Repros THERAPEUTICS INC

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

Repros Disclaimer

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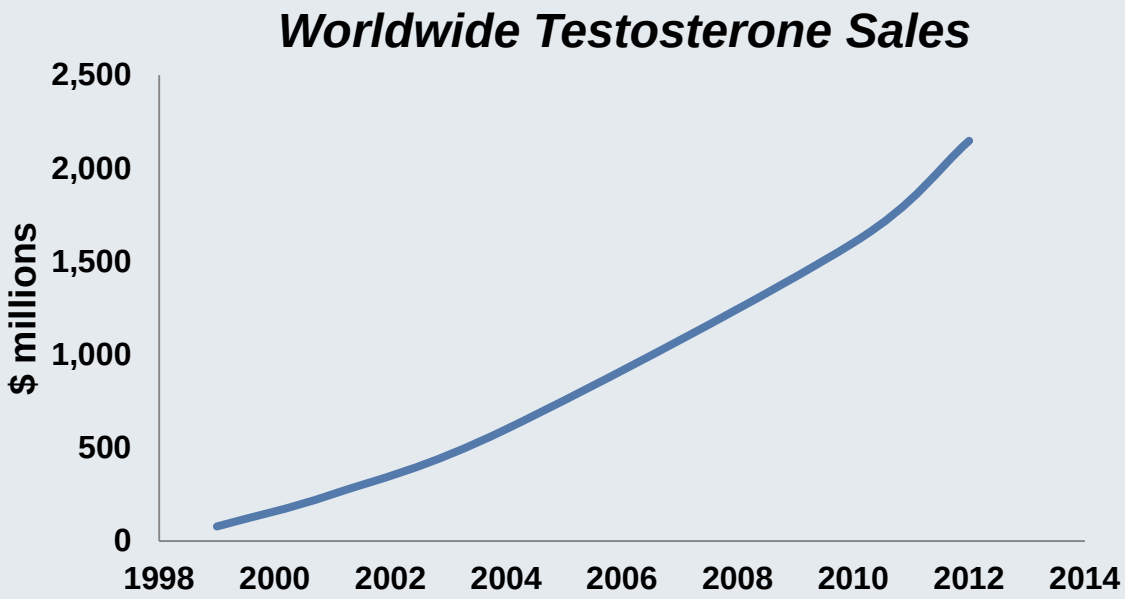
Investment Highlights

- **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 pending patent/ patent 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
- **Key late stage clinical & regulatory events expected in 2013**

Testosterone Market Continues to Grow

- ***2012 worldwide sales >$2.1B***
- ***US accounts for nearly 75% of global sales***
- ***Major pharmaceutical companies have moved to capture 83% of US opportunity***



Who are the men using testosterone?
Age & BMI of Subjects in Repros Androxal Studies

Study	IND	# of Subjects	Mean Age	Mean BMI
ZN-018	65,396	52	51.2	31.95
ZA-003	65,396	194	52.6	32.4
ZA-202	104,921	116	57.3	33.5
ZA-203	65,396	108	50.7	32.0
ZA-204	65,396	60	53.1	31.8

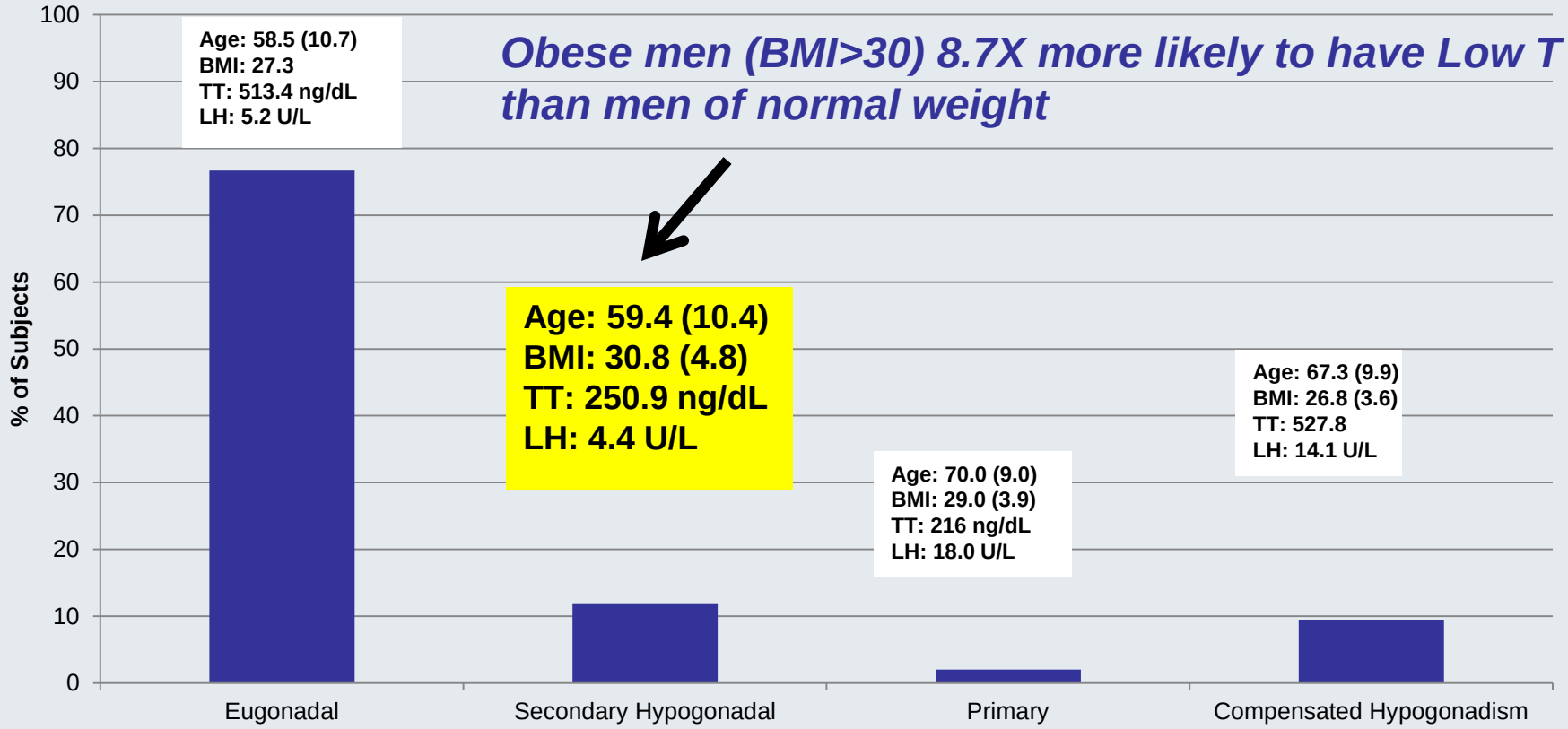
Who are the men using testosterone?

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)

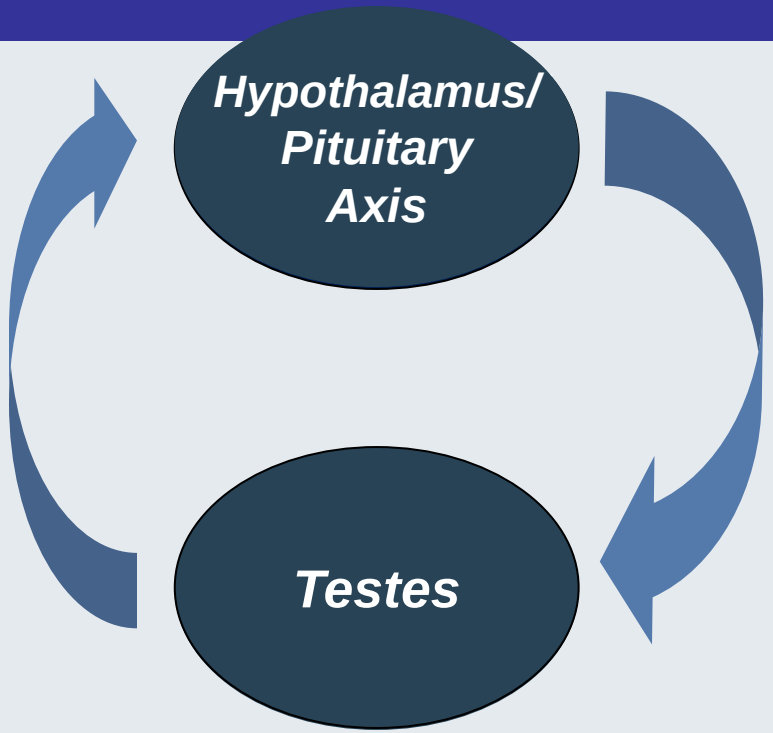
Data derived from over 3000 men



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

32% are obese

Secondary Hypogonadism

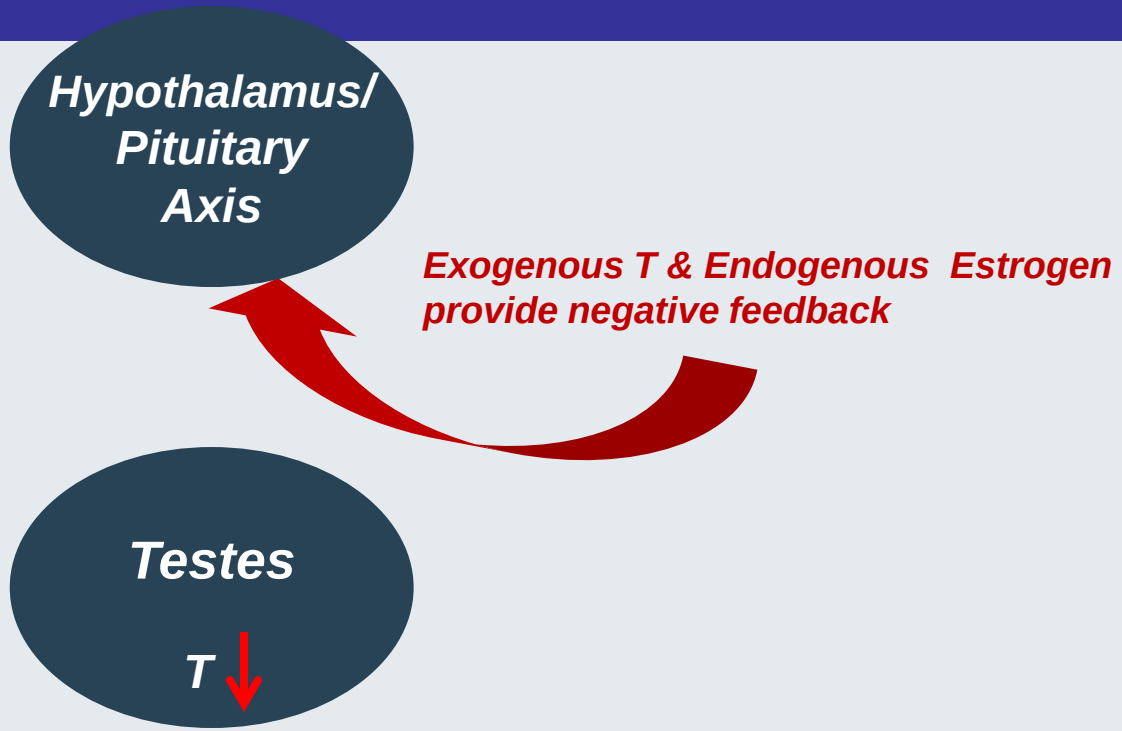


- ***Luteinizing hormone (LH) drives Leydig cell production of testosterone***
- ***Follicle Stimulating Hormone (FSH) drives spermatogenesis in the Sertoli cells of the testes***

- **Majority of men with low T have secondary hypogonadism**
- **Results from a suppression of secretion of pituitary hormones**
  - **Obese men are estrogenized**
- **LH & FSH secretions are low to low normal**
- **Testosterone Levels <300ng/dl**
- **Men with secondary hypogonadism are typically still fertile**

Approved T Replacement Products Shutdown Testicular Function

- *Pituitary secretions decrease or shut down*
- *Testicular function decreases or shuts down*
- *30% of men castrated at the level of the pituitary*



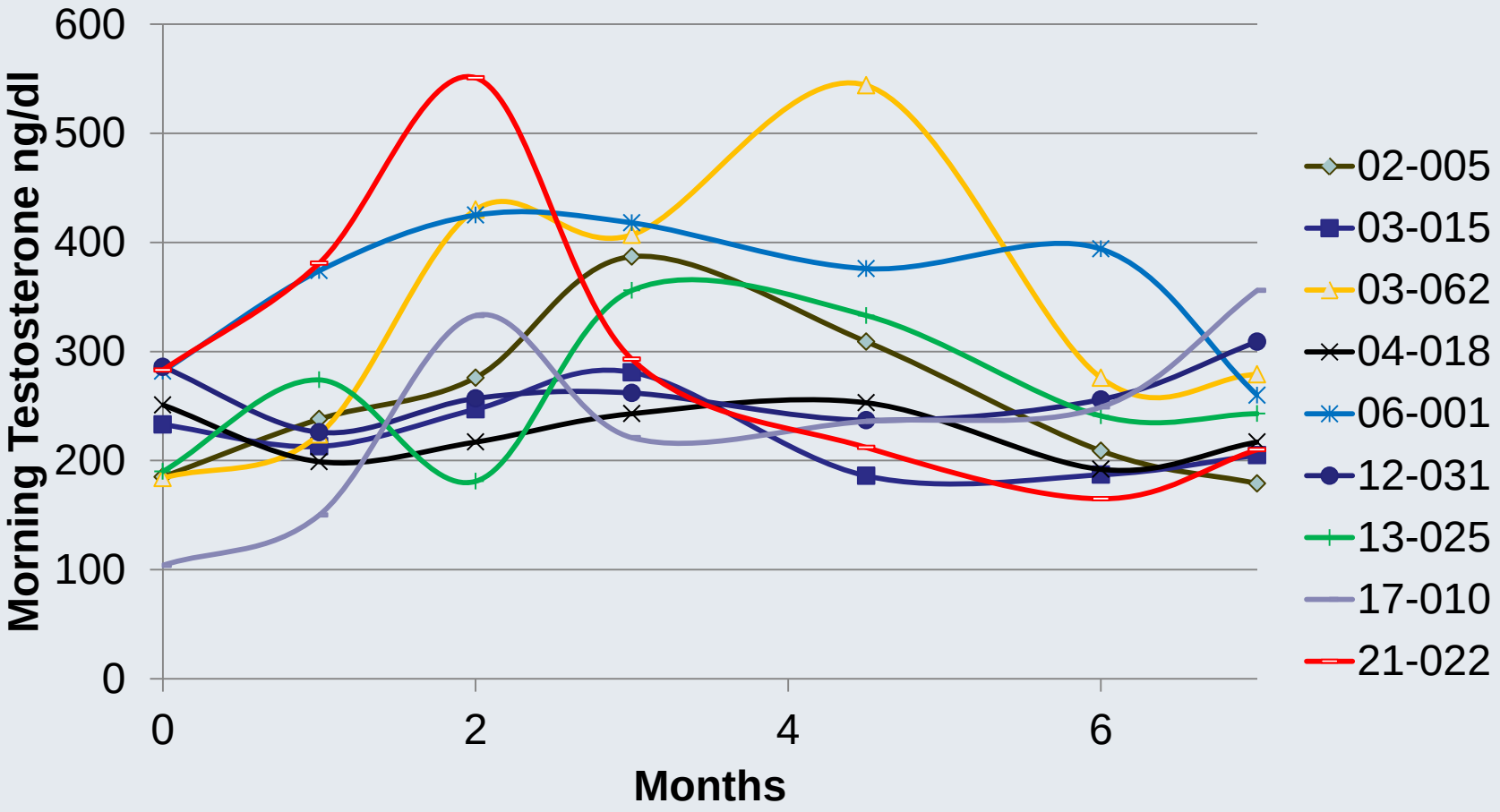
Leydig Cell Activity Suppressed
Spermatogenesis Suppressed Leading to Infertility

