Repros

THERAPEUTICS INC

Developing clinical stage small molecule therapeutics to treat hormonal and reproductive system disorders

Repros Disclaimer

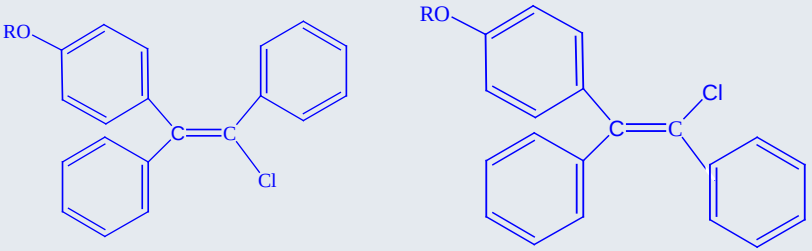
Any statements made by the Company that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including the ability to raise additional needed capital on a timely basis in order for it to continue to fund development of its Androxal® and Proellex® programs, have success in the clinical development of its technologies, the reliability of interim results to predict final study outcomes, and such other risks which are identified in the Company's most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. These documents are available on request from Repros Therapeutics or at www.sec.gov. Repros disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Investment Highlights

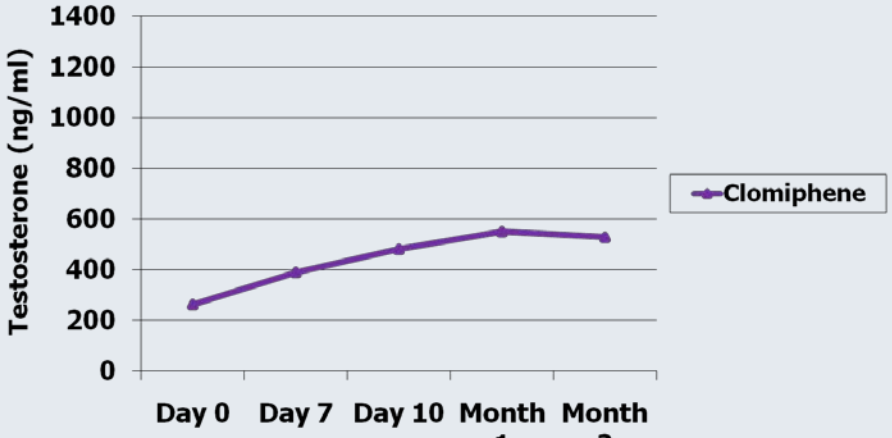
- **Focused strategy: small molecule therapeutics for reproductive disorders**
- **Two late stage clinical programs each with +$1B sales potential**
- **Androxal® : PHASE 3 (SPA) oral treatment for Low Testosterone with patented and pending patent's life to the mid 2020's(growing +$2B market)**
  - ***Restoration of testicular function and testosterone levels in treatment of 2º hypogonadism (most common cause of low T)***
- **Proellex: PHASE 2 treatment for uterine fibroids and endometriosis with pending patent/ patent life to the mid 2020's (+$5B market)**
  - Chronic relief of uterine fibroid symptoms
  - Fibroid de-bulking
  - Chronic relief of the symptoms associated with endometriosis
  - Potential breast cancer intervention
- **Key late stage clinical & regulatory events driven news flow in 2013**

Genesis of Androxal

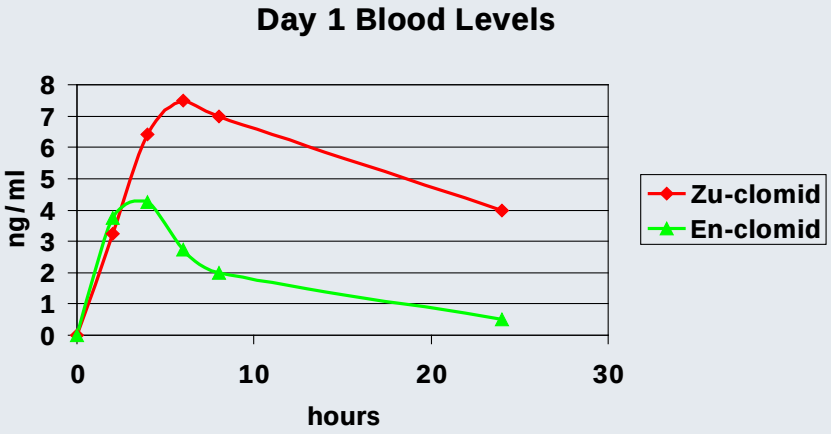
•**Clomid Commercial Material is 60% Trans**



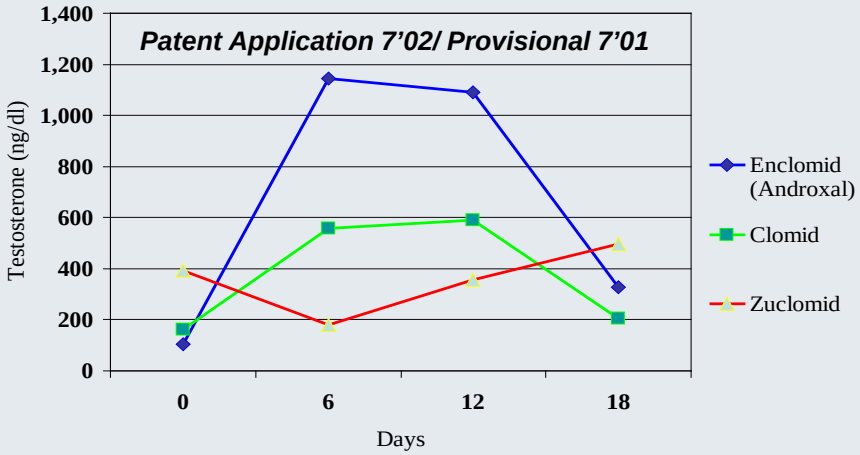
Clomid Stimulates Pituitary Gonadotropin (LH, FSH) Secretions in Treatment Of Female Infertility by Blocking Negative Feedback of Estrogen



•**Reference: Effect of Raising Endogenous Testosterone….with Clomiphene Citrate, Journal of Clinical Endocrinology and Metabolism, Vol. 80, No. 12, 1995**

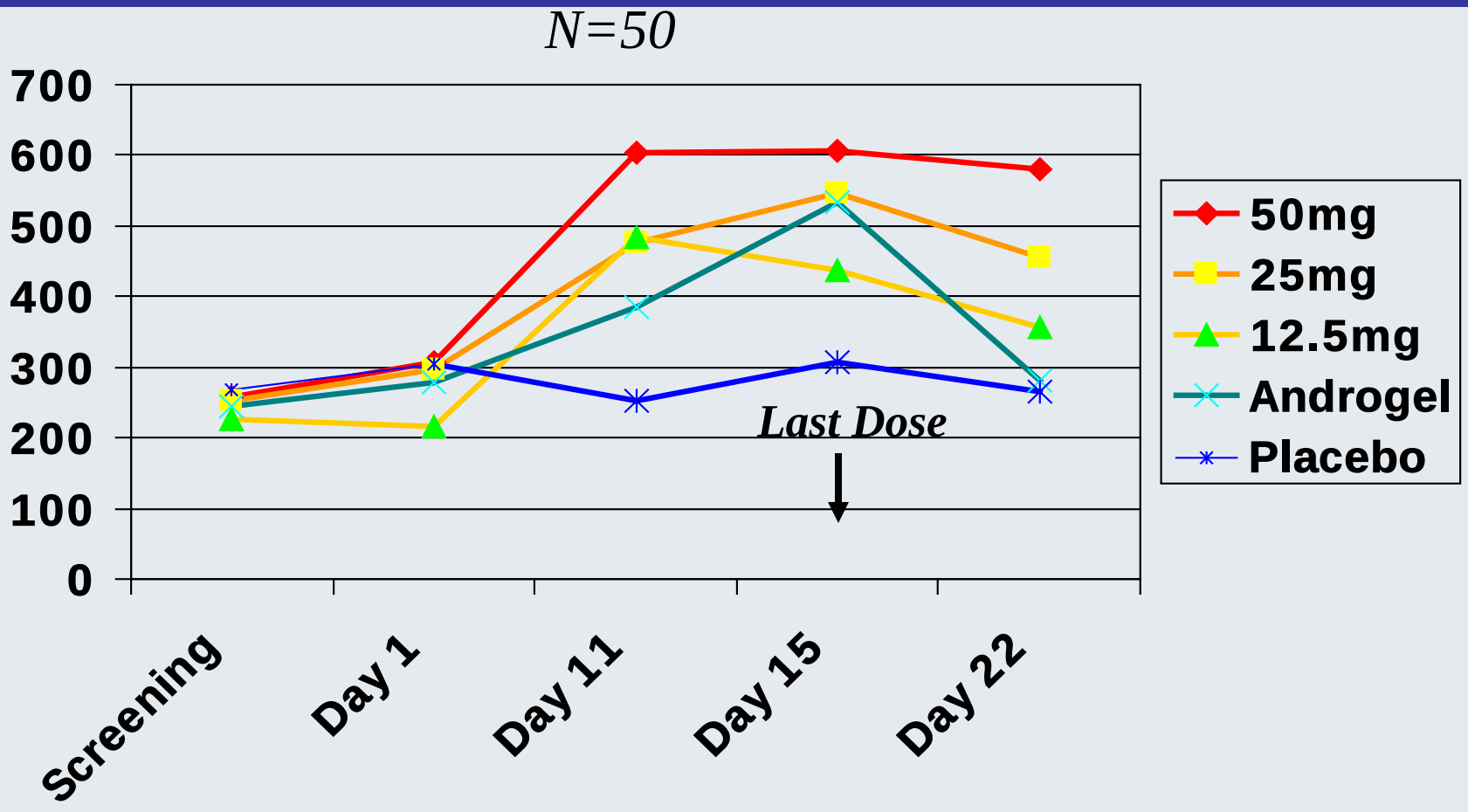


Mikkelson et al
Fertility and Sterility Vol. 46, No. 3, September 1986



Effects of Clomid and its Isomers on Testosterone in Baboons

Androxal ZN-018
IND Applied 7/15/2002
Effects on Testosterone in Hypogonadal Men



Androxal effects persist after last day of dosing

Evolving FDA Requirements for Endpoints

- July 2002 IND for Androxal to Treat 2° Hypogonadism
- Nov.'04 24hr Serial Testosterone to determine average and maximum concentration
- Nov.'04(+1) Testosterone endpoint not acceptable because Androxal is not testosterone
- 2007 Even though Androxal is non inferior to Androgel with numerous advantages, T still not an acceptable endpoint
- 2010 Endocrine Division accepts IND for to study Androxal's glycemic effects in diabetic men
- Nov. '10 Urology Division accepts testosterone as an endpoint for studies of Androxal in the treatment of secondary hypogonadism
- June'12 SPA Obtained for Androxal

