71% reduction in nighttime awakenings

■ **Clear dose response curve**

■ **Excellent safety**

- Loose stools not observed



Menerba – Current / Planned Development to NDA

■ Phase 3A - ongoing

- Primary endpoint change in frequency of moderate-to-severe hot flashes, several secondary endpoints
- 1200 patients for 12 weeks treatment
- Three arms, 5 g/day, 10 g/day and placebo (new formulation)
- Interim futility analysis planned for Q4 2012
- Complete data by Q1 2013

■ Phase 3B - planned

- Primary endpoint change in frequency of moderate-to-severe hot flashes, several secondary endpoints
- Pivotal study in 680 patients for 12 weeks treatment blinded, 40 weeks unblinded safety thereafter
- Two arms x g/day, placebo

■ Nonclinical studies to complete NDA package - planned

- Planned 2 year carcinogenicity, repro-tox, Qt studies

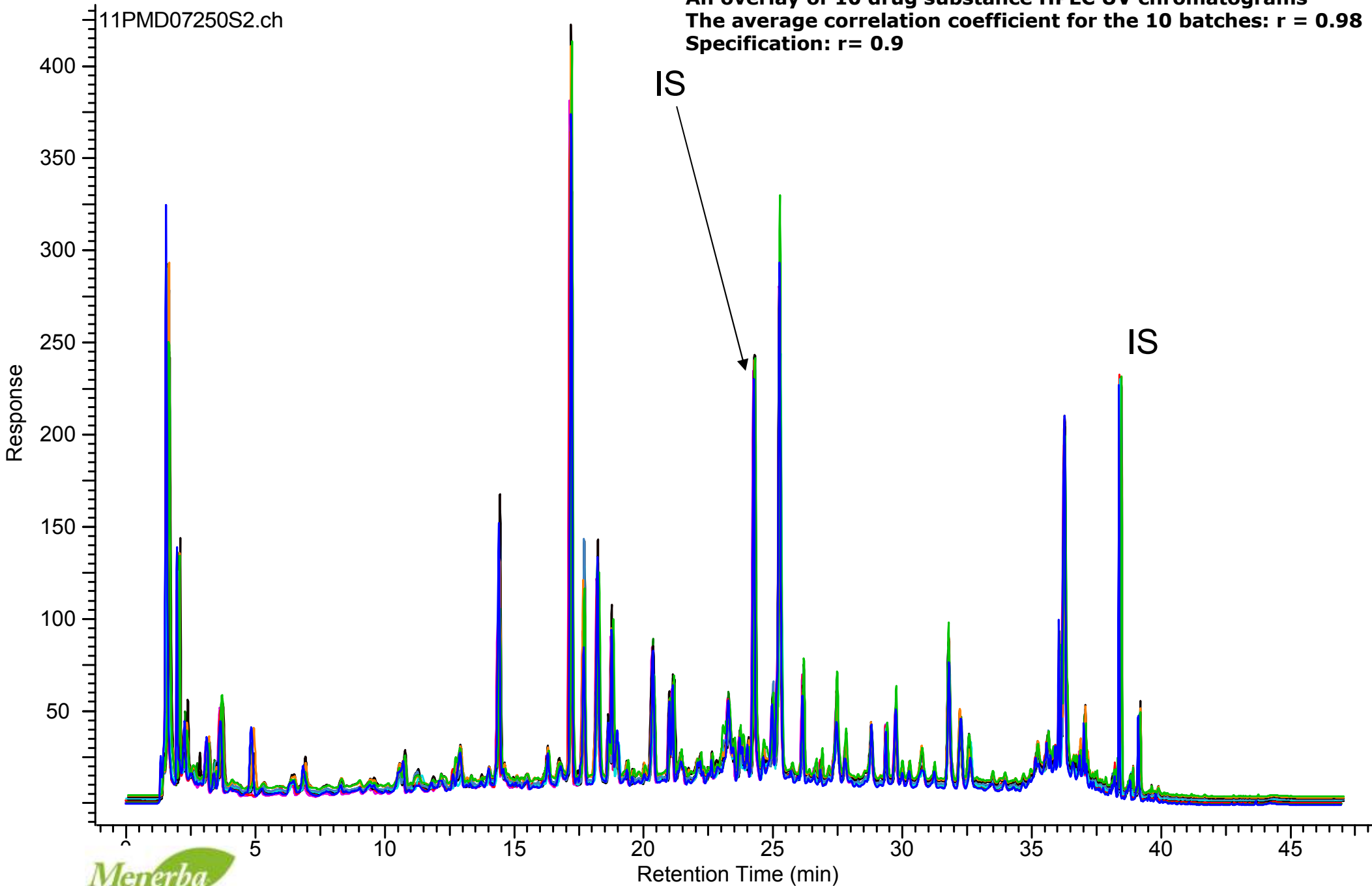
Menerba Manufacturing

- Manufacturing process established for FDA for Phase 3 supply
- Consistent, reproducible results
- Analytical methods in place
- Facility in place to control process and meet needs for expansion to commercial supply



Production of 10 Drug Substance Batches

An overlay of 10 drug substance HPLC UV chromatograms
The average correlation coefficient for the 10 batches: $r = 0.98$
Specification: $r = 0.9$



Other Pipeline Products – Bezielle and Seala

■ Bezielle

- For advanced breast cancer
- Cancer cell selective glycolysis inhibitor
 - Induces cell death selectively in tumor cells through oxidative stress by inhibiting glycolysis
- Phase 2 ready
- Data from two clinical studies in patients show good efficacy and safety
- Un-partnered, no royalties due
- IP protection



■ Seala

- For vaginal dryness
- Selective estrogen receptor beta agonist
- Phases 1 ready
- Strong preclinical data package
- Un-partnered, no royalties due
- IP protection



Intellectual Property Review

Bionovo relies on patents, trade secrets, technical know-how and continuing innovation to develop and maintain its competitive position

- Bionovo has internally discovered and developed all drug candidates using proprietary biological and chemical techniques
- Bionovo has 126 approved and pending patents and owns 100% of its IP for its entire product portfolio
- **38 patent applications to protect Menerba**
 - One patent issued by the US Patent and Trademark Office covering Menerba mixture
 - **Issued patent covers IP through 2026**
 - Other patent applications cover composition of matter, structure-function and methods of treatment
- Six patent applications filed related to various aspects of Bezielle, including composition of matter, chemical components combination and methods of therapeutic use
 - One patent issued by the US Patent and Trademark Office which covers Bionovo's method and use of Bezielle(R) formulation as a monotherapy for the treatment of breast cancer
 - Other patent applications cover composition of matter, structure-function and additional methods of treatment
- Seven filed patent applications related to various aspects of Seala (a product under development for the treatment of vaginal atrophy), including composition of matter and therapeutic use
- 15 patents are filed on other drugs and technologies in the pipeline
- All patent applications have also been filed in key international jurisdictions

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THANK YOU!