Over 30% of men with secondary hypogonadism administered an approved topical testosterone have undetectable pituitary and testicular function
They are castrated at the level of the pituitary

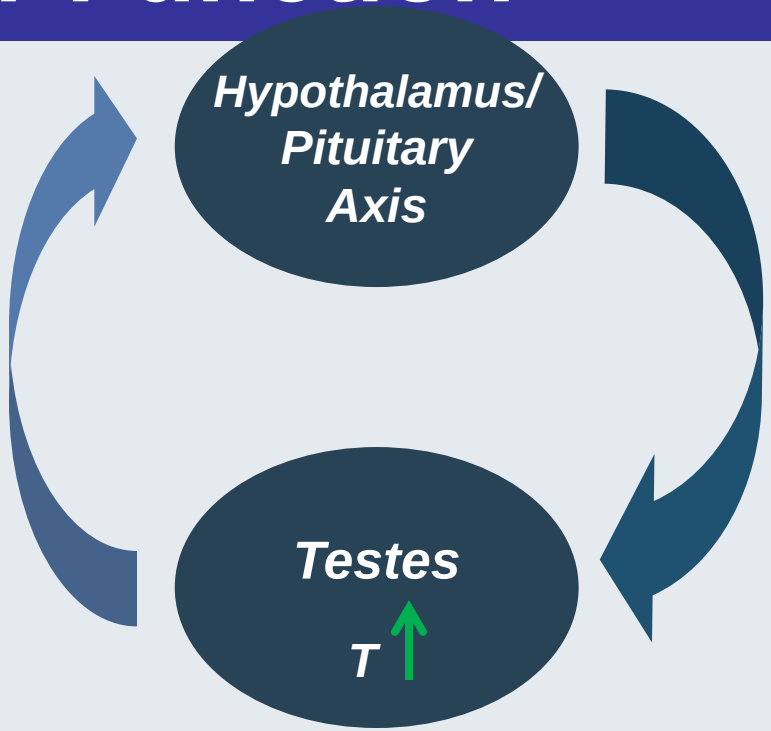
Day to Day Morning T Variability

Sampling of Placebo Subjects ZA-003

Should these men be prescribed testosterone replacement therapy?



Androxal Restores Normal Testicular Function



Androxal

- *Androxal blocks estrogen at the level of the pituitary*
- *Allows responsiveness to low T conditions*
- *Leads to increased LH & FSH to stimulate normal testicular function*

- *Increased LH and FSH levels*

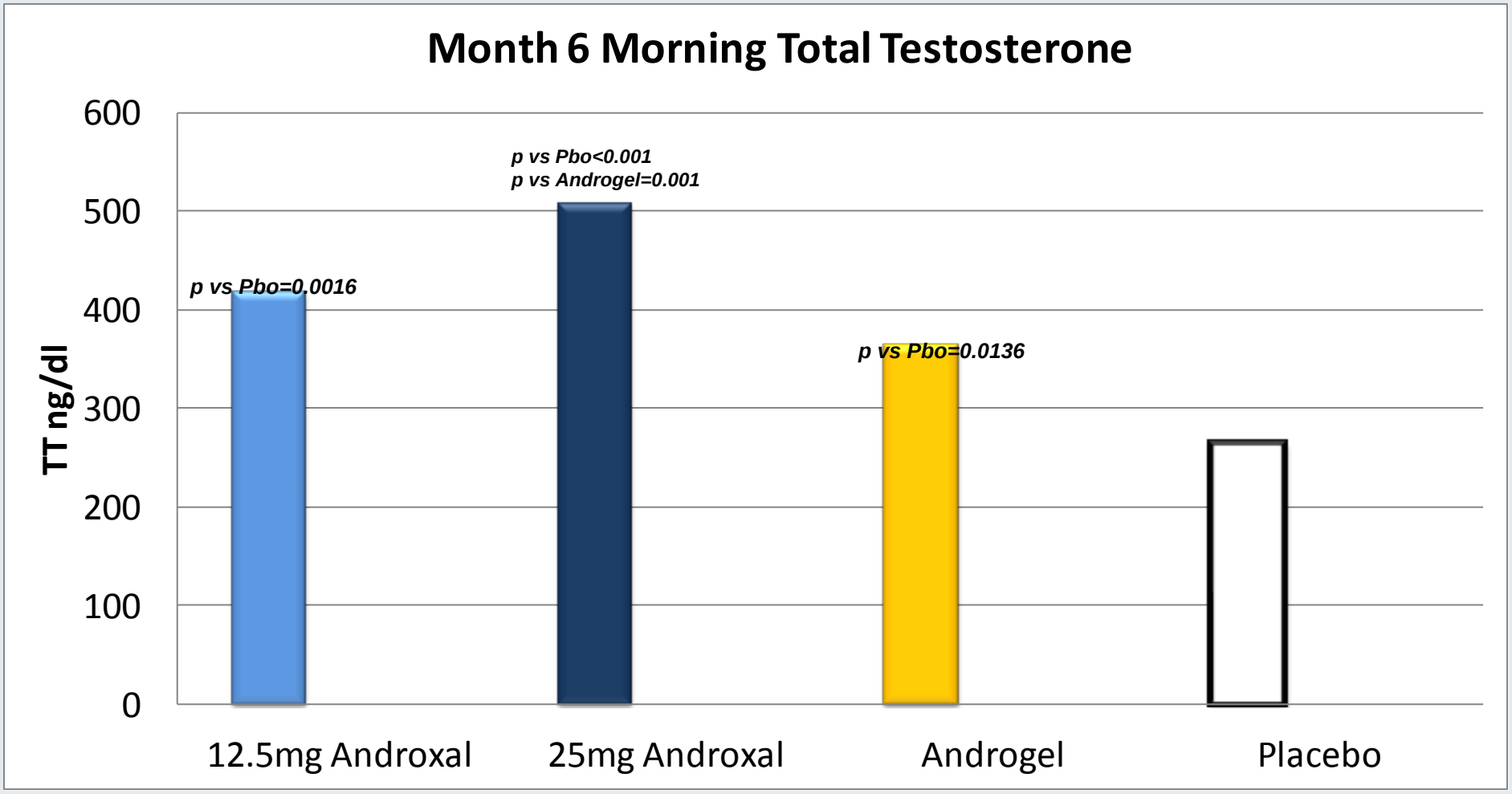
Increased Testosterone Secretion

FDA Accepts Phase 3 Protocol Under an SPA

- **Phase 3 pivotal studies being conducted under SPA**
  - 2 identical trials (BMI > 25, Age ≤ 60)
    - 152 subjects in each trial (114 on Androxal, 38 on placebo)
      - Men with morning T<300 ng/dL assessed twice on two separate days
    - Up-titration from 12.5 to 25
    - 3 month duration
  - Co-primary endpoints
    - 75% of men achieve T in normal range (300-1040 ng/dL)
    - Non inferior to placebo regarding change in sperm counts
- **Safety Requirements**
  - >100 for one year
  - >800 for 6 months
  - 100 subject one year DEXA study (bone marker data suggests Androxal builds bone)
- **Goal to Submit NDA Q2 2014**

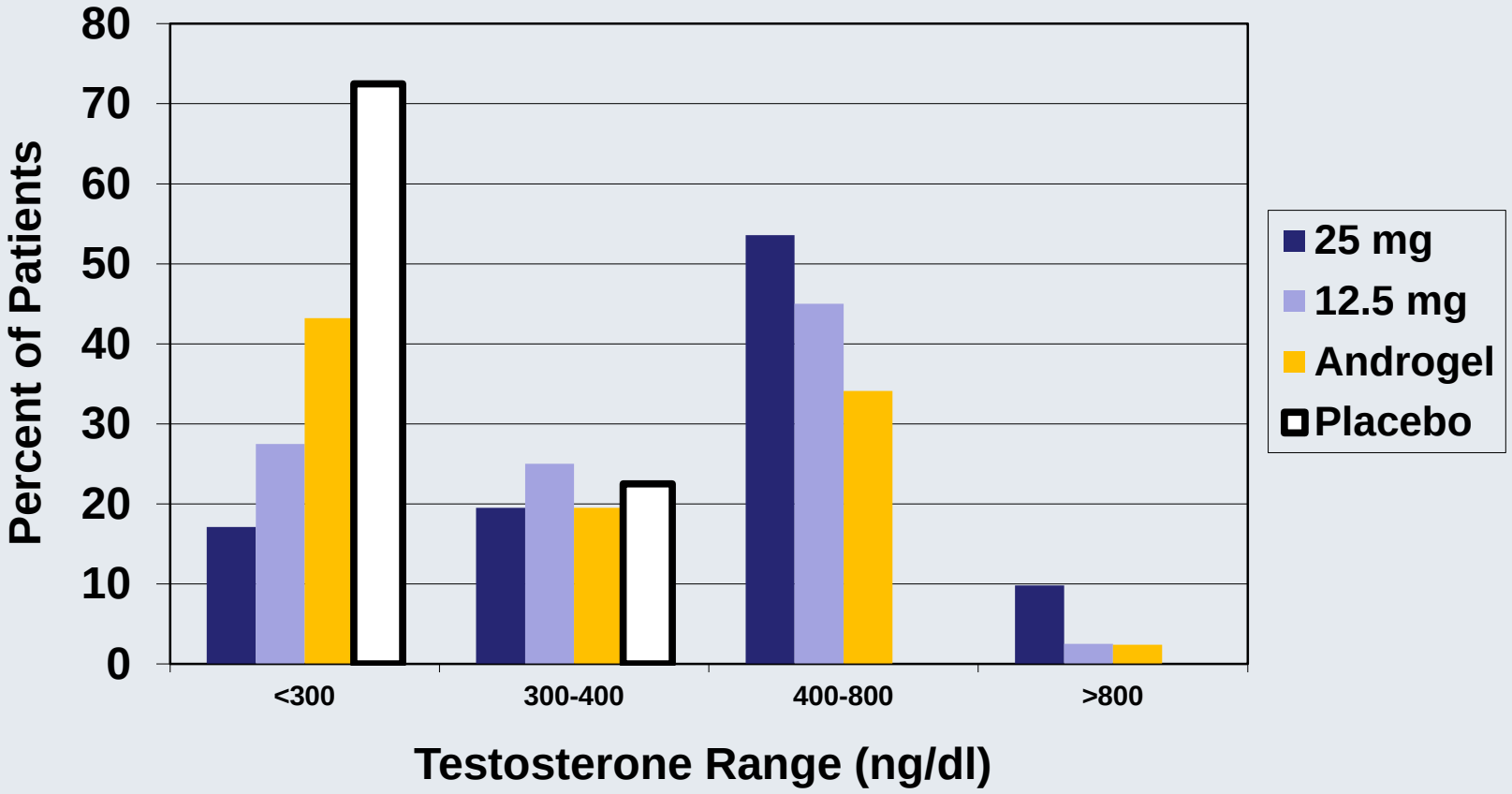
Previous Androxal Experience ZA-003

n=200



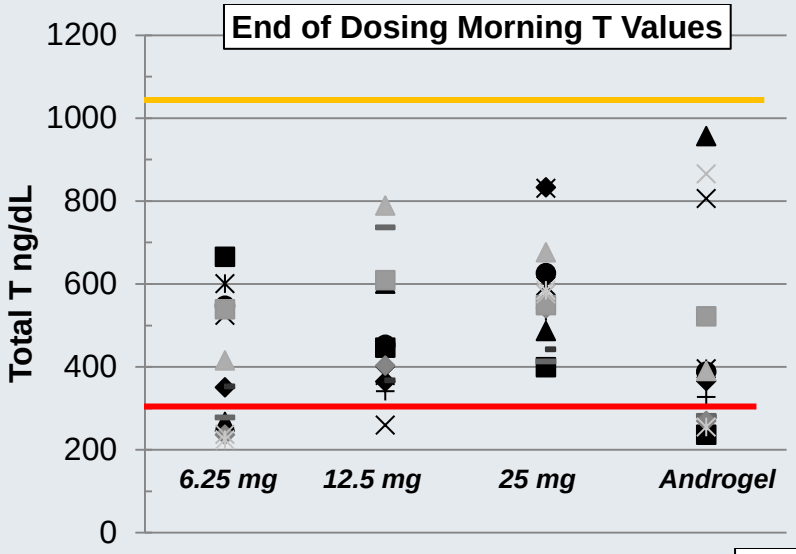
Previous Studies Suggests Favorable Outcome