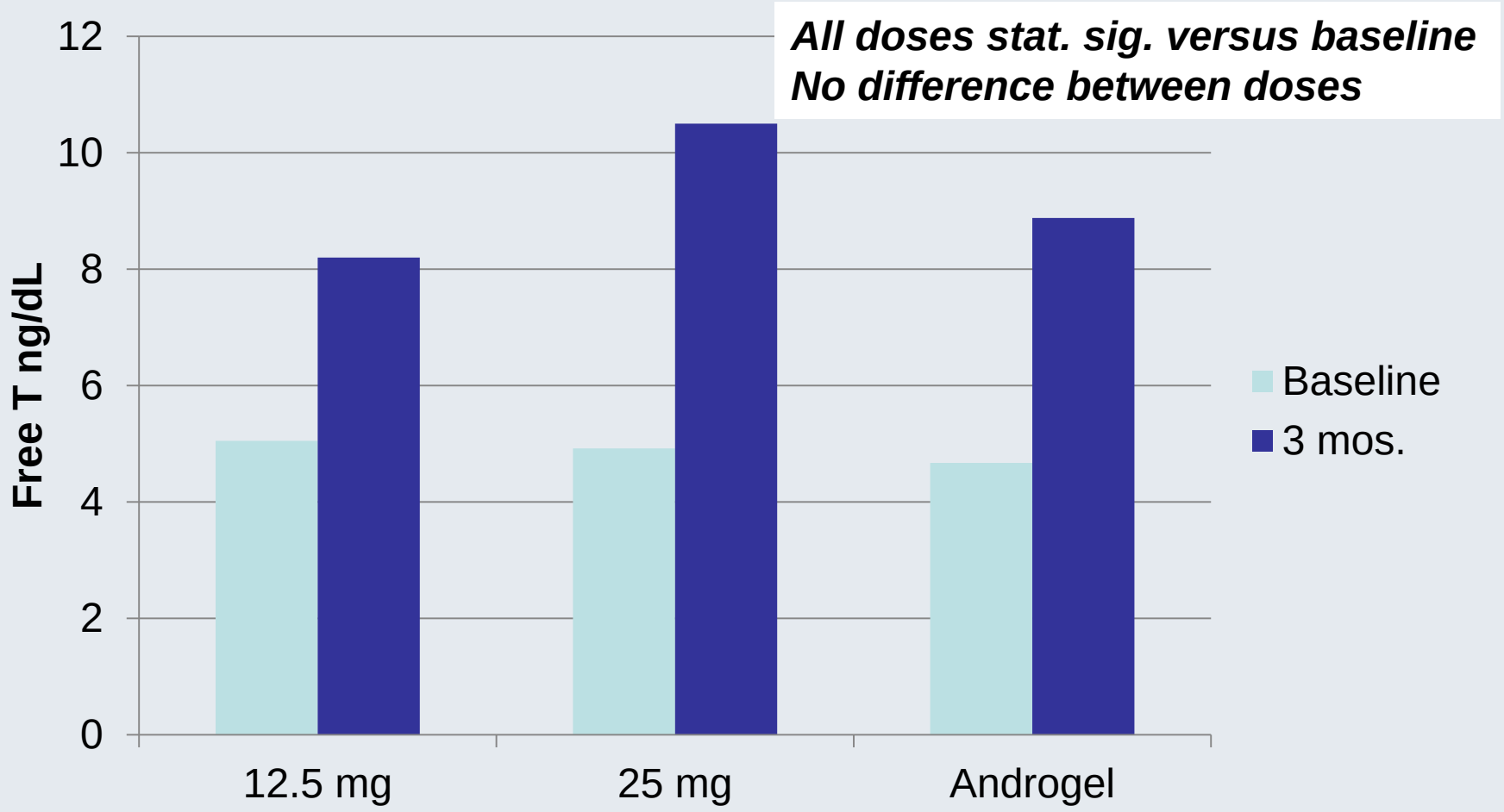
Impact on Patient Reported Outcomes

A Comparison of Androxal and Androgel

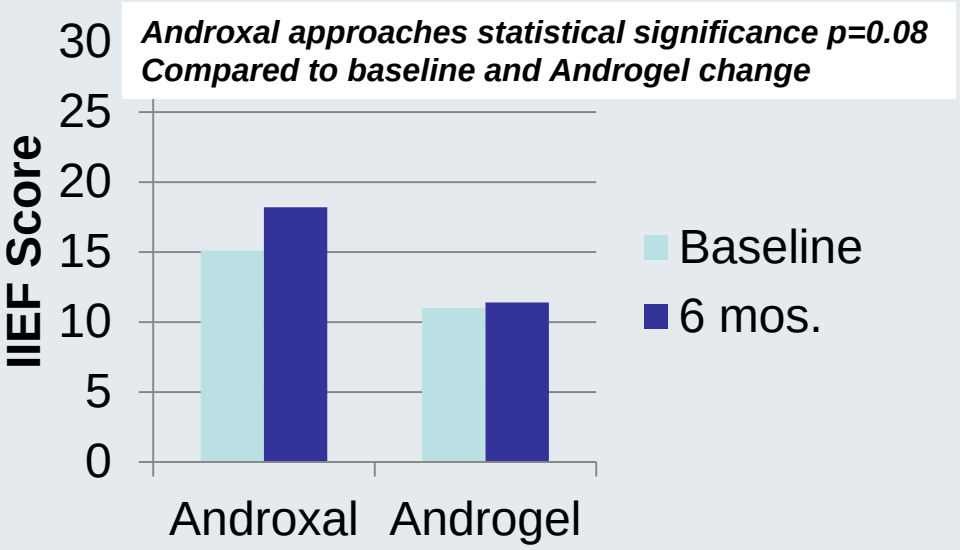
ZA-003

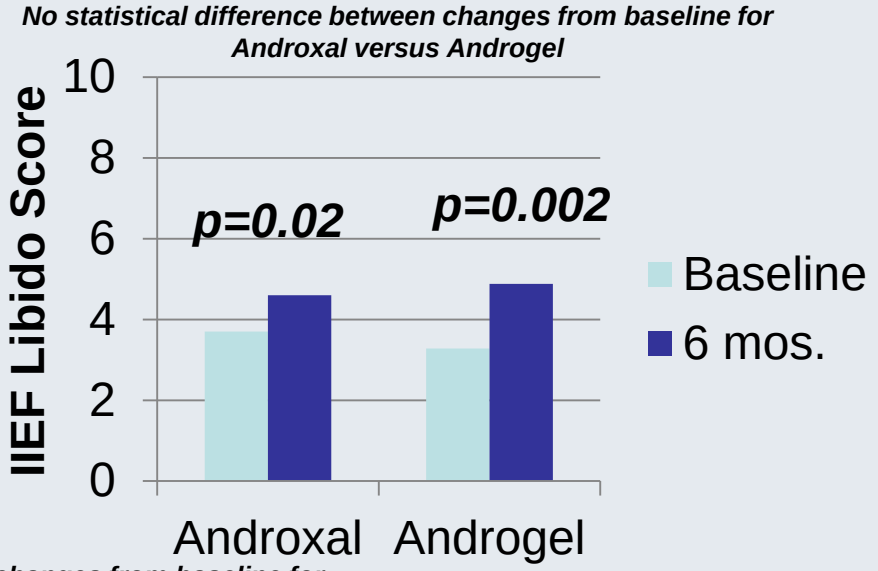
Submitted to FDA, 2007

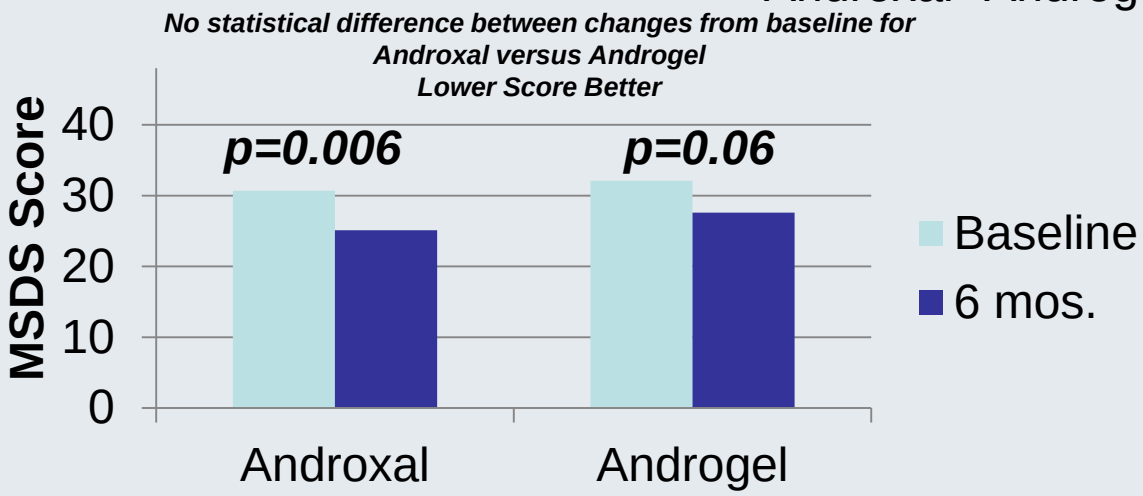
Change in Free T from Baseline
ZA-003



Androxal Exhibits Patient Reported Effects Equivalent to Androgel

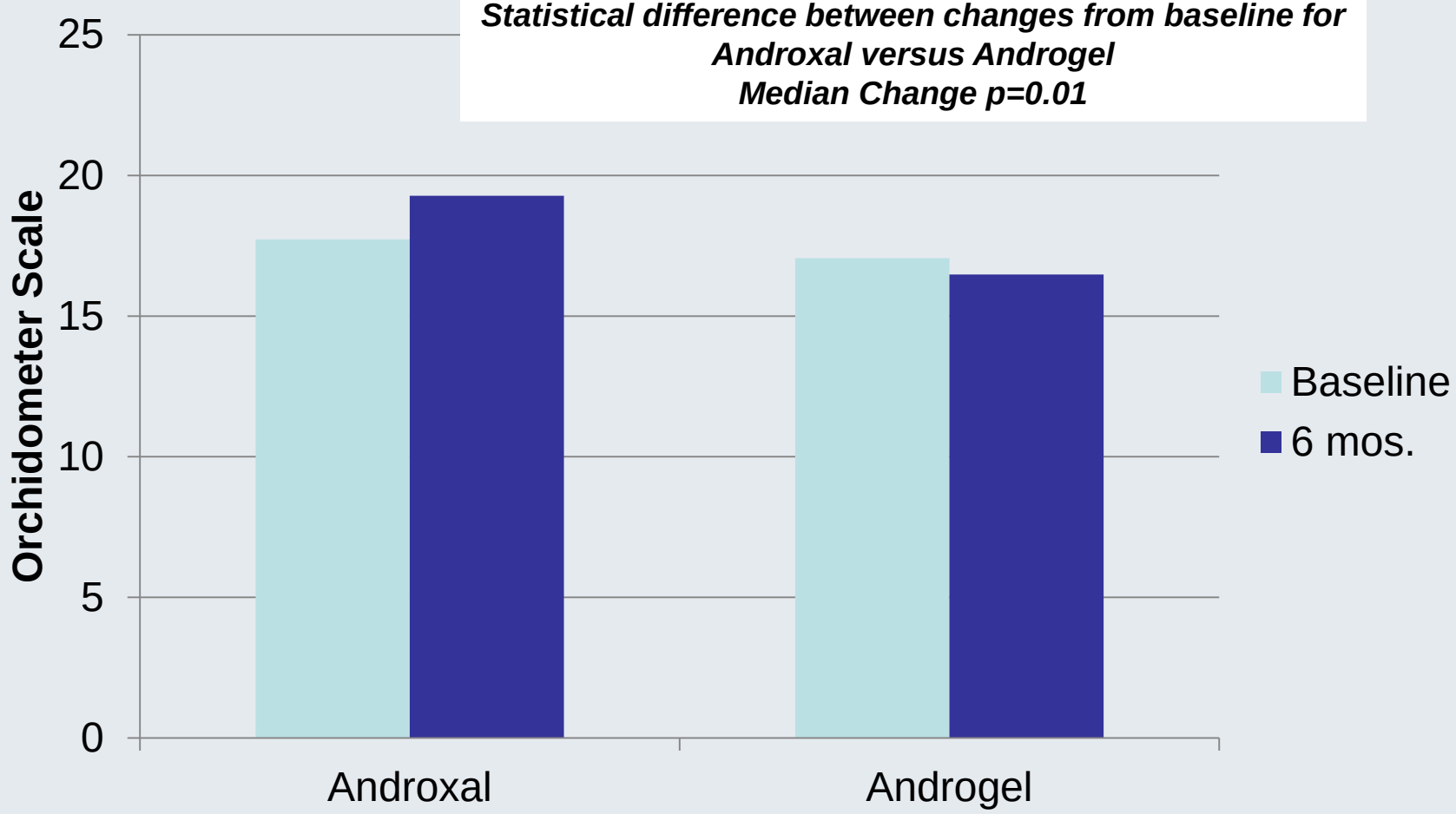






Change in Testicular Size
ZA-003

Statistical difference between changes from baseline for Androxal versus Androgel
Median Change p=0.01



ZA 003

Androxal – Serious Adverse Events

Test Article	Serious Adverse Event	Relatedness to Drug
Androxal 12.5mg	Pneumonia	No
Androgel	Coronary Artery Disease	No
Androgel	Depression	No
Placebo	Urinary Tract Infection	No

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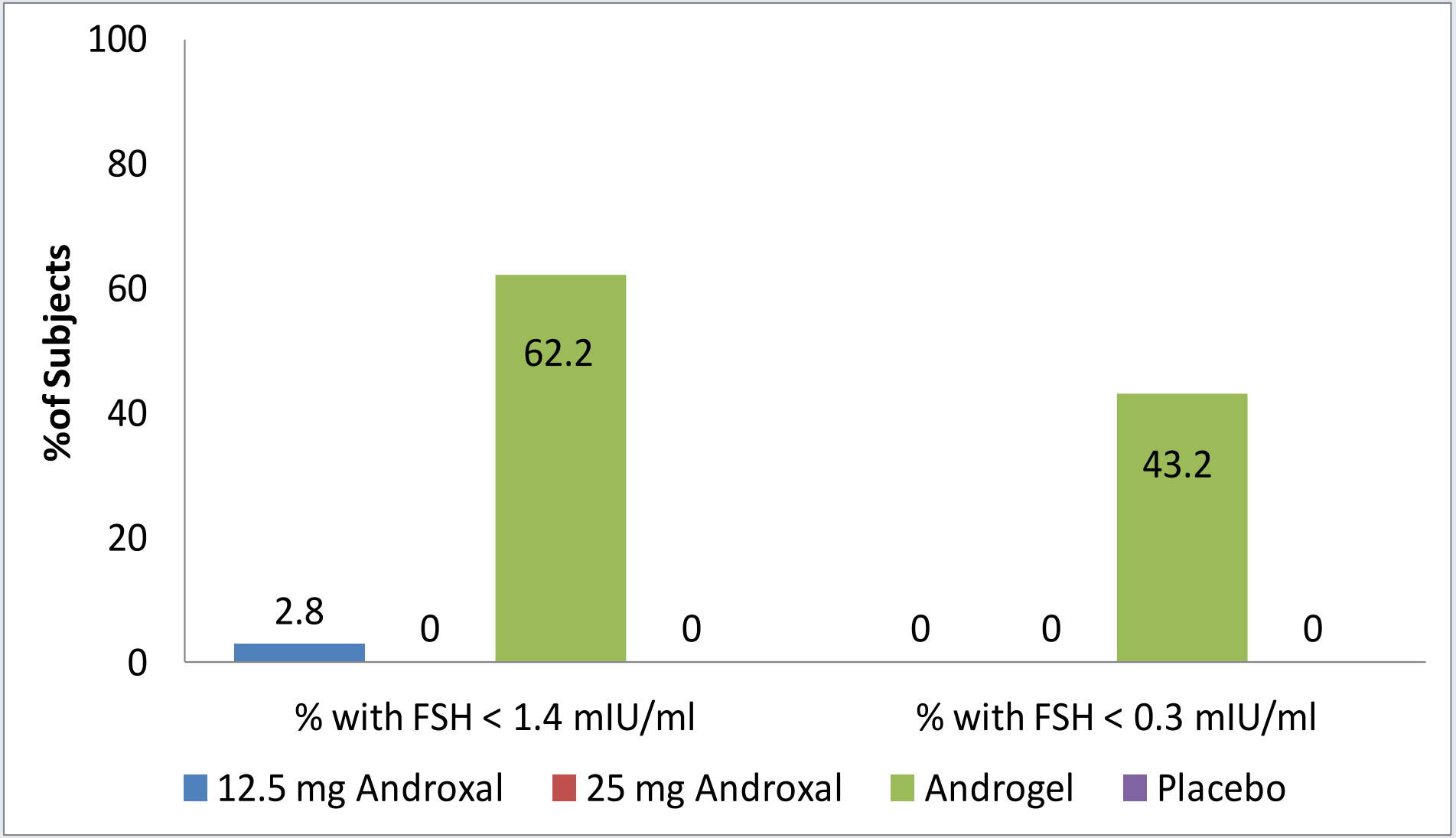
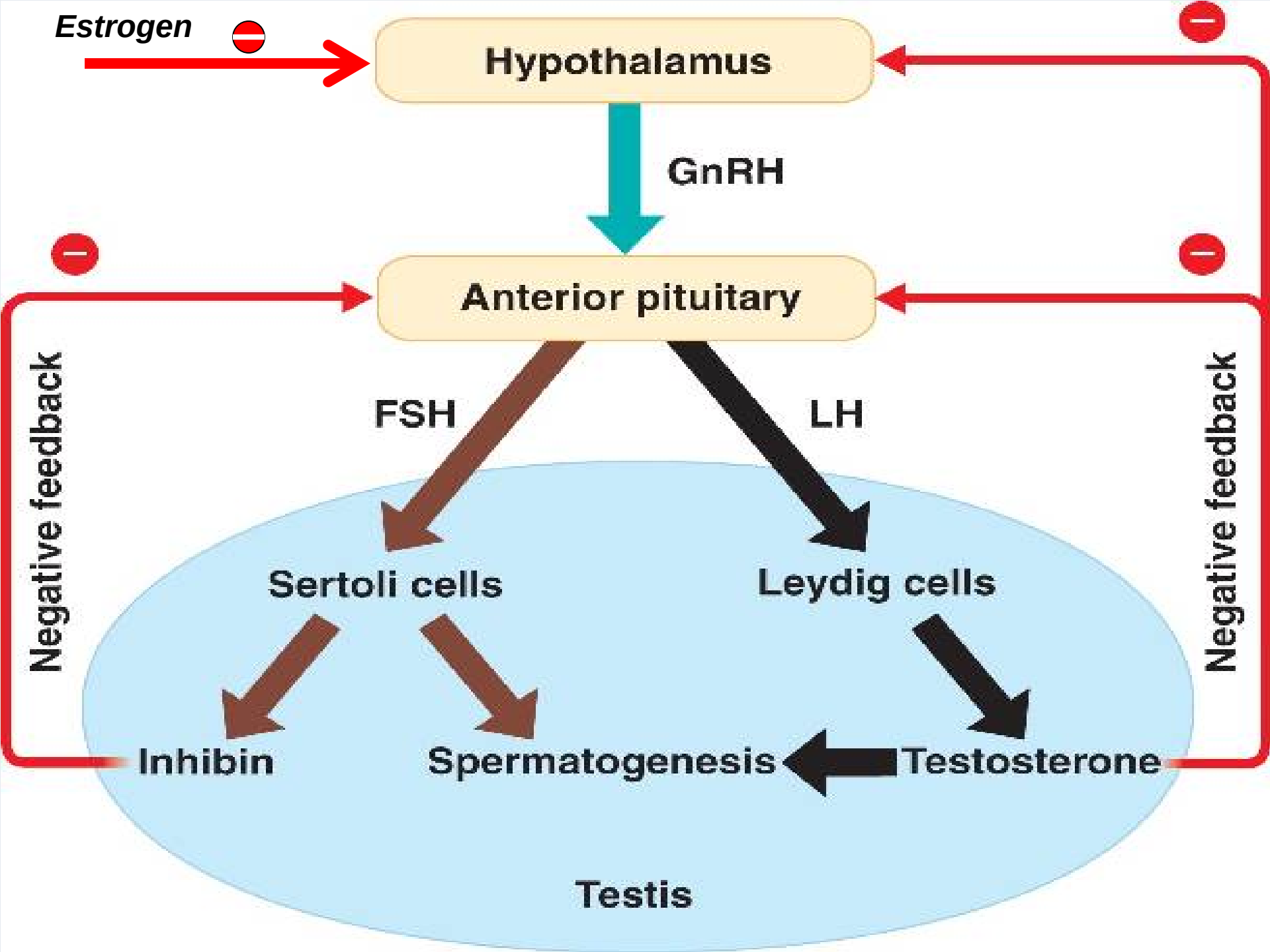
ZA 003