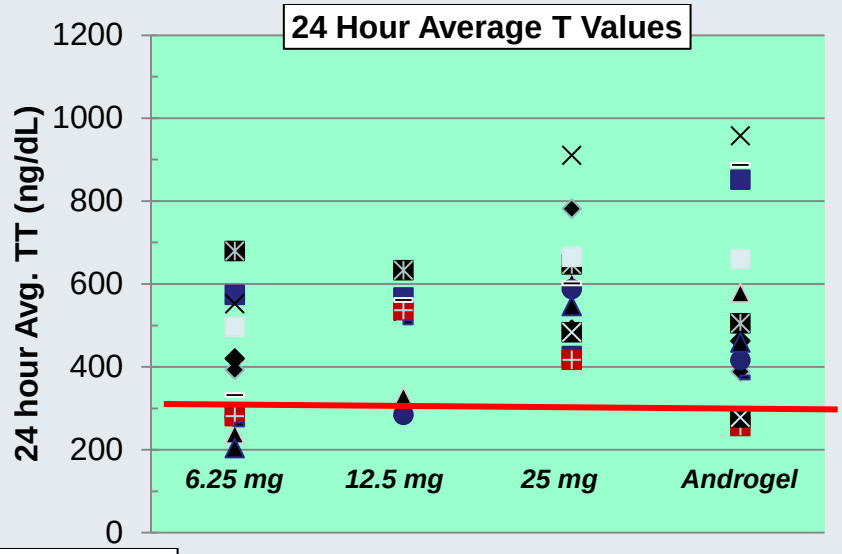
ZA-003 Testosterone Distribution (6 Month Data)

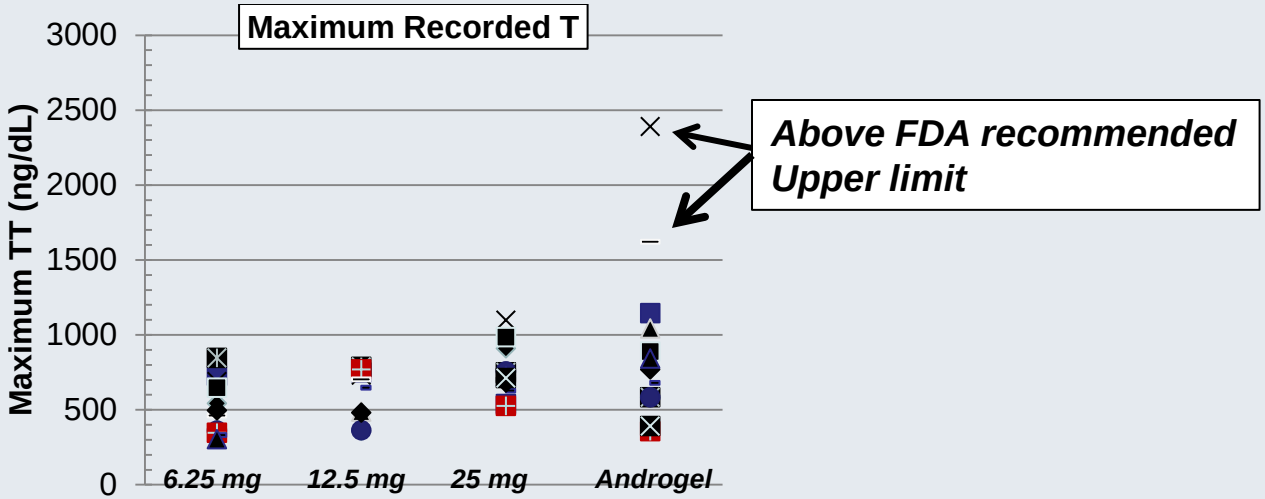


n=162 patients

ZA-204 End of Dosing Outcome Suggests Favorable Outcome in Phase 3 Studies

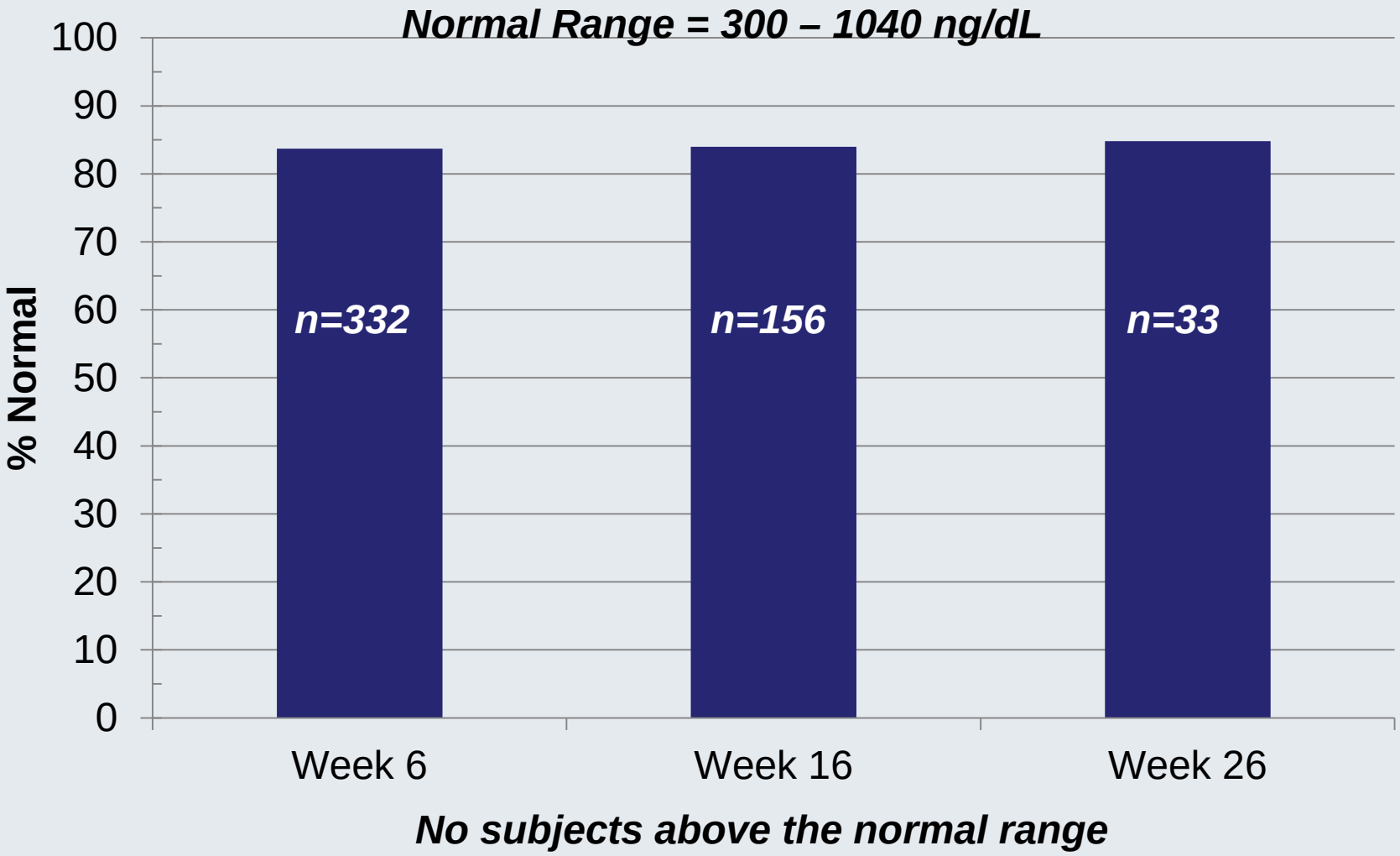






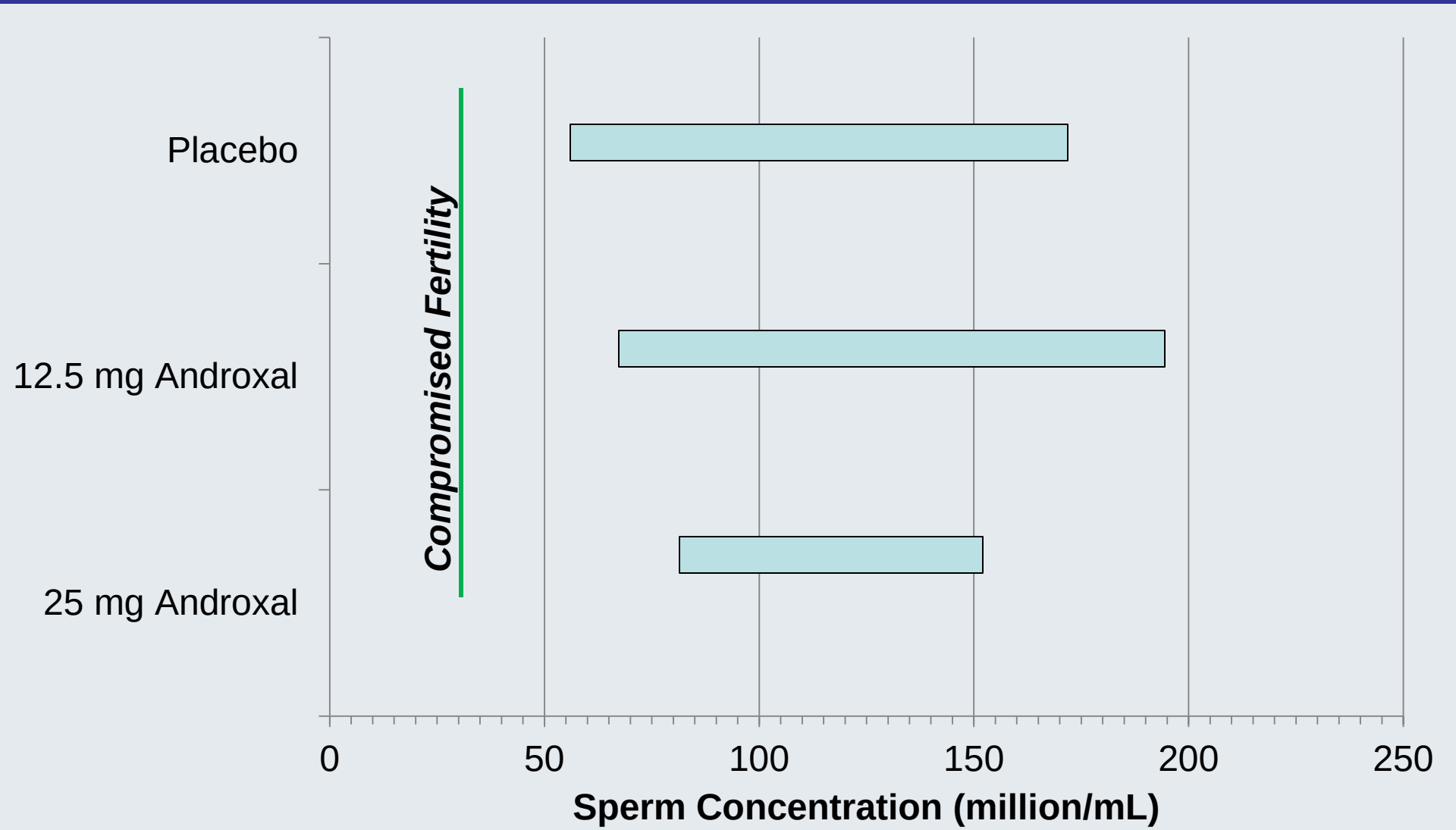
ZA-300: % of Men with T in the Normal Range

(26 week open label study, n=500 planned, 409 enrolled as of 1/2/13, ~30% previous T use)



No subjects above the normal range

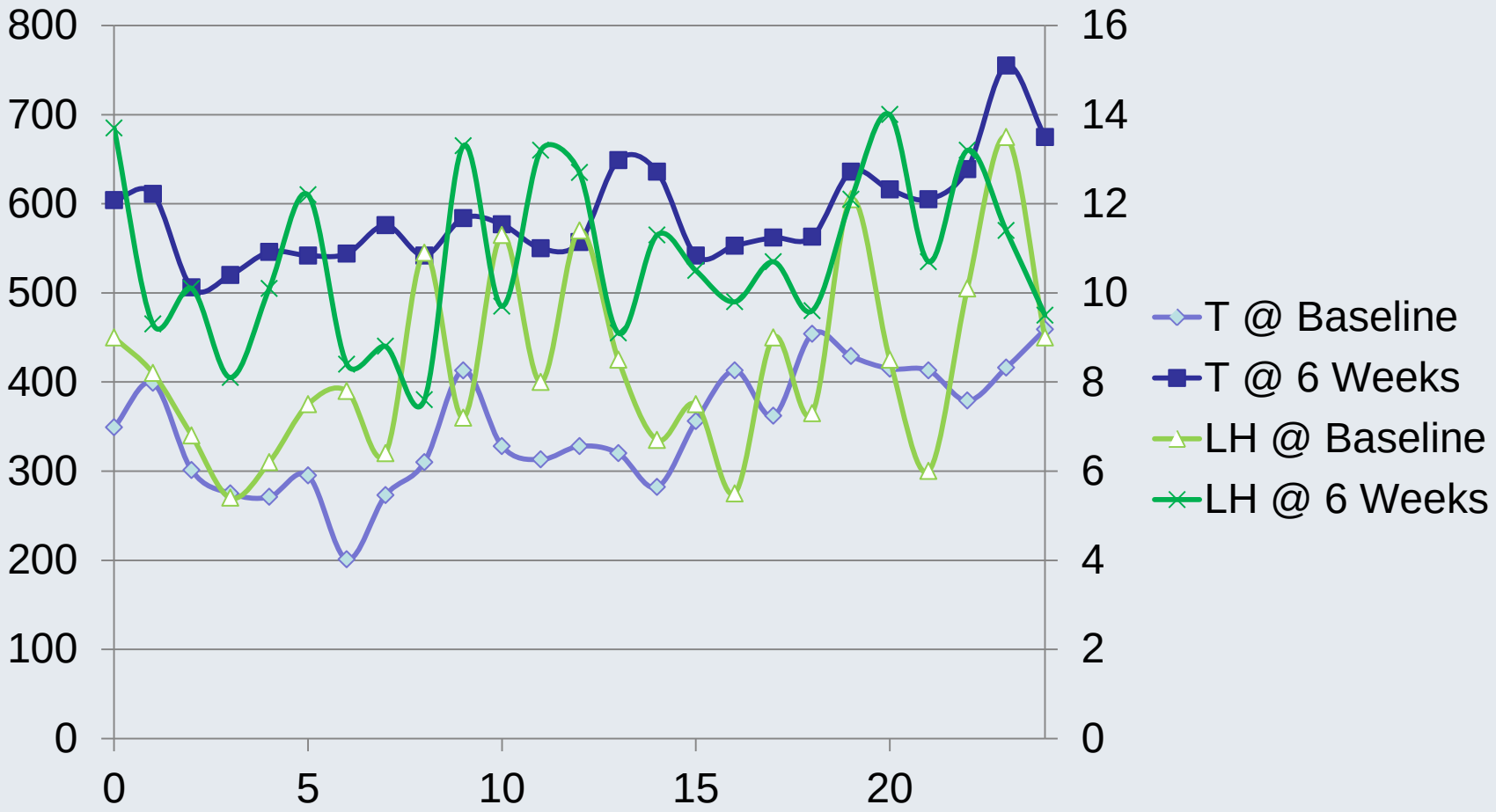
ZA-203 Average Sperm Counts Over Study
95% Confidence Interval for Sperm Counts