Androxal – Adverse Events Leading to Study Discontinuation

Test Article	Adverse Event
Androxal 12.5mg Age: 68	Hemoglobin Increase 16.9 -17.7 (13.0-17.5 g/dl)
Androxal 25mg Age: 66 (hypertension history)	Mild Hot flash/hypertension
Androgel	Hematocrit/hemoglobin Increase
Androgel	Renal function tests elevated
Androgel	Hemoglobin Increase
Androgel	Hemoglobin Increase
Androgel	Allergic Dermatitis
Placebo	Edema due to cardiac disease

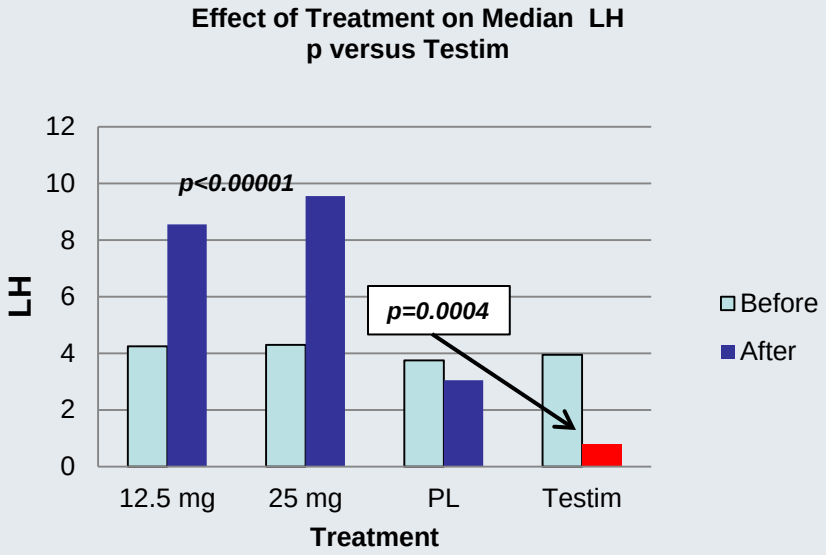
% of Subjects with FSH Below the Lower Limit of Normal and Below the Lower Limit of Detection (0.3 mIU/ml) after 3 months ZA-003 “Completer” Analysis

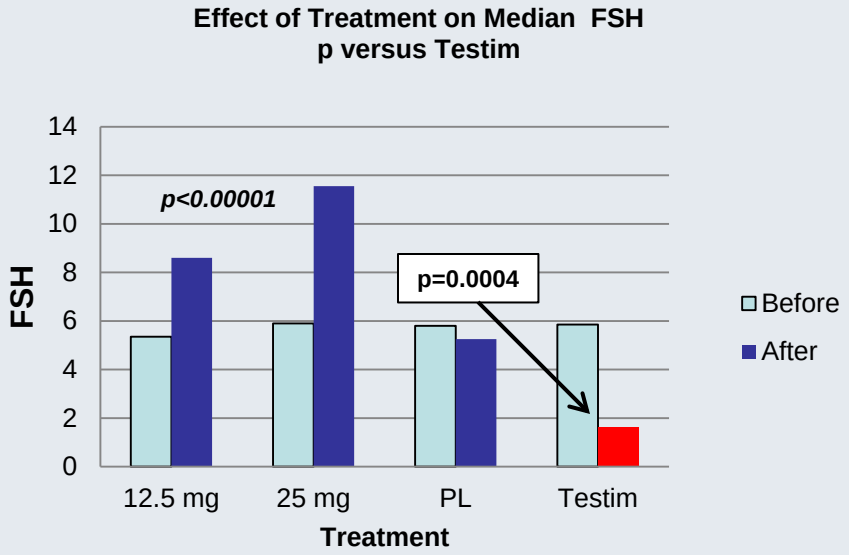


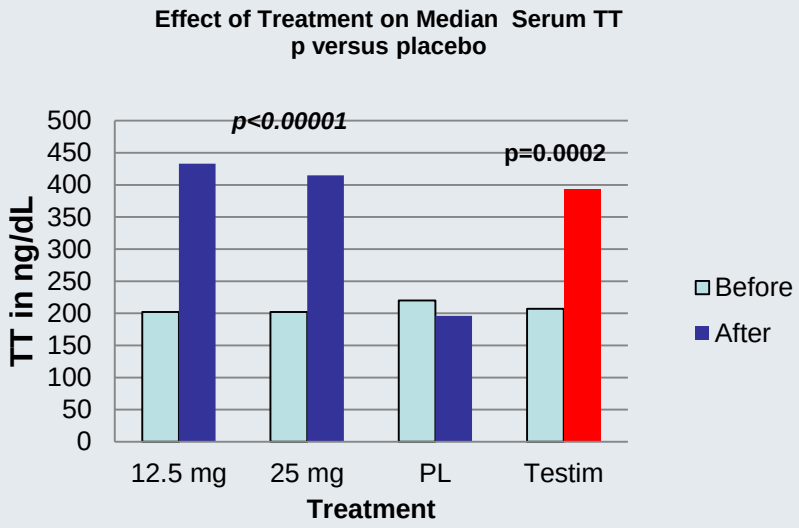

Estrogen
Hypothalamus
GnRH
Anterior pituitary
FSH
LH
Negative feedback
Negative feedback
Sertoli cells
Leydig cells
Inhibin
Spermatogenesis
Testosterone
Testis

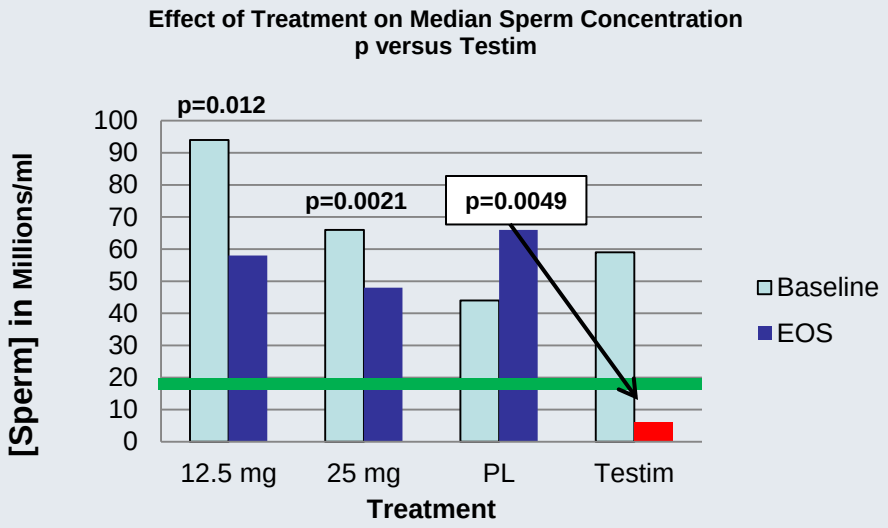
ZA-203 Hormone and Sperm Effects

Exogenous T Suppresses Pituitary Hormones and Testicular Function









Androxal Pivotal Study Primary Endpoints
Excerpt: FDA SPA Minutes

1) Proportion of subjects with average serum concentration (Cavg) for T in the normal range (i.e. serum T of 300 ng/dL – 1040 ng/dL).
2) Proportion of subjects with a 50% or greater decrease in sperm concentration from baseline to endpoint.
To demonstrate efficacy with regards to the first endpoint, at least 75% of subjects in the Androxal group should achieve a Cavg for T in the normal range with the lower bound of the 95% confidence interval not below 67%. At least 100 Androxal subjects would be required to demonstrate a point estimate of 75% or better. 3:1 randomization drug to pbo (n=151)

ZA-301 outcome: 79% ITT (LOCF,BOCF), 83% Completer Analysis

For the second endpoint, Androxal should be non-inferior to placebo with respect to the difference in responder rates We have found a 20% non-inferiority margin to be acceptable in prior similar trials.

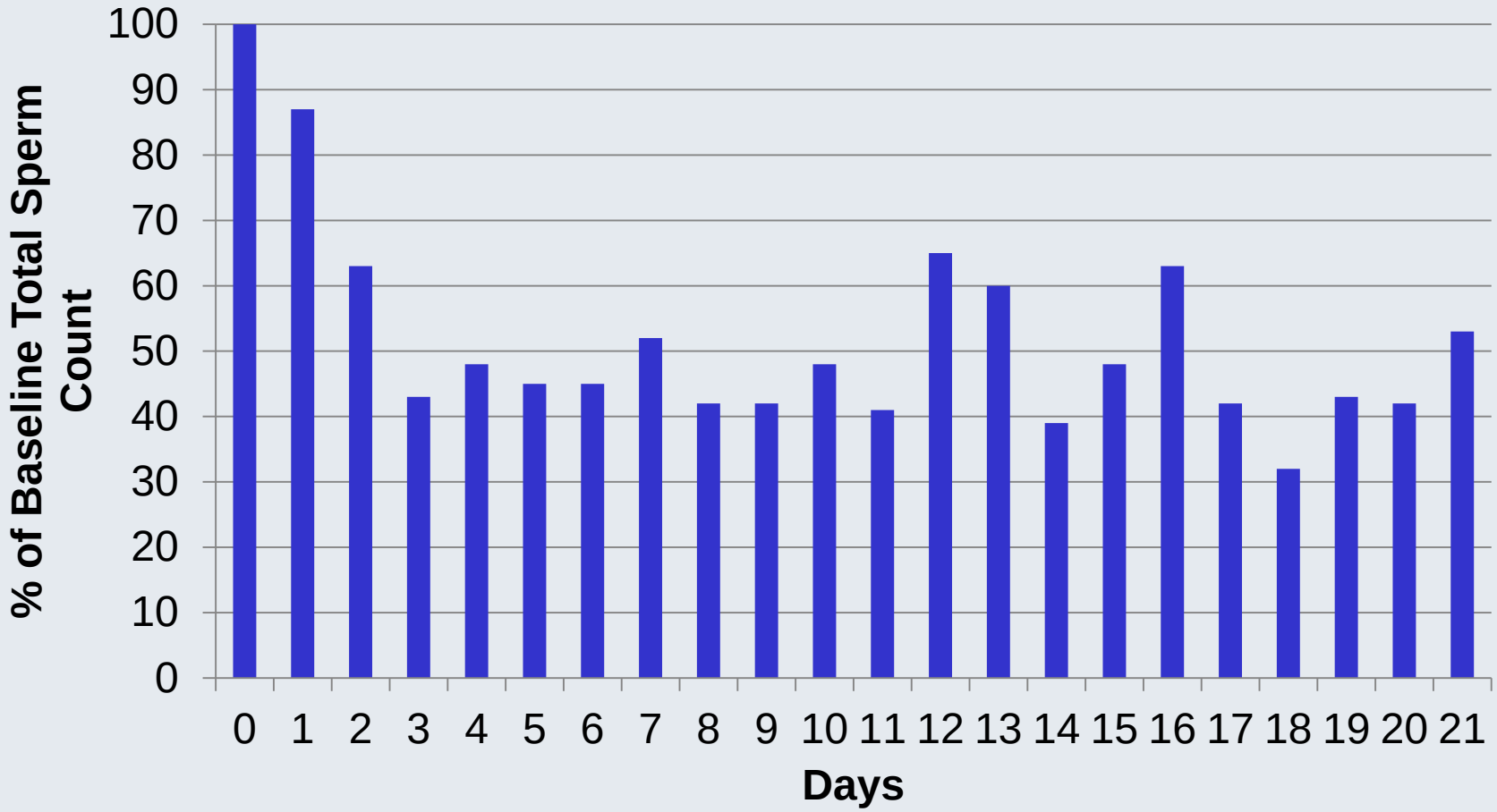
ZA-301 outcome: <20% margin, no statistical difference compared to placebo for any sperm assessment