Androxal Preserves Testicular Function

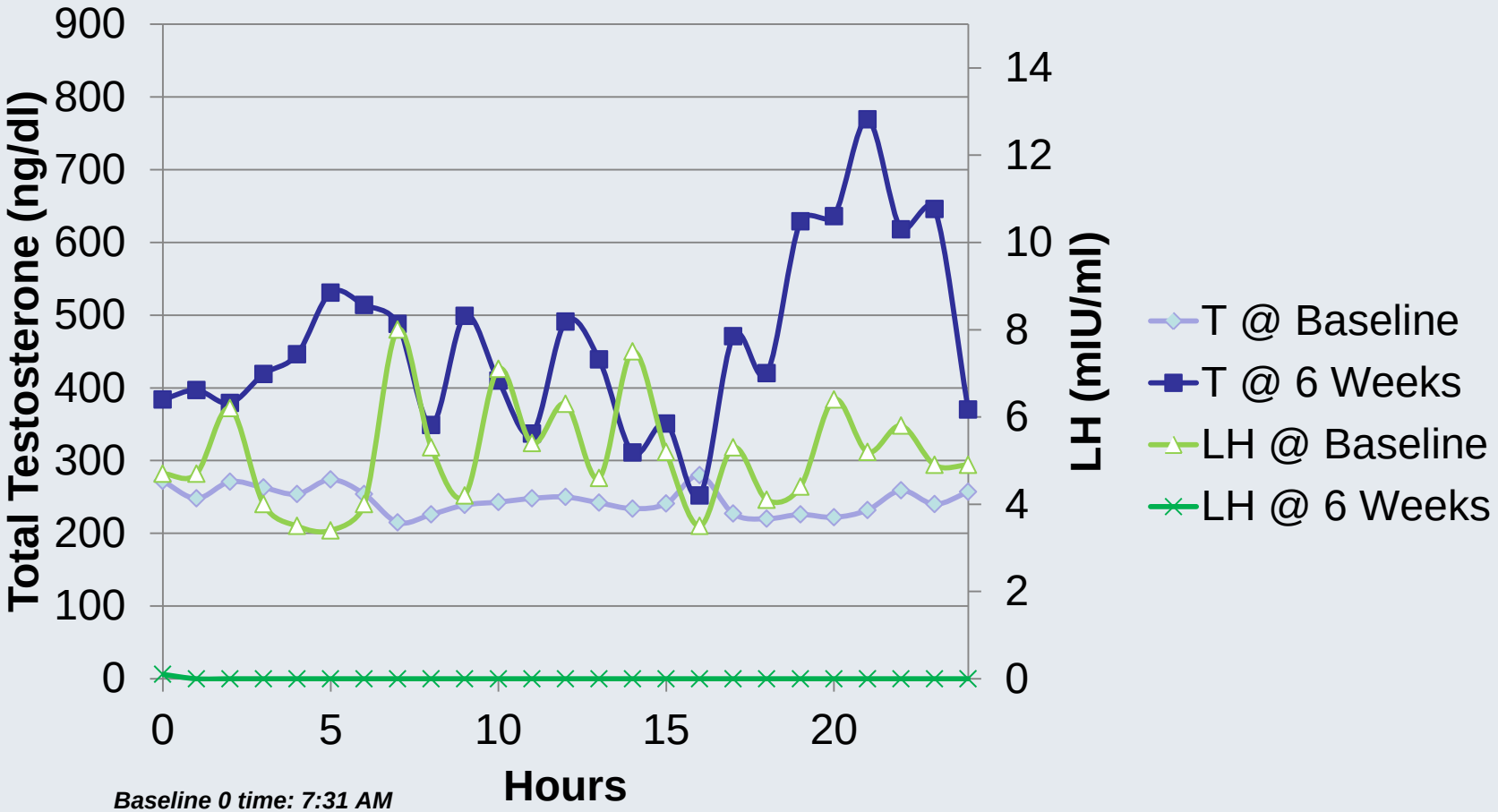
Approved Topical Products Suppress the Hypothalamic-Pituitary-Testes Axis

24 Hour T & LH
25 mg Androxal Subject Study ZA-204
Subject 2-003 Age: 55, BMI: 32



Baseline 0 time: 8:09 AM
Week 6 0 time: 7:25 AM

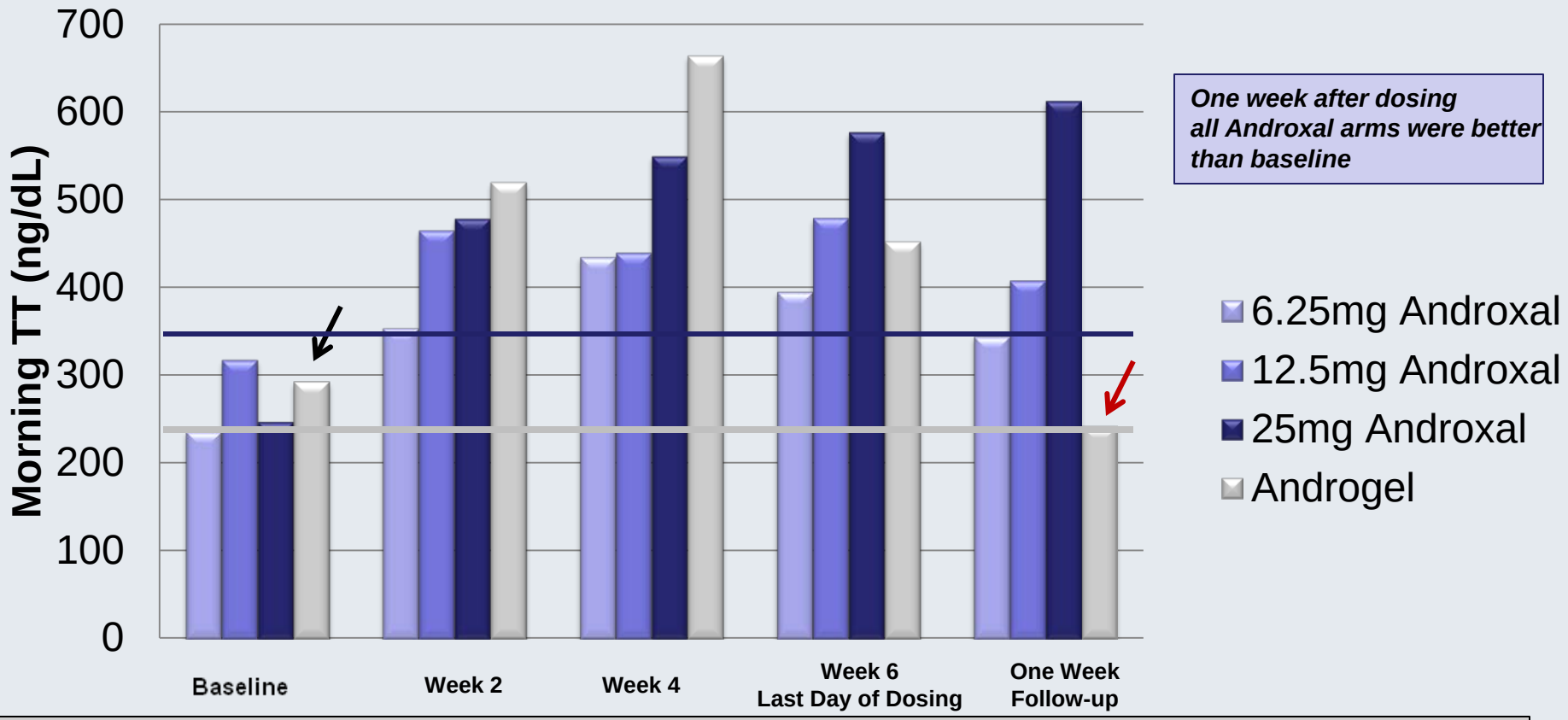
24 Hour T & LH
Androgel Subject Study ZA-204
Subject 2-049 Age: 58 , BMI: 24.1



Baseline 0 time: 7:31 AM
Week 6 0 time: 6:19 AM

Men on Androxal exhibit continued improvement in T even after dosing has stopped

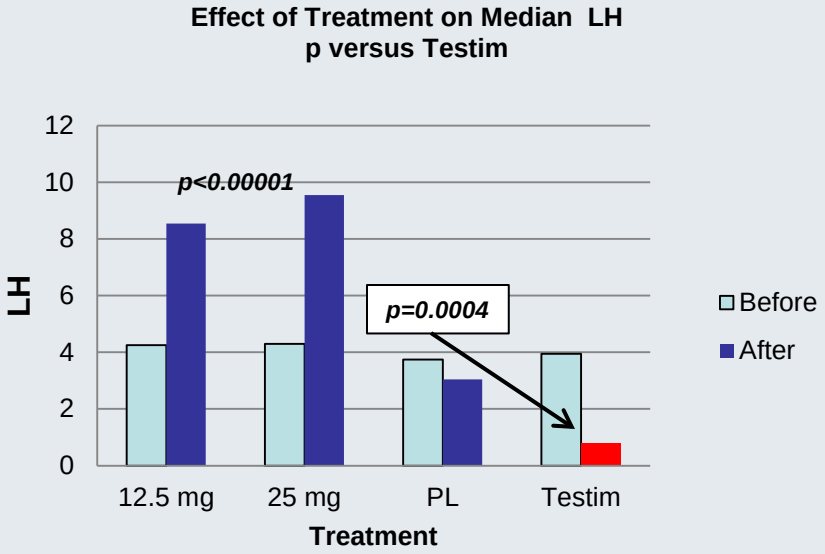
Fig. 14: Mean Morning TT Over Time (ZA-204)

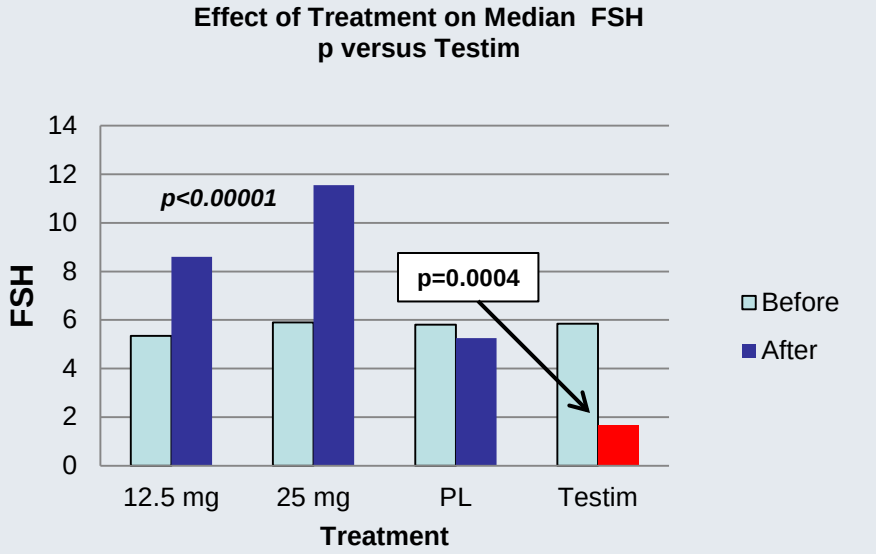


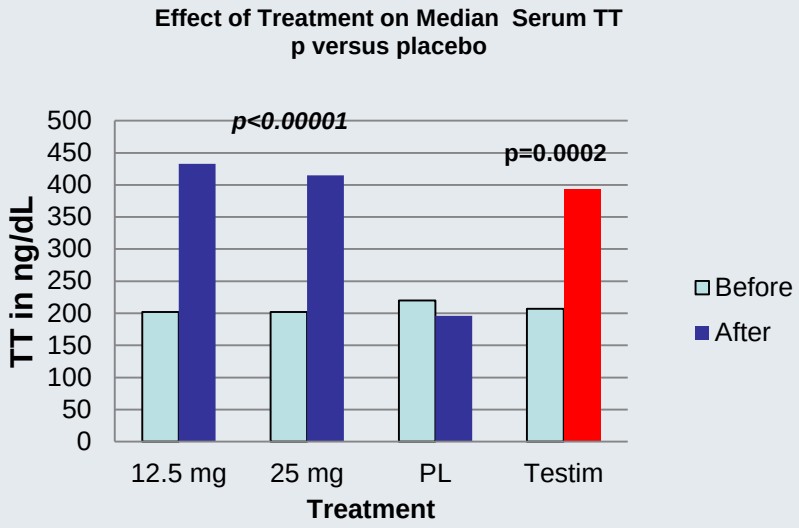
One week after dosing the Androgel arm was worse than baseline

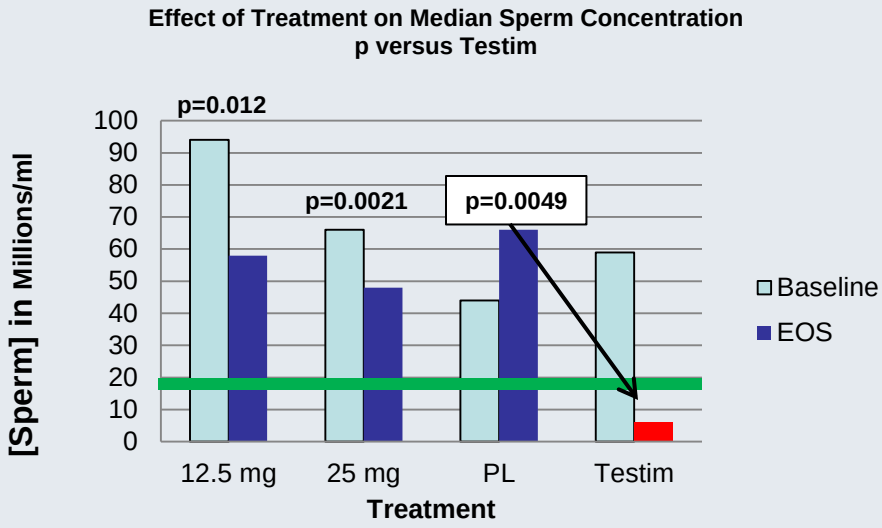
ZA-203 Hormone and Sperm Effects

Exogenous T Suppresses Pituitary Hormones and Testicular Function



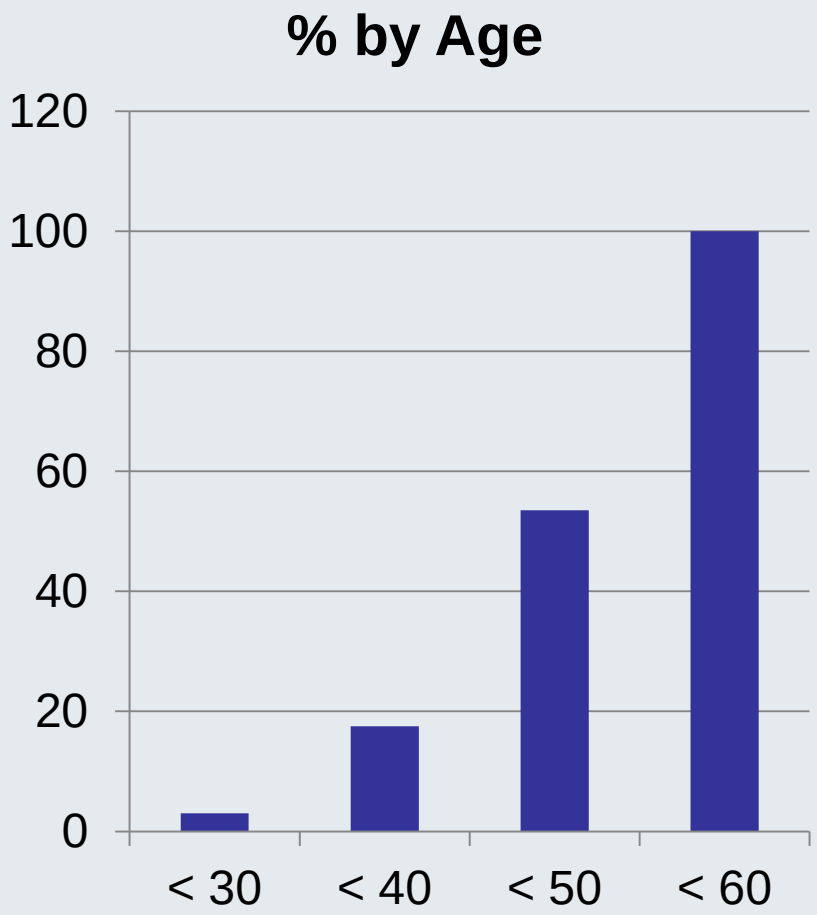


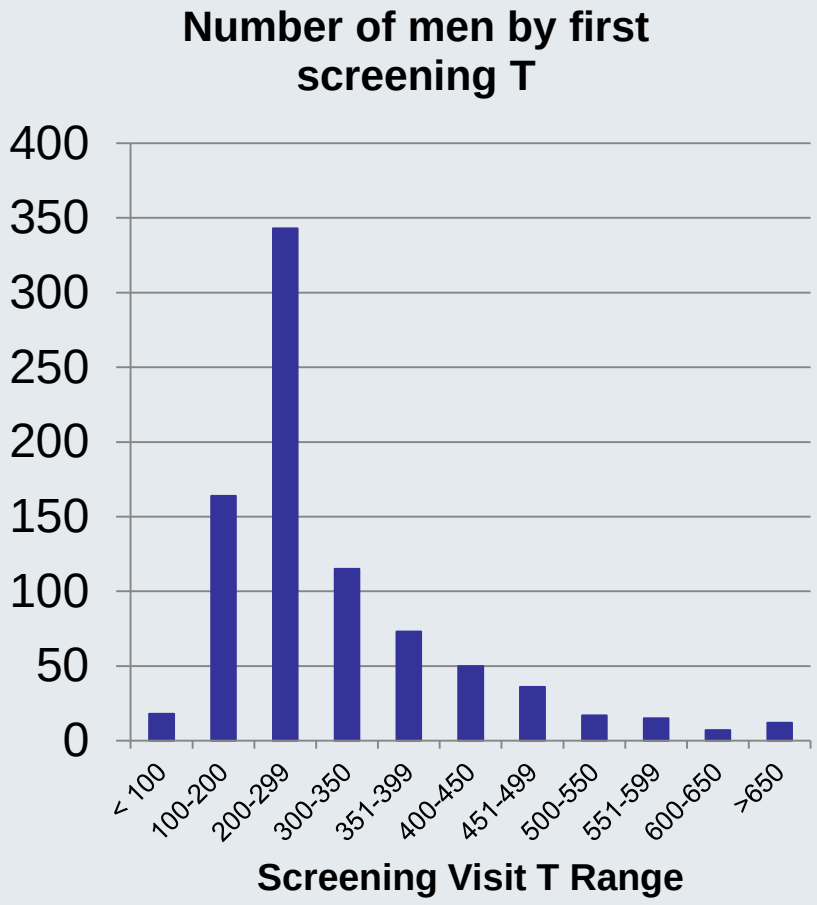




Distribution of Men Screened into ZA-300

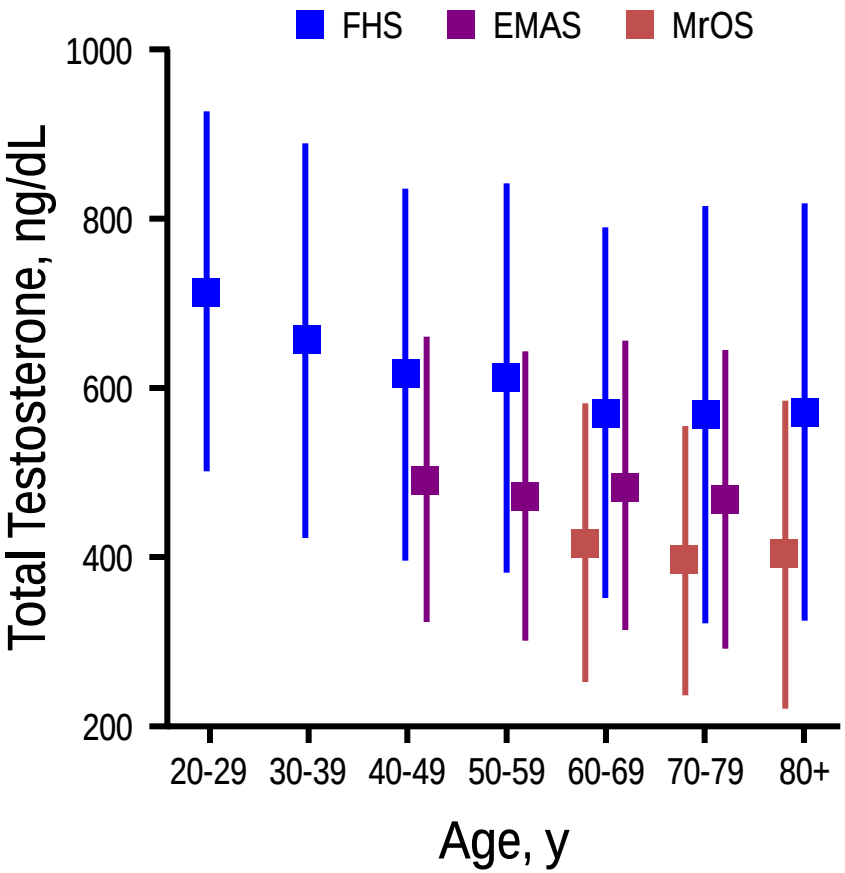
850 subjects screened as of 11/10/12

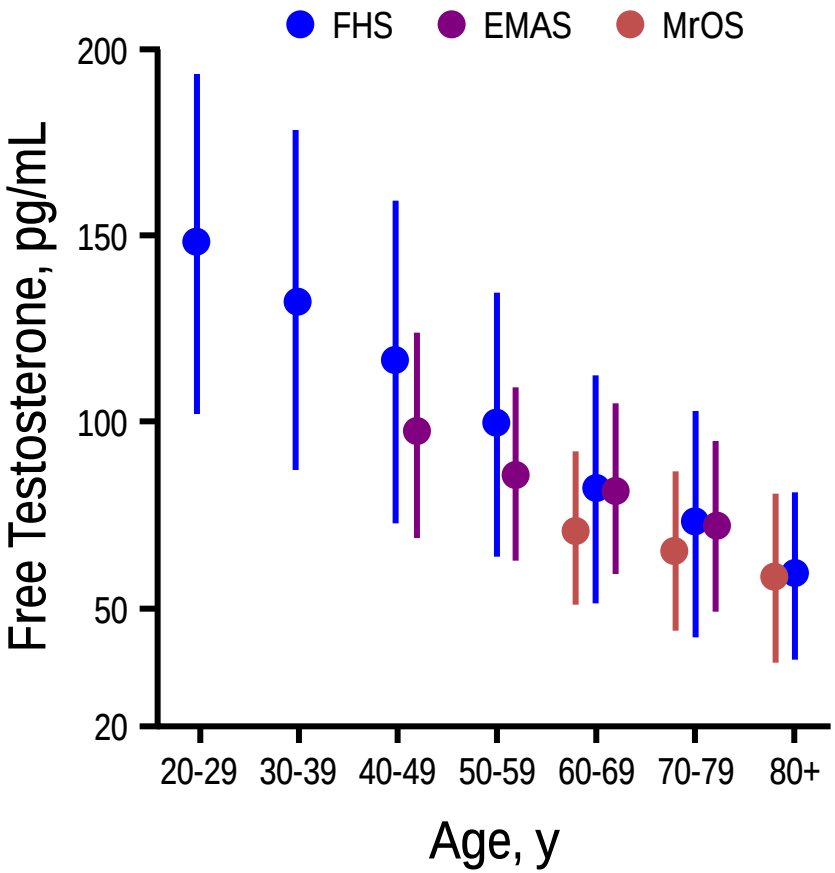




Testosterone Levels

Age-related Changes





EMAS, European Aging Male Study; FHS, Framingham Heart Study; MrOS, Osteoporotic Fractures in Men Study.
Bhasin S, et al. *J Clin Endocrinol Metab*. 2011;96(8):2430-2439.

Phase III Androxal Program Status:1/3/13
NDA Target: June 2014

Study	Target Enrollment	Study Duration	Subjects Screened	Subjects Enrolled	Subjects Pending	Projected Full Enrollment
ZA-300 Safety	500	6 months	1088 (28 sites)	415 332@wk6 83.7% >300ng/dL	~15	Q1 ’13
ZA-301 Pivotal	152	3 months (+ 6 weeks)	571 (17 sites)	152	Enrolled in < 12 weeks	**Fully Enrolled**
ZA-302 Pivotal	152	3 months (+ 6 weeks)	138 (16 sites)	50	~35	Q1 ’13
ZA-303 Safety	150	1 year	419 (10 sites)	150		**Core Fully 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	

Third Party Study Indicates 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***

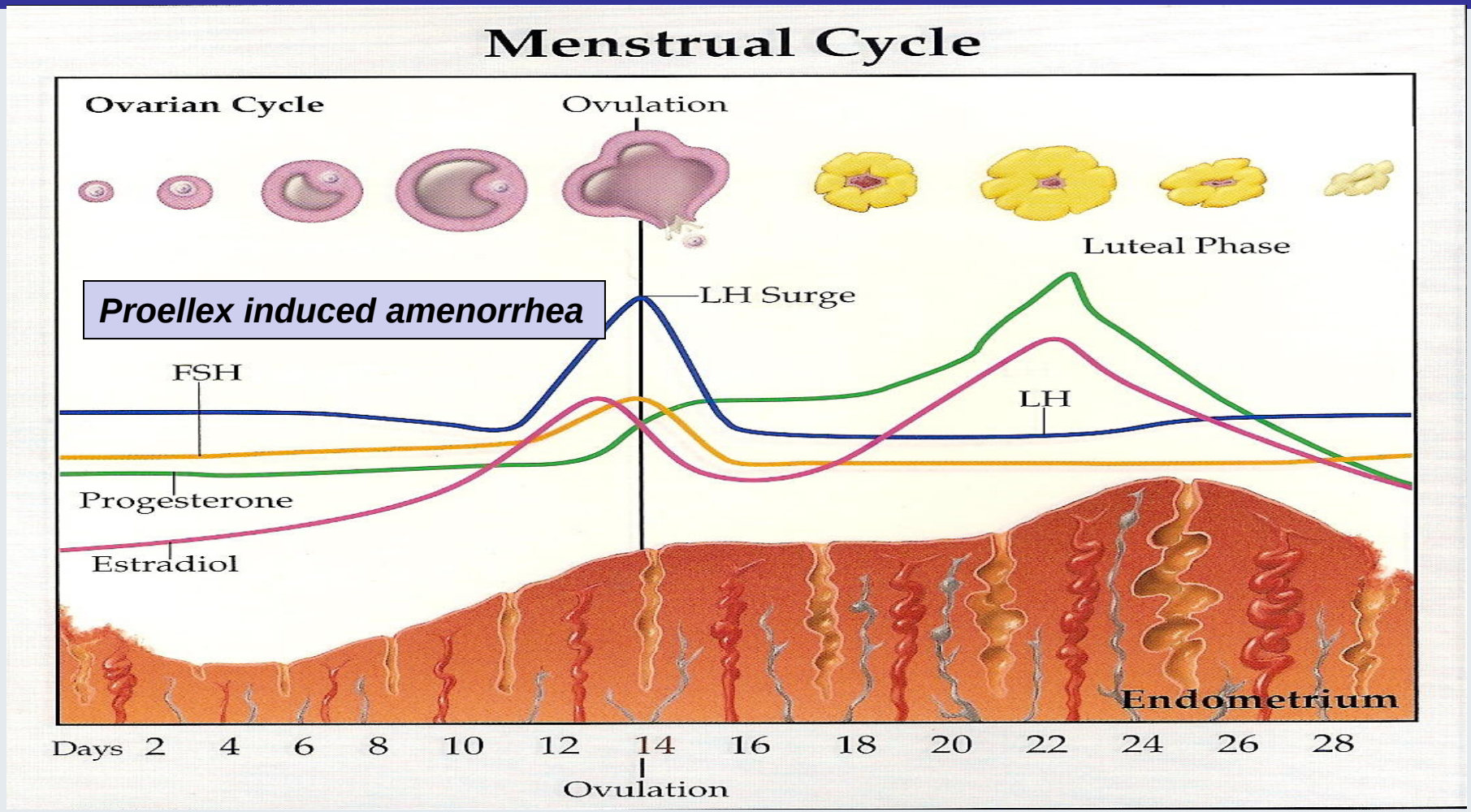
Proellex for the Treatment of Uterine Fibroids and Endometriosis