Values for serum T and sperm concentration at baseline and endpoint should be based on at least two assessments. Semen sampling at each time point (baseline and endpoint) should be separated by at least 48 hours.
Cmax is an important safety issue. The percentage of patients with Cmax above the following three pre-determined limits (listed below) should be a secondary endpoint:

- ***Cmax>1500 ng/dL***
- ***Cmax>1800 ng/dL and <2499 ng/dL***
- ***Cmax>2500 ng/dL***

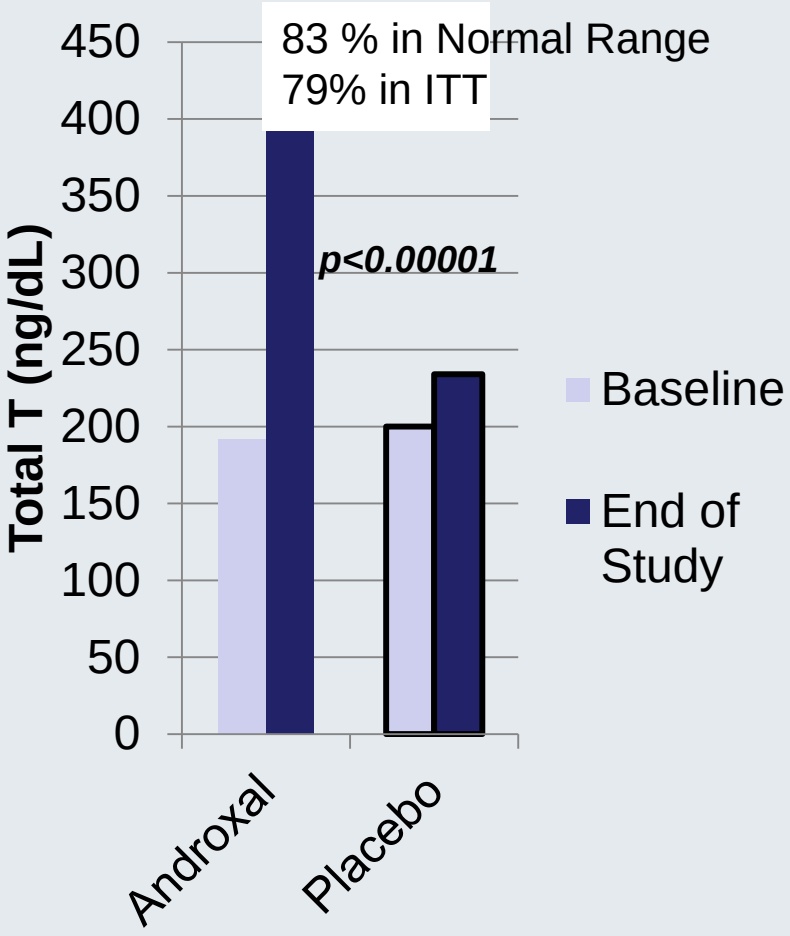
ZA-301 outcome: no Cmax >1040 ng/dL at any time or timepoint

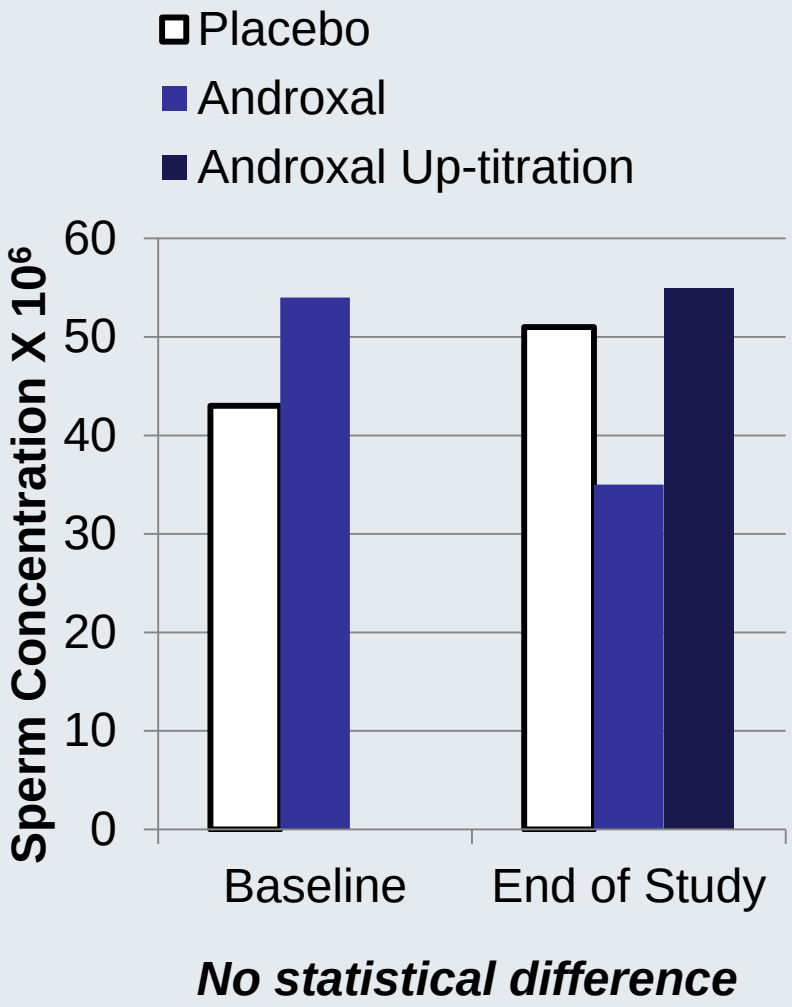
Ejaculation Frequency Reduces Sperm Numbers (n=12 subjects (age 18-25)



Fertility and Sterility, Levine et al
Vol.5, No. 5, May 1986

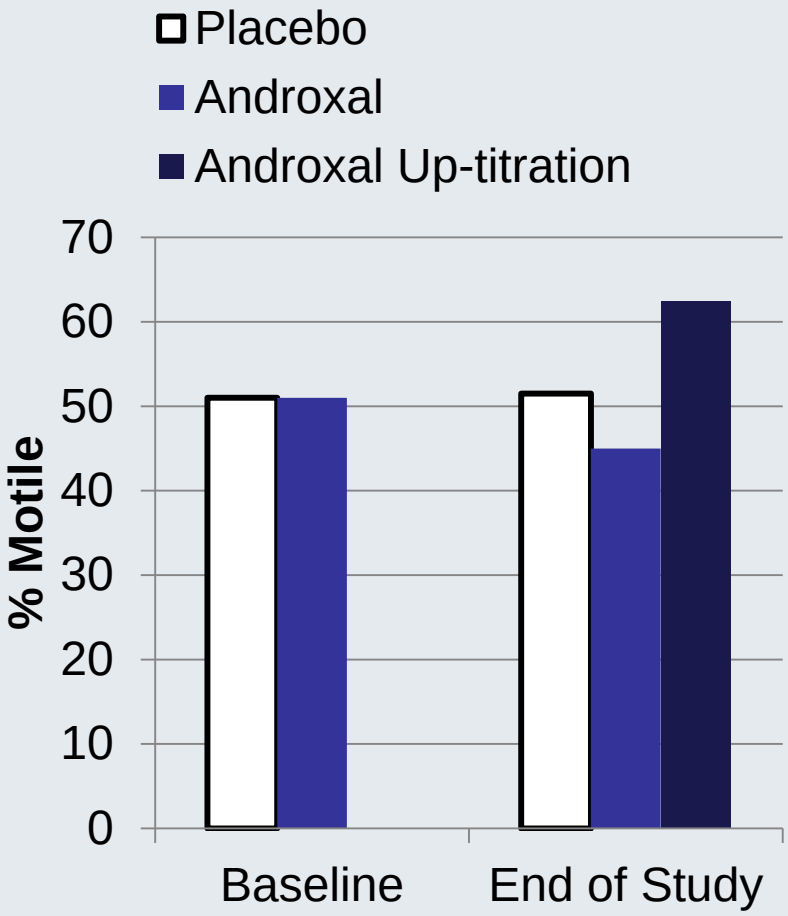
Androxal Improves T without Affecting Sperm