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

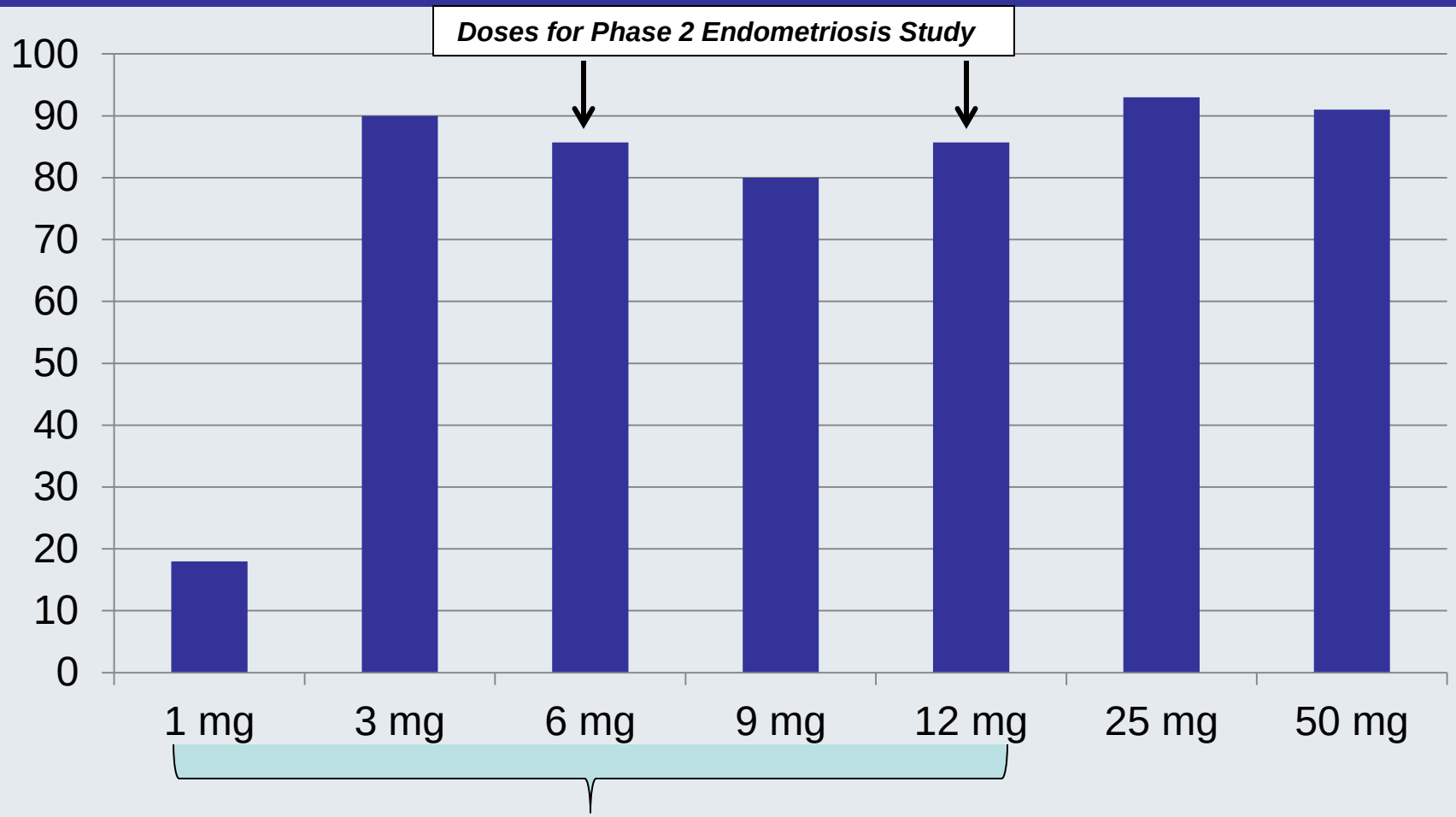
Over 300,000 hysterectomies performed every year in the US to treat these two disorders

No acceptable chronic therapeutic options available today

An Effective Dose of Proellex Stops Menstruation in Majority of Women

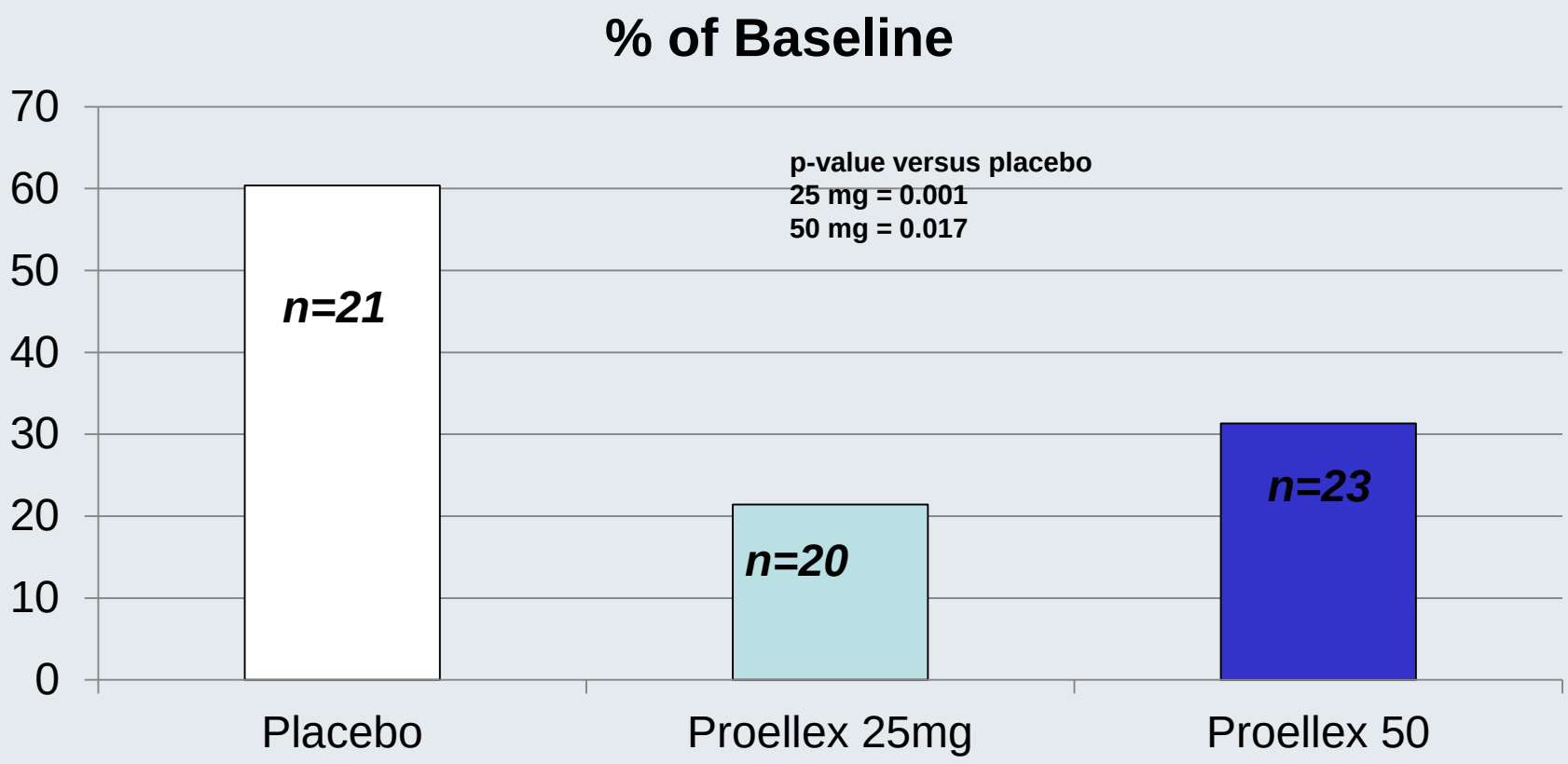


% of Women Experiencing Proellex Induced Amenorrhea in Low Dose Study



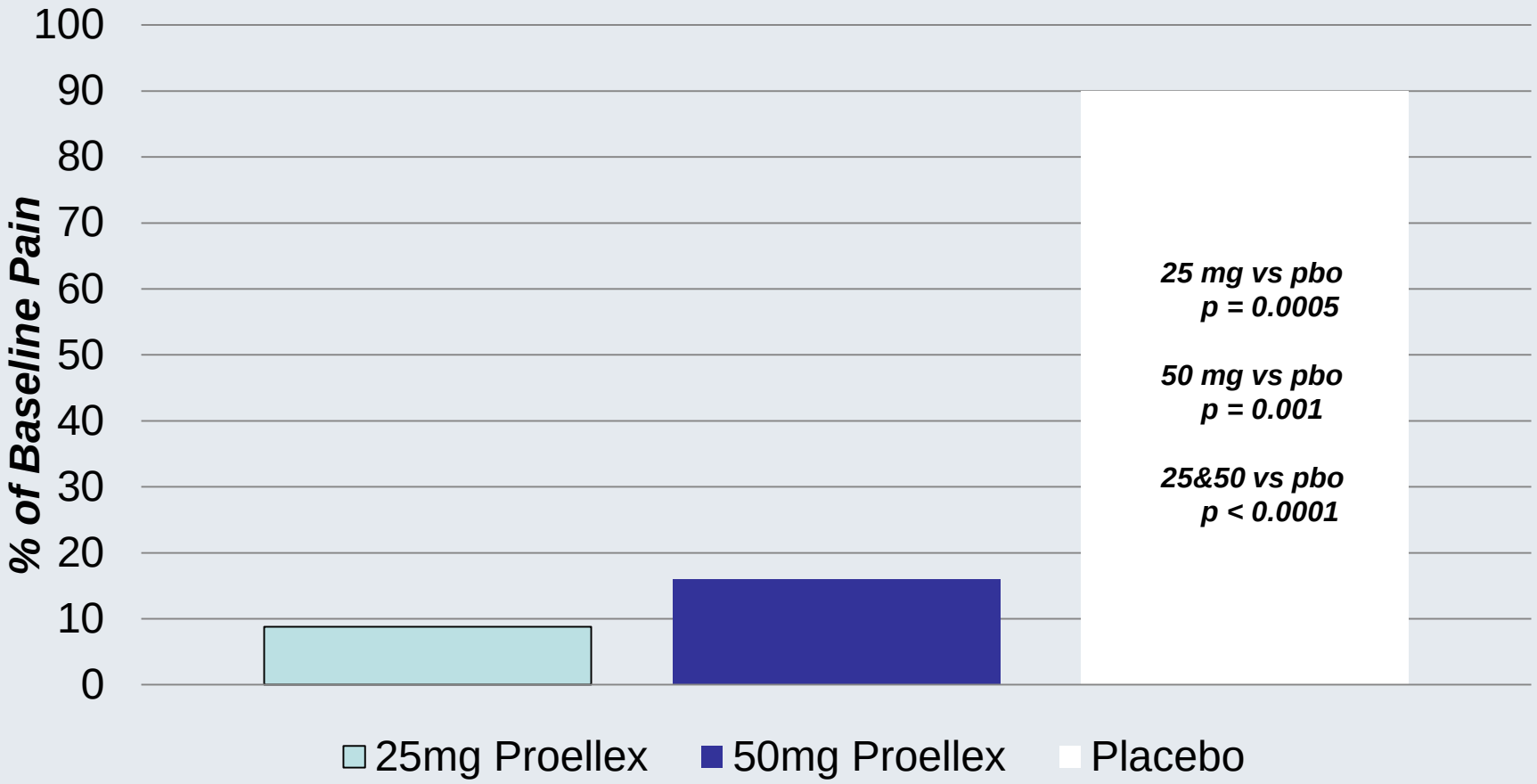
Doses safely tested in Phase 2 trial

Baseline vs Last 28 Days
All Patient Reported Endometriosis Pain



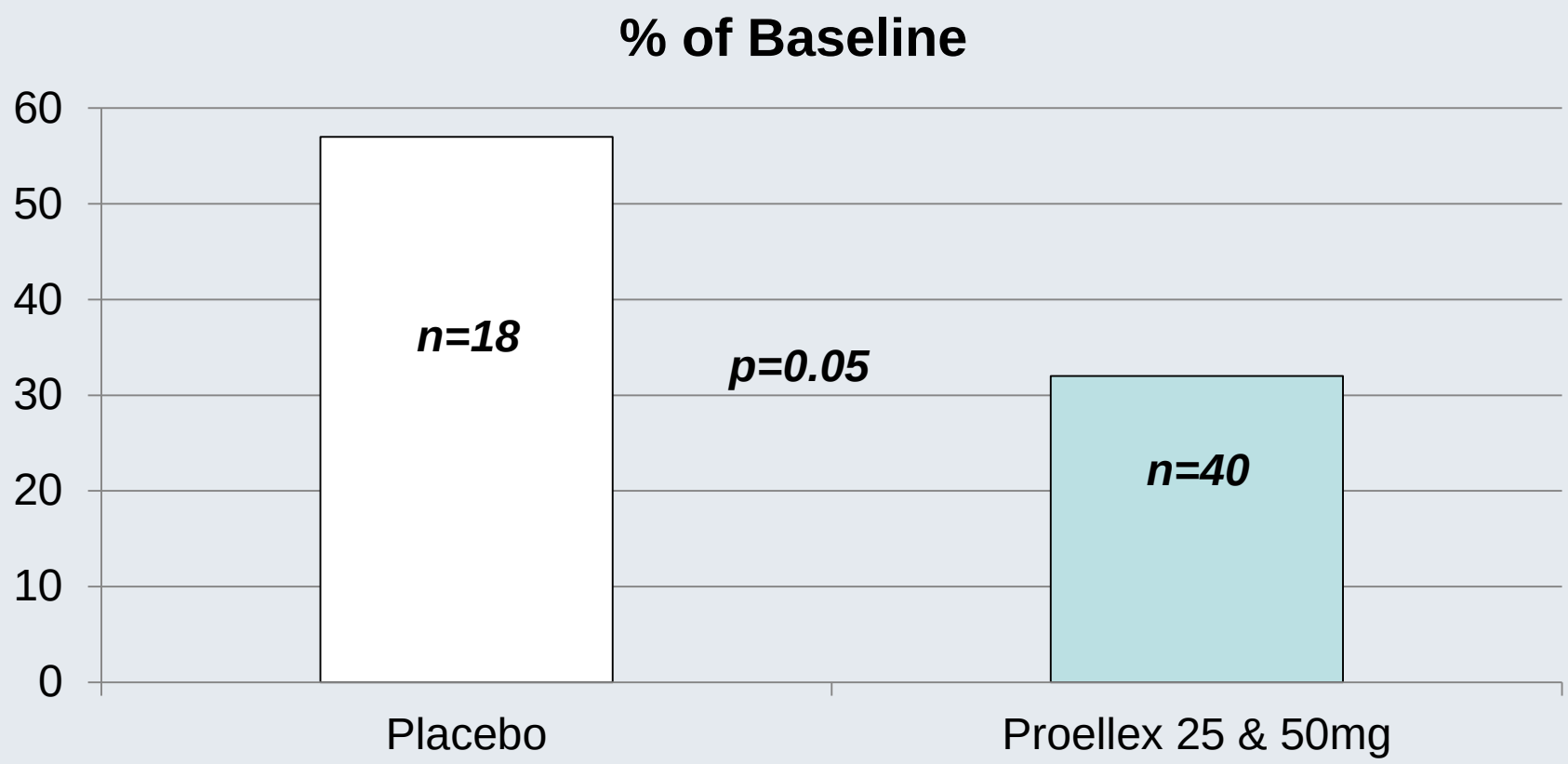
Dysmenorrhea, Dyspareunia and Non Menstrual Pelvic Pain