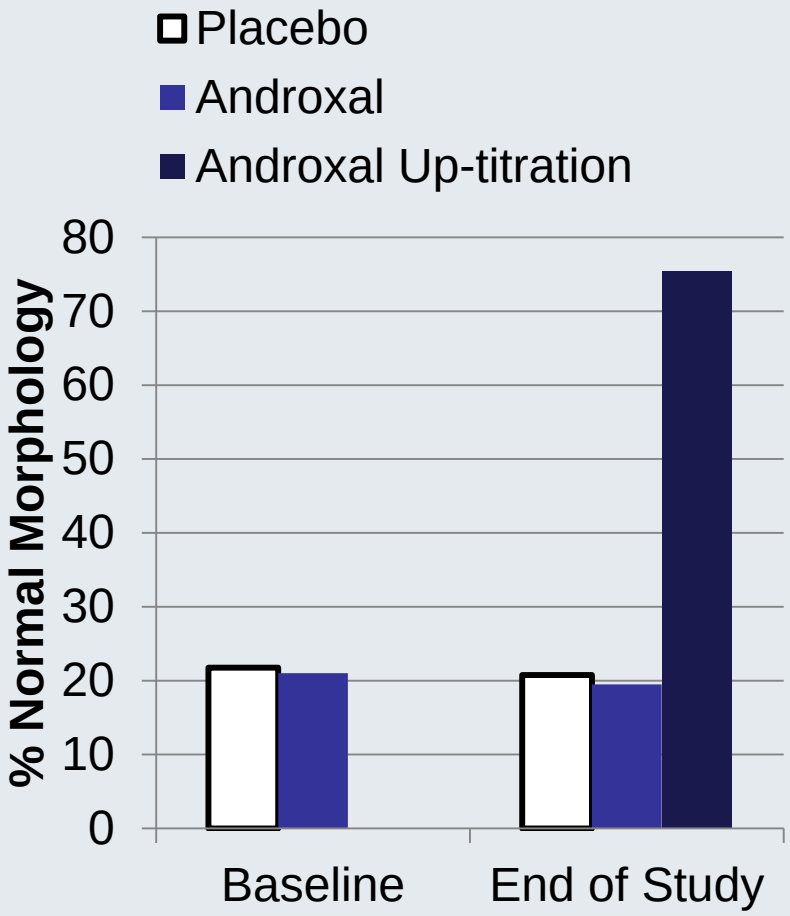




No statistical difference

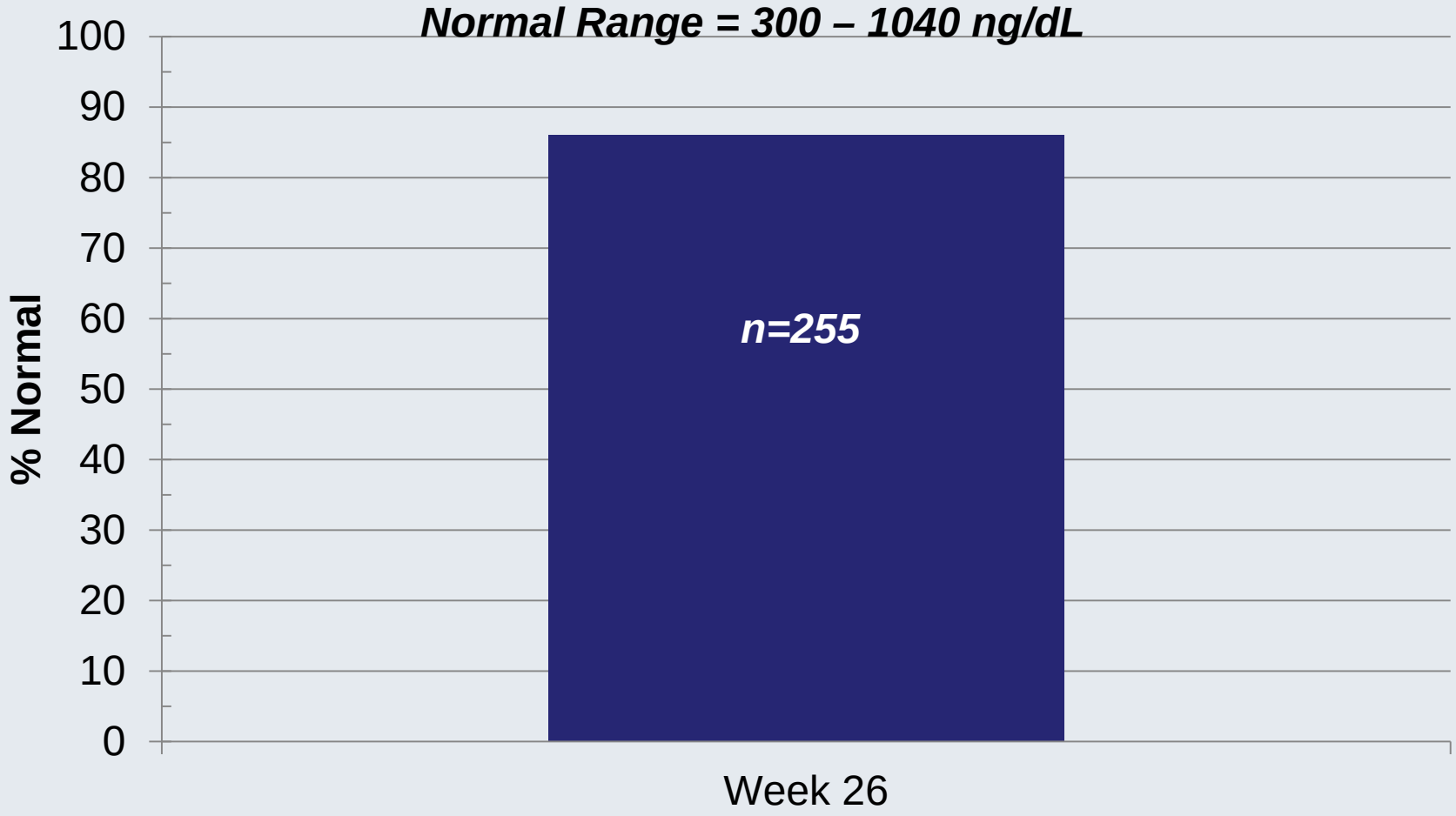
Androxal Exhibits No Negative Effects on Important Sperm Parameters





No statistical difference

ZA-300: % of Men with T in the Normal Range Fully Enrolled



Up-titration if morning T <450ng/dL
~50% up-titrated

Phase III Androxal Program Status:5/1/13
NDA Target: June 2014

Study	Target Enrollment	Study Duration	Subjects Screened	Subjects Enrolled	Subjects Pending	Projected Full Enrollment
ZA-300 Safety	500	6 months	1288 (28 sites)	500		**Fully Enrolled**
ZA-301 Pivotal	152	3 months (+ 6 weeks)	571 (17 sites)	151	Enrolled in < 12 weeks	**Fully Enrolled**
ZA-302 Pivotal	180	3 months (+ 6 weeks)	395 (16 sites)	180		**Fully Enrolled**
ZA-303 Safety	150	1 year	419 (10 sites)	150		Core Study Enrolled

Androxal Profile Favorable Compared to Leading T Products

	T Gels/Creams	Androxal	*Advantage Androxal*
Administration	Applied to Skin	Oral	
Controlled Substance	Yes	No	
Sexual Partner & Risk to Children	Yes	No	
Unpredictable Response	Yes	No	
Super High T Levels	Yes	No	
Prostate Risk	Yes	No	
Shuts Down Testes	Yes	No	
Requires Chronic Treatment	Yes	No	

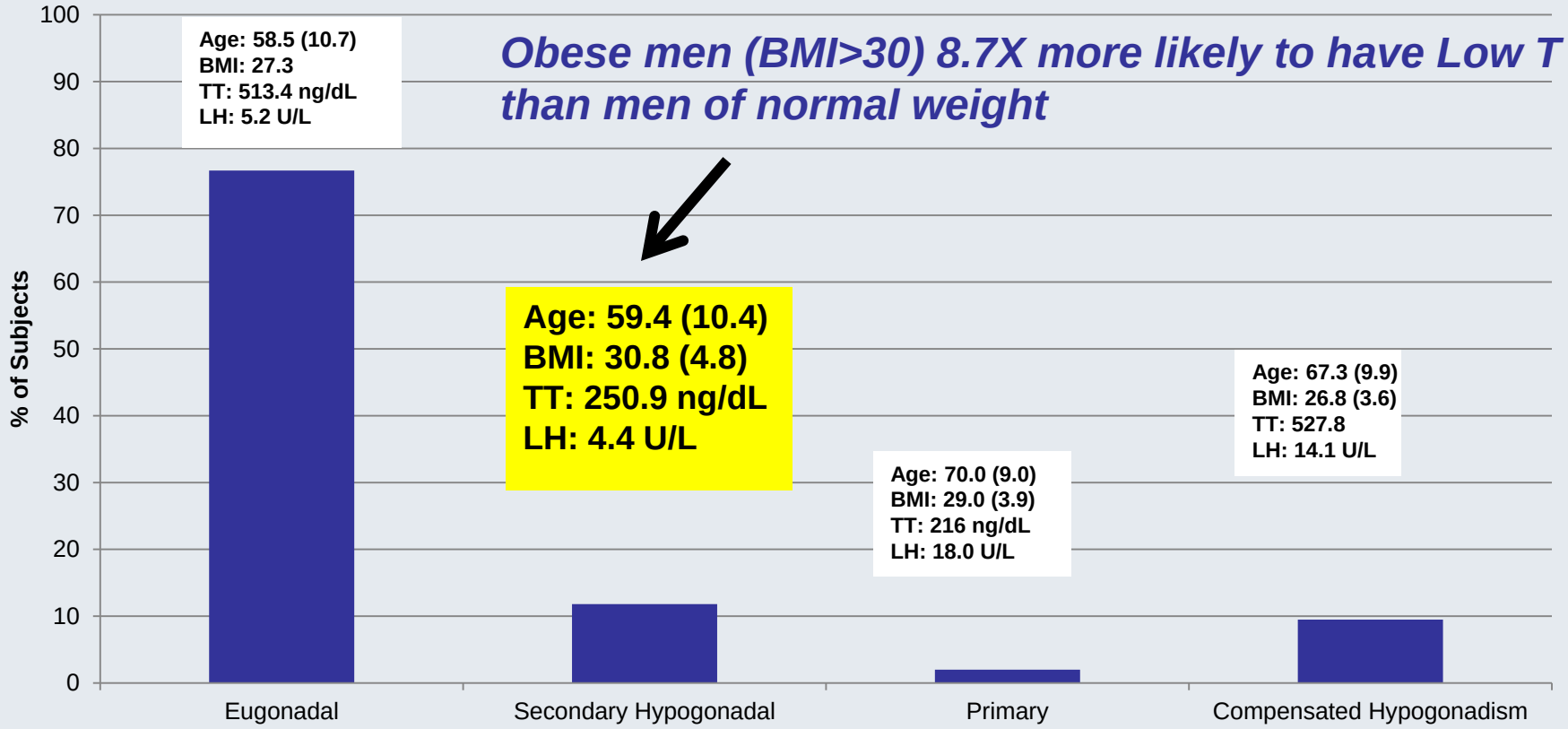
Who are the men using testosterone?