BASELINE vs LAST 28 DAYS DYSMENORRHEA

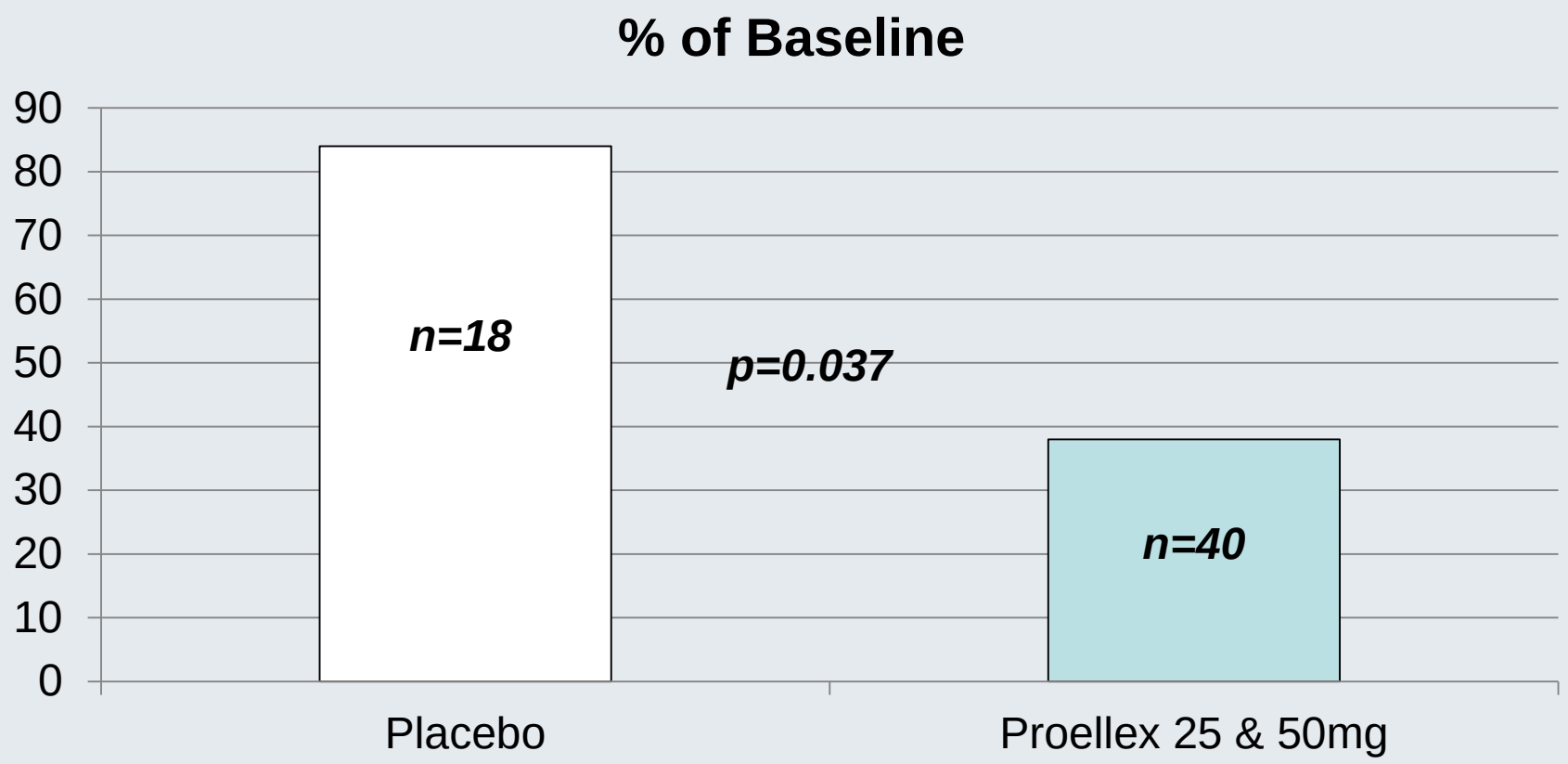


N = 18 for placebo and 25 mg
N = 22 for 50 mg

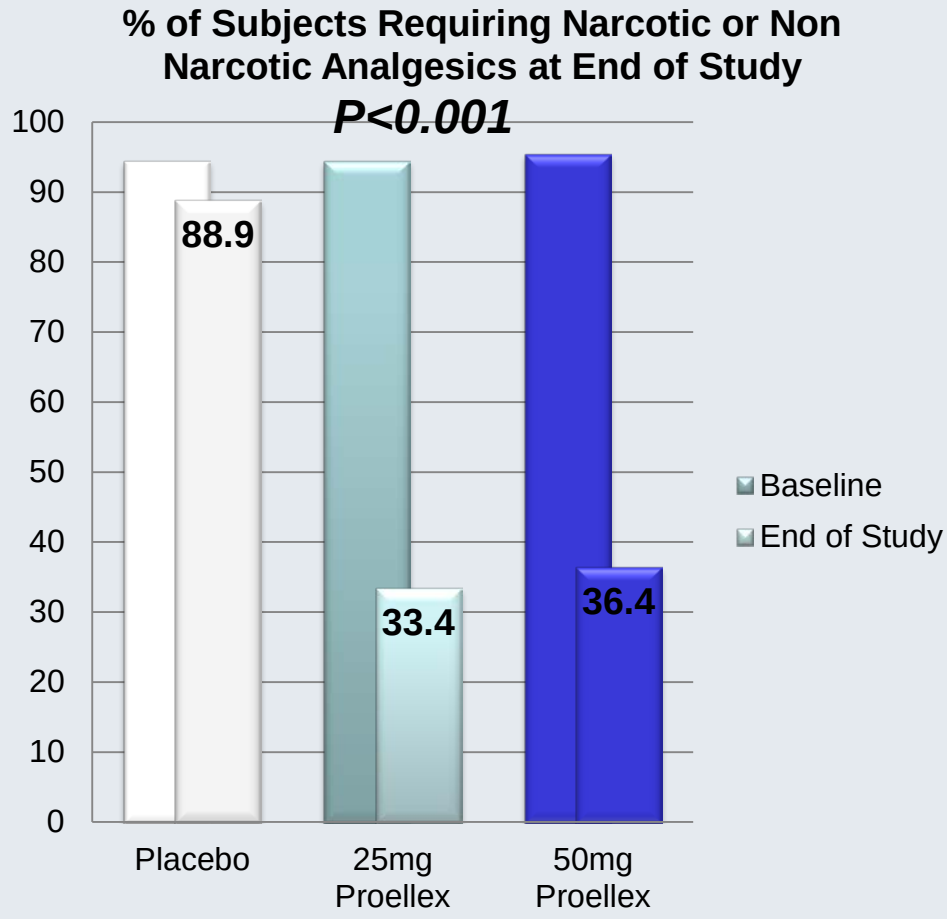
Baseline vs Last 28 Days Non Menstrual Pelvic Pain

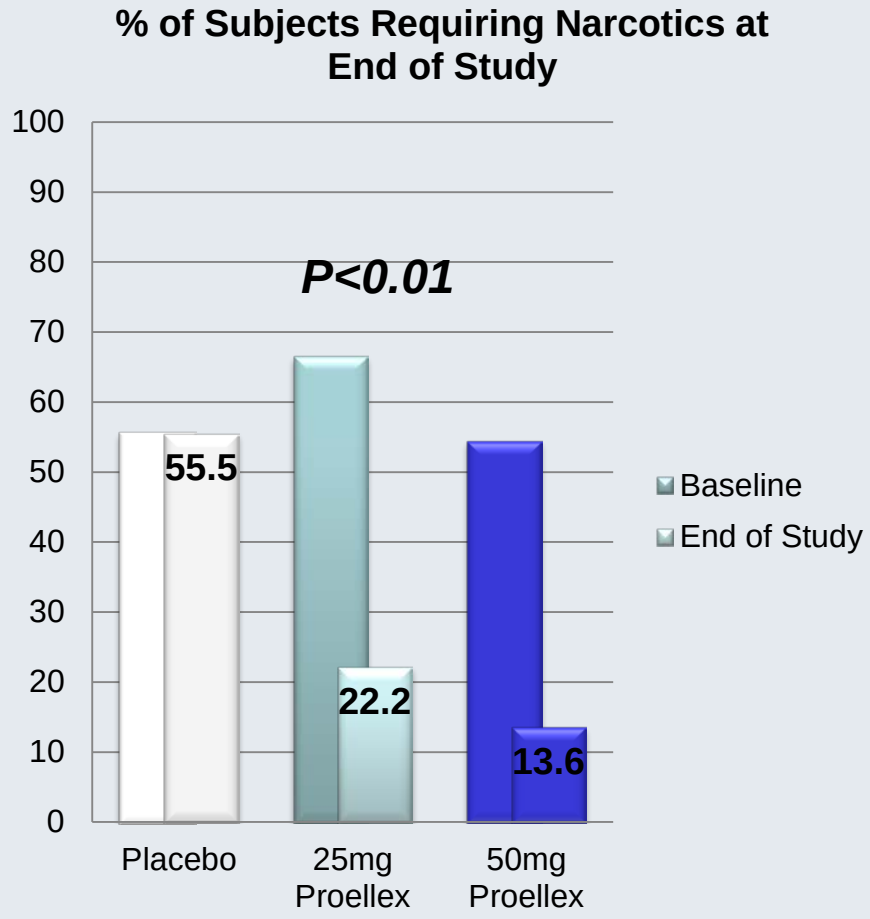


Baseline vs Last 28 Days Dyspareunia



Doses That Stop Menses Have Significant Impact on Analgesic Use in the Control of the Pain Symptoms of Endometriosis





FDA allows Repros to conduct Phase 2 study in women with severe endometriosis

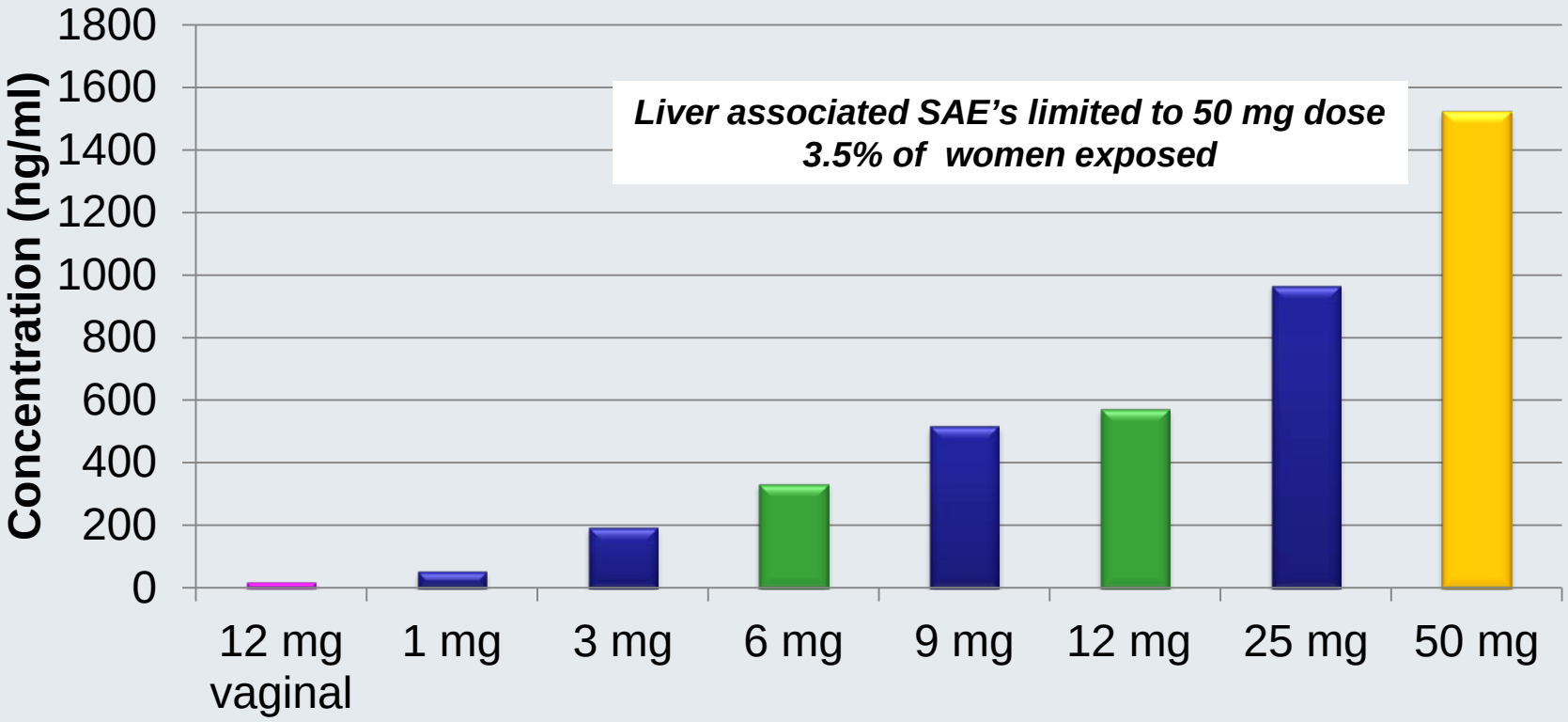
Vaginal Proellex Expected to Eliminate the Need for Hysterectomy in Most Situations