European Male Aging Study

Distribution and Selected Characteristics of Men Ages 40-79 (Tajar et al)

Overweight BMI > 25 (6' 190# male BMI=25.8)
Obese BMI > 30 (6' 230# male BMI =31.2)

Data derived from over 3000 men



In 2010 there were ~90 million men in the US between the ages of 20 and 65

32% are obese

Third Party Study Suggests Favorable Reimbursement Potential for Androxal

Majority of payers believe Androxal's oral administration and non-chronic use may offer overall cost savings

- **Third party assessment of payers indicates vast majority (>90%) would add Androxal to formularies**
  - Cost will be key for tier placement
  - **50% of plans indicated they would require a PA(Prior Authorization) to show proper diagnosis**

- **62% of respondents expect Androxal to be priced at parity to Androgel**
  - Anticipated Androxal pricing of $170-350/month would be competitive with Androgel

Androxal Take Home Message

- Because of Obesity, 30% of American Males are at Risk of Secondary Hypogonadism
  - Co-morbidities include diabetes and cardiovascular disease
- Approved T Products Worsen the Underlying Condition
- ***We believe only Androxal + Diet + Exercise can reverse this disorder***

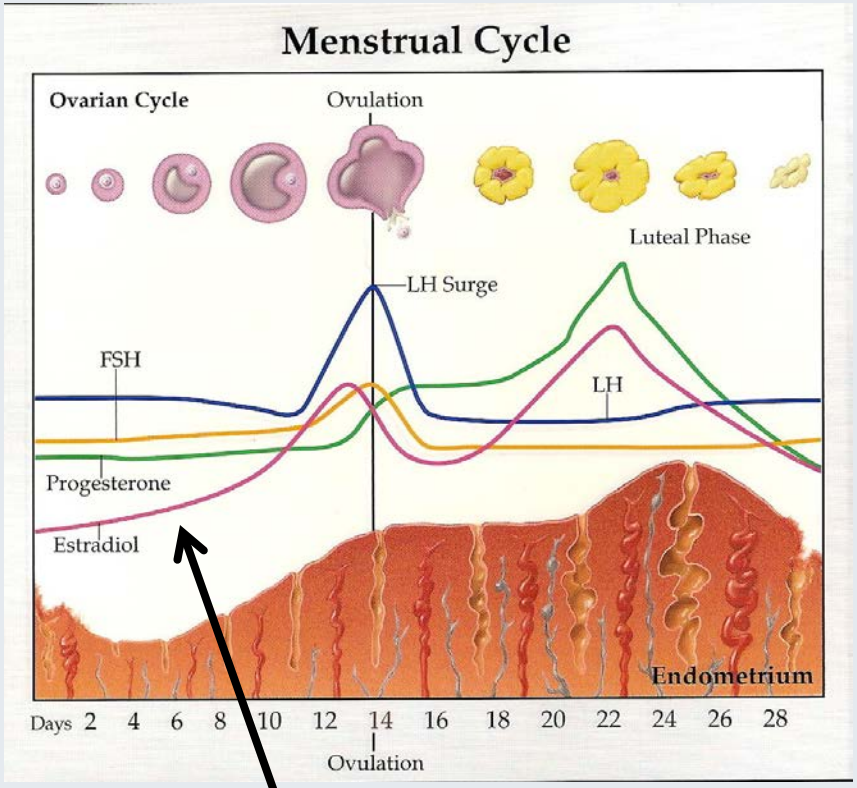
Proellex for the Treatment of Uterine Fibroids and Endometriosis

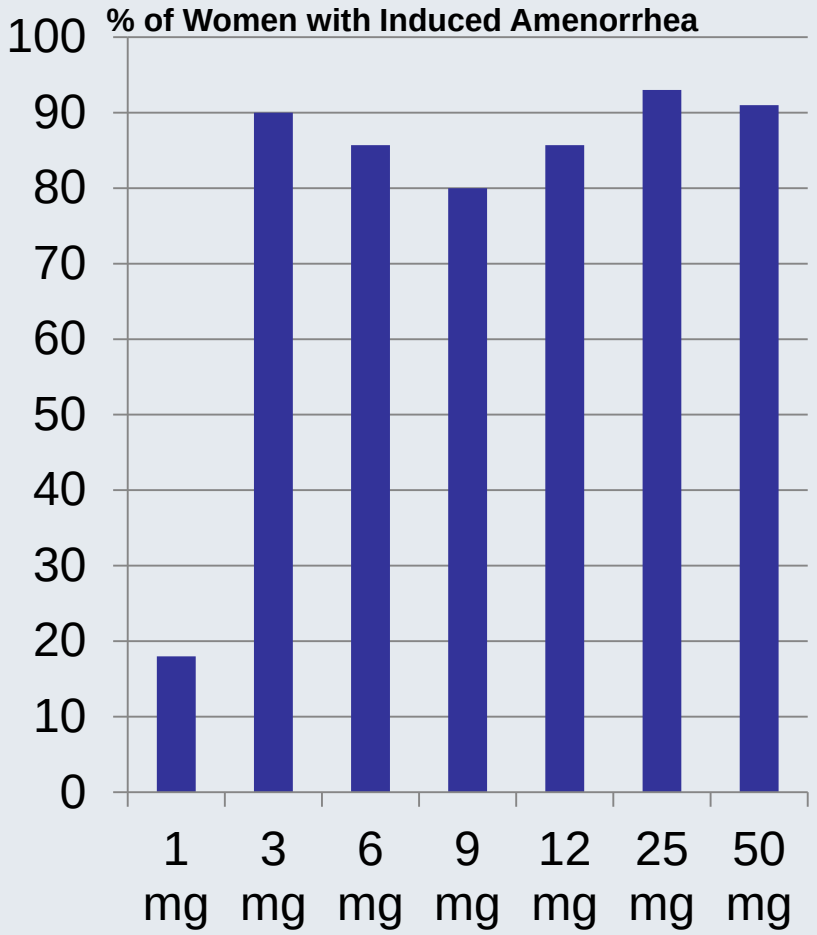
Over 30 million women of reproductive age in the US afflicted with symptomatic uterine fibroids or endometriosis

Over 300,000 hysterectomies performed every year in the US to treat these two disorders

No acceptable chronic therapeutic options available today

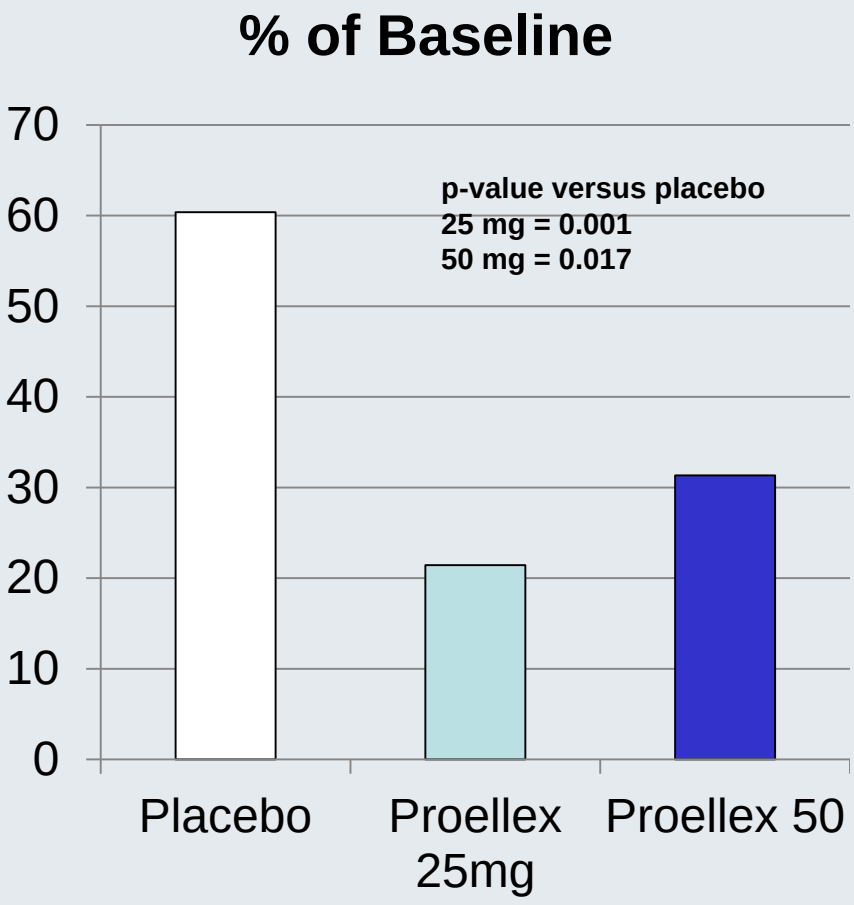
An Effective Dose of Proellex Stops Menstruation in Majority of Women

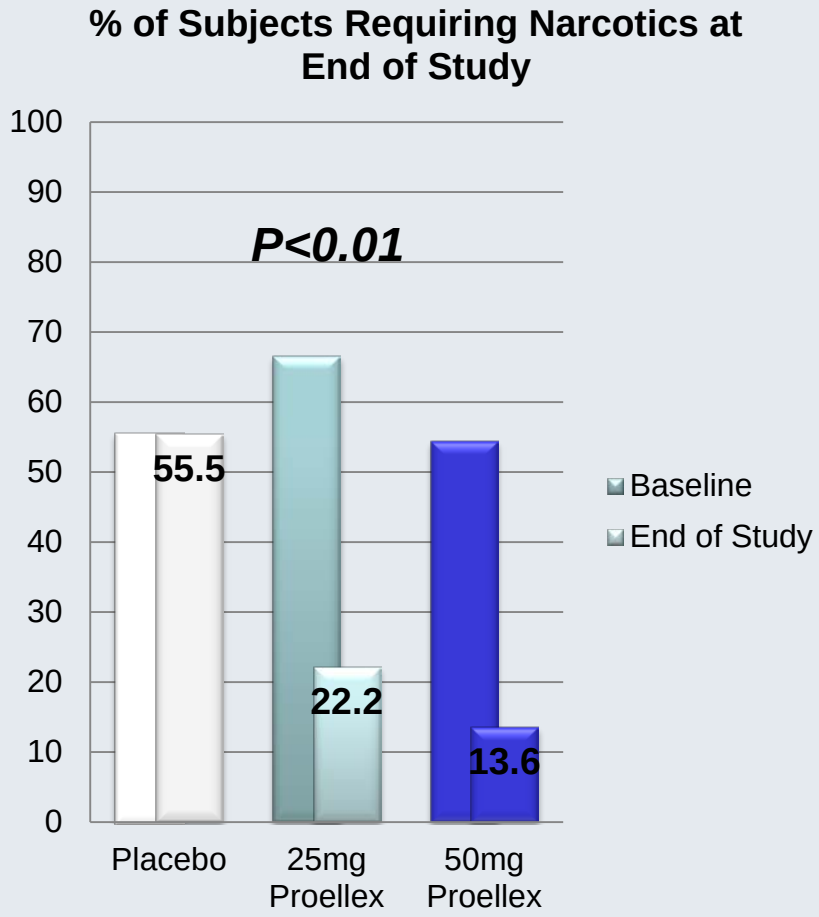




Proellex induced amenorrhea
Mimics early follicular phase
Without progesterone

Proellex Eliminates the Pain and Need for Analgesics to Control the Pain of Endometriosis





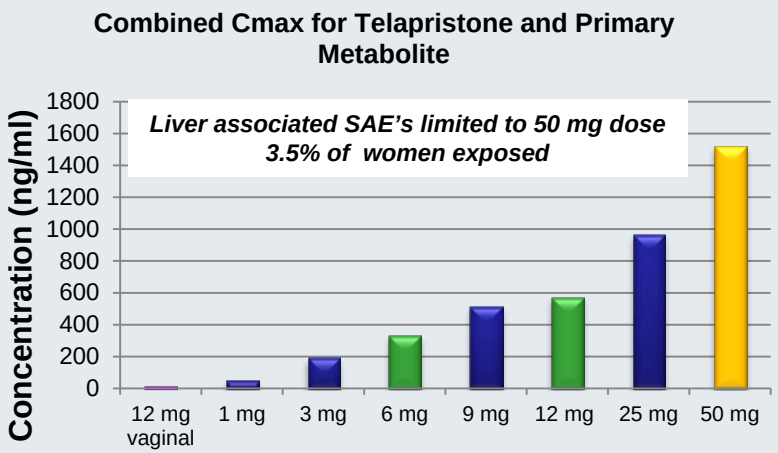
ZPE-202 Phase 2 Endometriosis Study

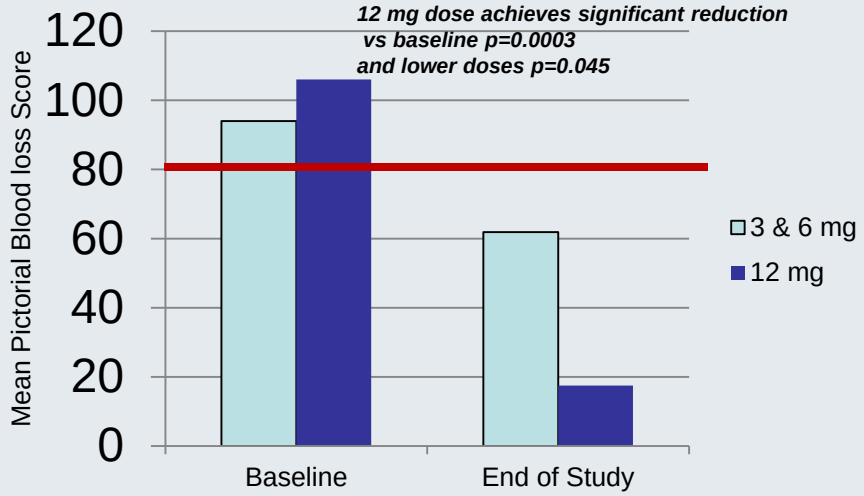
- 90 subject double blind placebo controlled study balanced between placebo, 6 and 12 mg oral Proellex
  - Subject population (confirmed endometriosis)
    - Severe endometriosis as determined by BBSS score
    - Requiring narcotics or prescription analgesics to control endometriosis related pain
  - Study Duration: 4 months
  - Study endpoints:
    - Reduction in need for analgesics from baseline
    - Change from baseline in BBSS pain scores
  - Status: enrolling sites and subjects

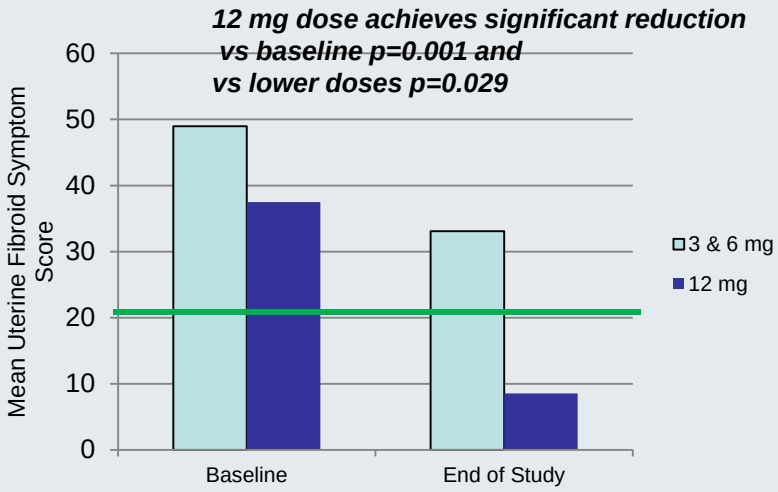
Vaginal Proellex to Eliminate the Need for Hysterectomy in Most Situations

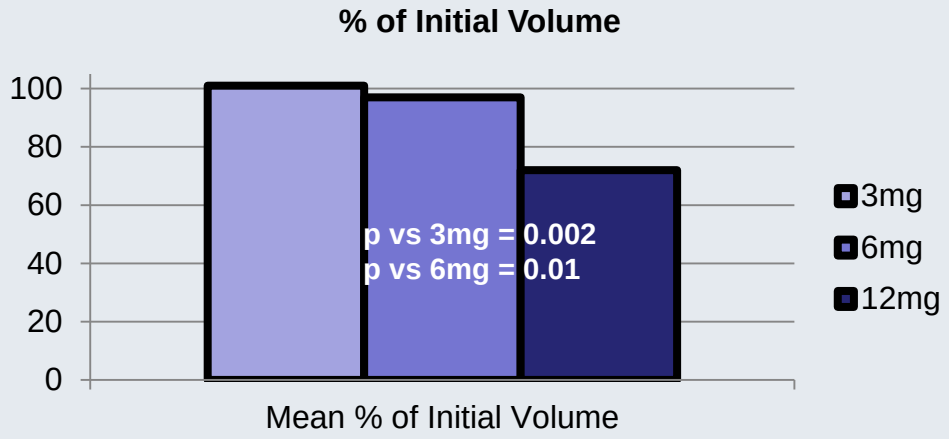
- Initial Phase 2 study to test four doses of vaginal administration in the treatment of uterine fibroids completed
  - Assess reduction of fibroid size and elimination of symptoms
  - Top line data reported
- End of Phase 2 meeting request with FDA accepted by Agency for end of May 2013
- Propose 90 subject 1st Phase 3 study and…..
  - 2 Phase 3 studies
  - 200 subjects for +1 year
  - 300-600 subjects for +6 months
- Separate IND from low dose oral

Vaginal Proellex Achieves Significant Improvement with Very Low Exposure

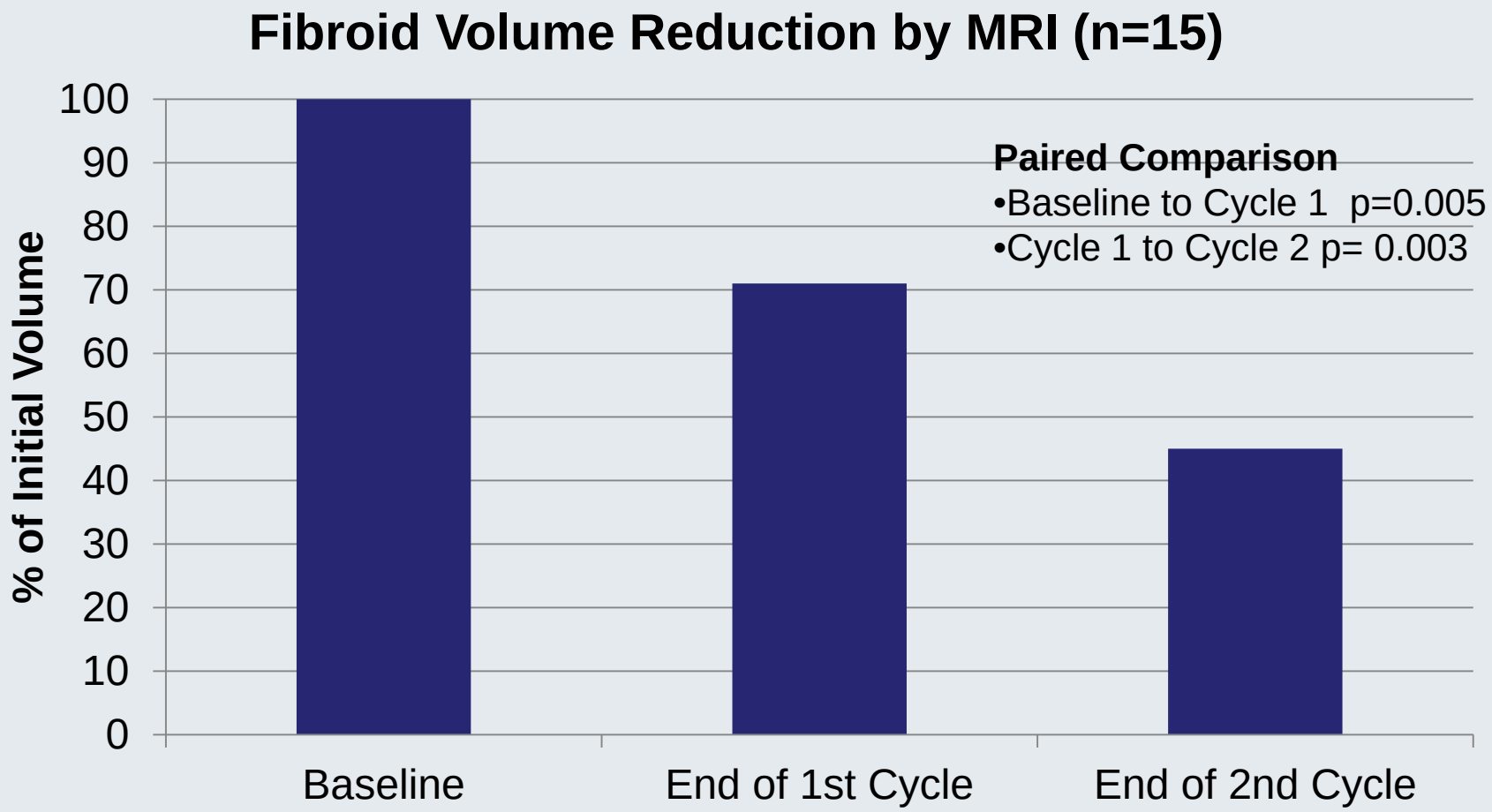








ZPV-200 Ext. Proellex Open Label Update (12mg dose)



Financial Summary

- **Cash and equivalents** (as of 4/1/13) $17.2 M

- **Cash runway:** Q1 2014
- **Current shares outstanding:** 18.6 M shares
  - Warrants Outstanding – Series A – 877,137 (purchased in unit deal @ $2.45); Series B – 855,680 @ $2.49 exercise price.

2013 Milestones

• Report results for Phase 2 Vaginal Proellex Study	Q1-13
• Fully Enroll 1 year Dexa Study	Q1-13
• Fully Enroll 500 subject 6 mos. Androxal Study	Q1-13
• Report Results for 1st Pivotal Androxal Study	**Q2-13**
• End of Phase 2 Meeting with FDA for Vaginal Proellex	**Q2-13**
• **Analyst Day, NYC**	**6/6/13**
• Commence Phase 3 Vaginal Proellex Study	Q3-13
• Complete 500 subject 6 mos. Androxal Study	Q3-13
• Report Phase 2 low dose Oral Proellex Study	Q4-13
• Report 2nd Pivotal Androxal Study	Q4-13
• Request Androxal Pre-NDA Meeting with FDA for Q1’14	Q4-13
• Submit Androxal NDA	Mid-2014