- New IND effective
  - Unaffected by oral outcomes
- Initial Phase 2 study to test four doses of vaginal administration in the treatment of uterine fibroids
  - Assess reduction of fibroid size and elimination of symptoms
  - Top line data reported

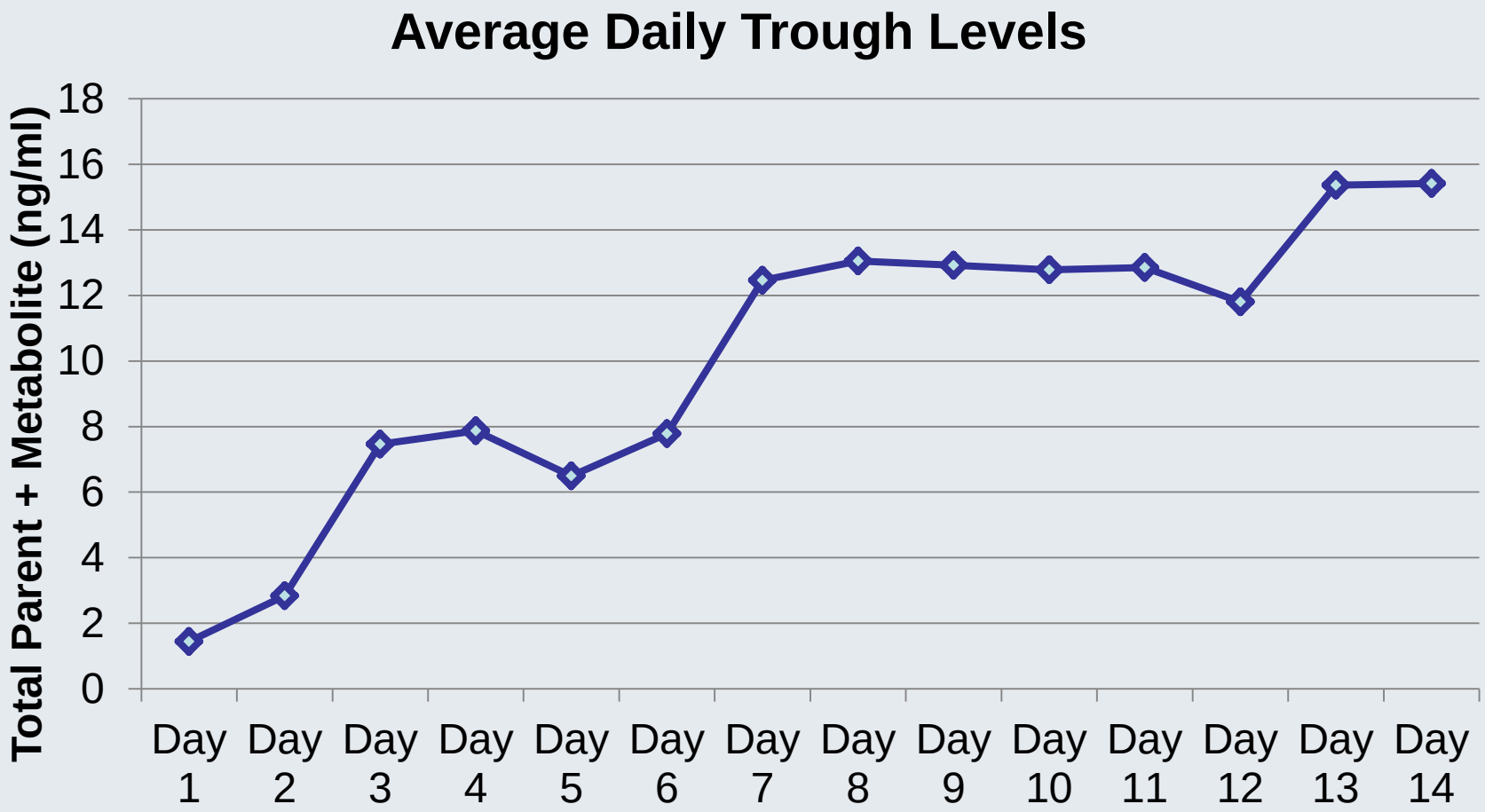
Systemic Exposure to Oral Proellex Varies in a Dose Dependent Manner

Significant reduction in exposure via vaginal delivery

Combined Cmax for Telapristone and Primary Metabolite



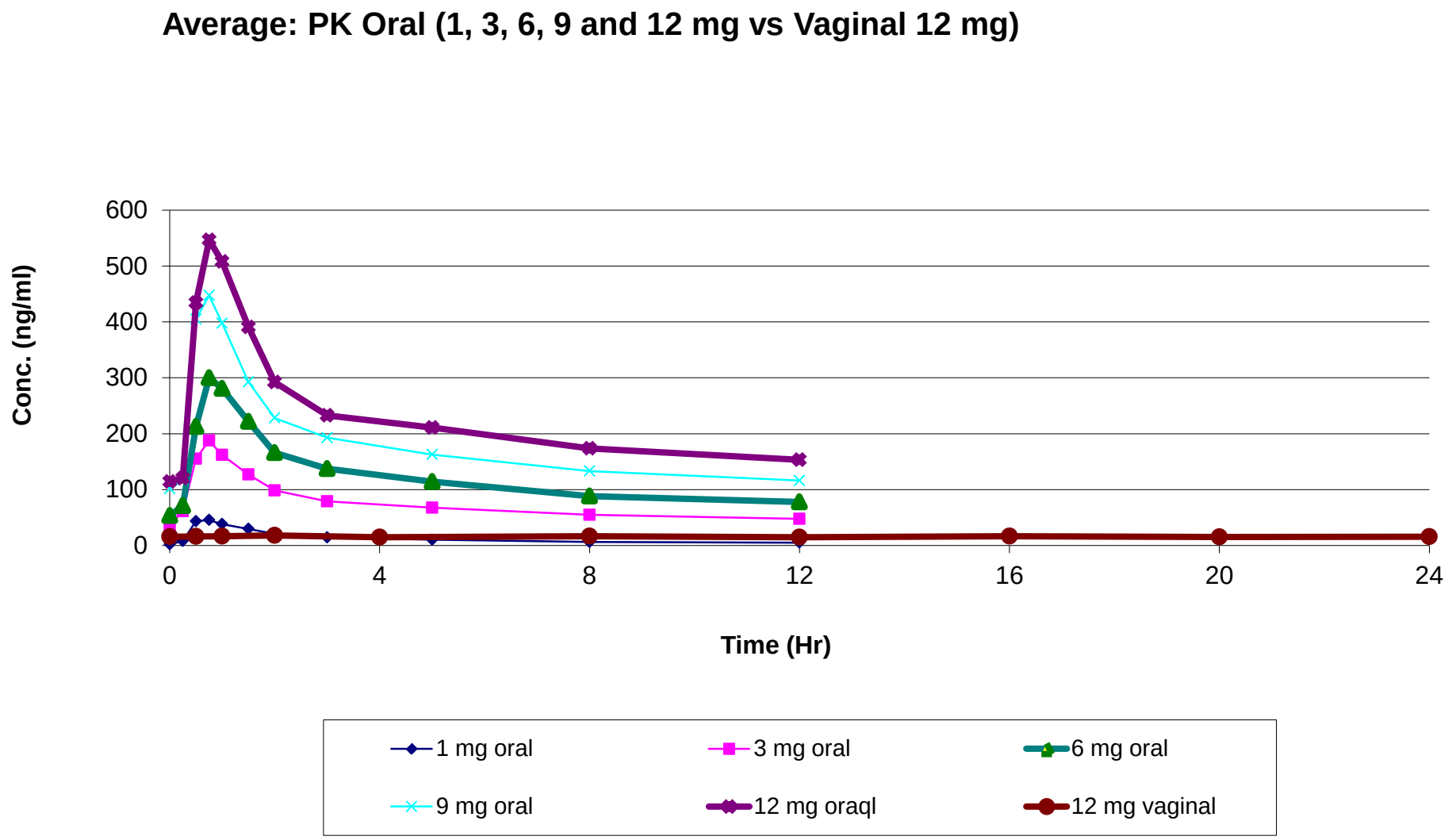
Proellex-V Slow to Reach Steady State



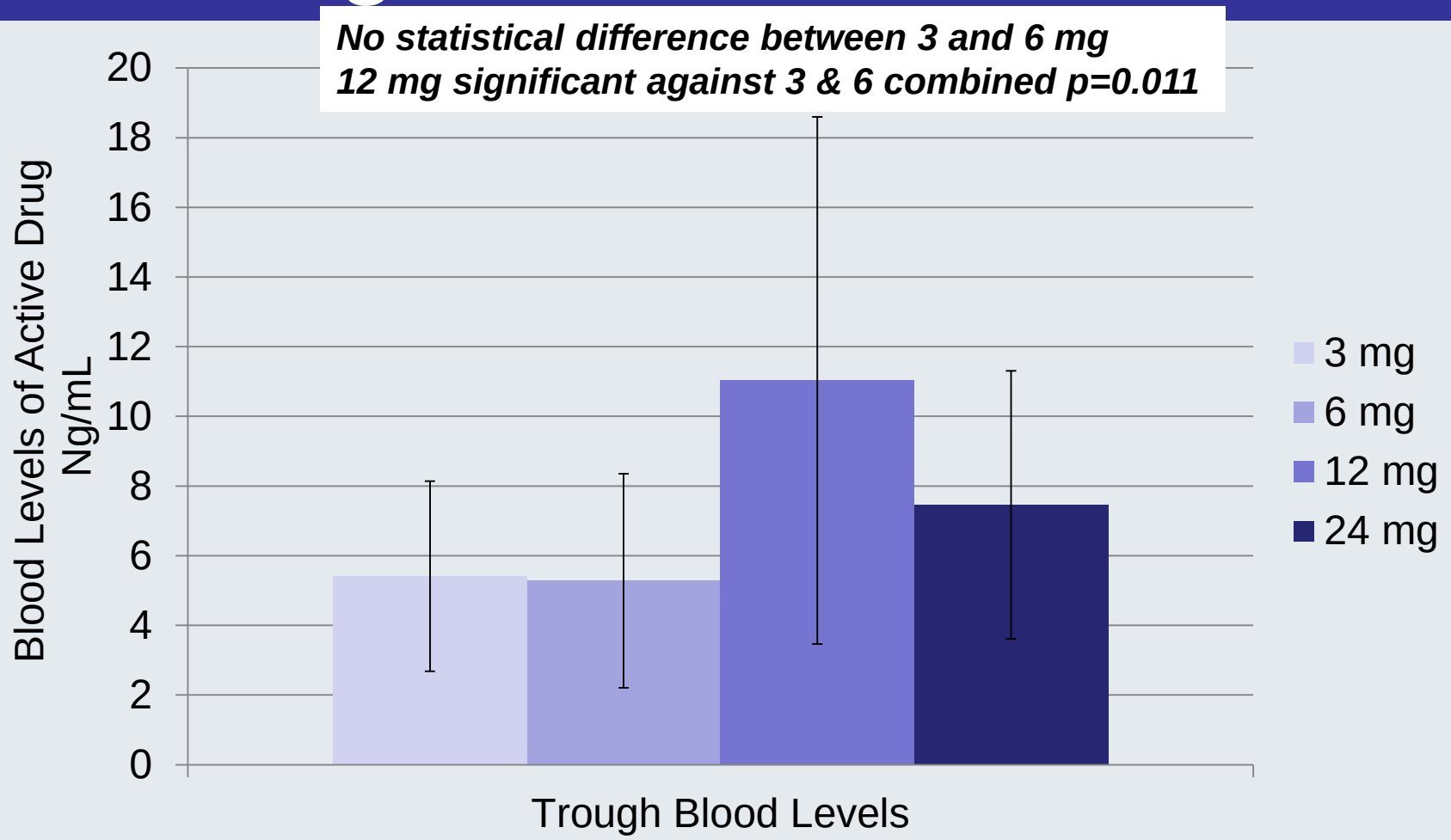
Steady State Drug Concentrations at Week 2

Subject 1: 14.2 ng/ml ***Subject 2: not detected*** ***Subject 3: 14.8 ng/ml***
Subject 4: 20.0 ng/ml ***Subject 5: 22.4 ng/ml*** ***Subject 6: 5.6 ng/ml***

At Steady State Proellex-V Yields Flat Exposure Profile



Systemic Drug Exposure for Four Vaginal Doses of Proellex-V

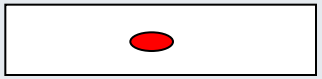
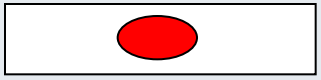
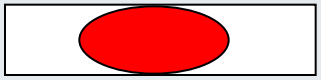
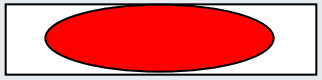
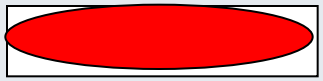


Phase IIb Primary Endpoint
Pictorial Blood Assessment Chart

Validated method for the determination of blood loss during menses

- ***All patients provided with same sanitary product***

Menstrual Pad Scoring

	Score (ml of blood)	***Number per Category per period***	***Score***
	***1***	***x***	
	***2***	***x***	
	***3***	***x***	
	***4***	***x***	
	***5***	***x***	

Wyatt et al. Fertil Steril 2001; 76:125-131

Total Score

Phase IIb Primary Endpoint
Pictorial Blood Assessment Chart

Validated method for the determination of blood loss during menses

- ***All patients provided with same sanitary product***

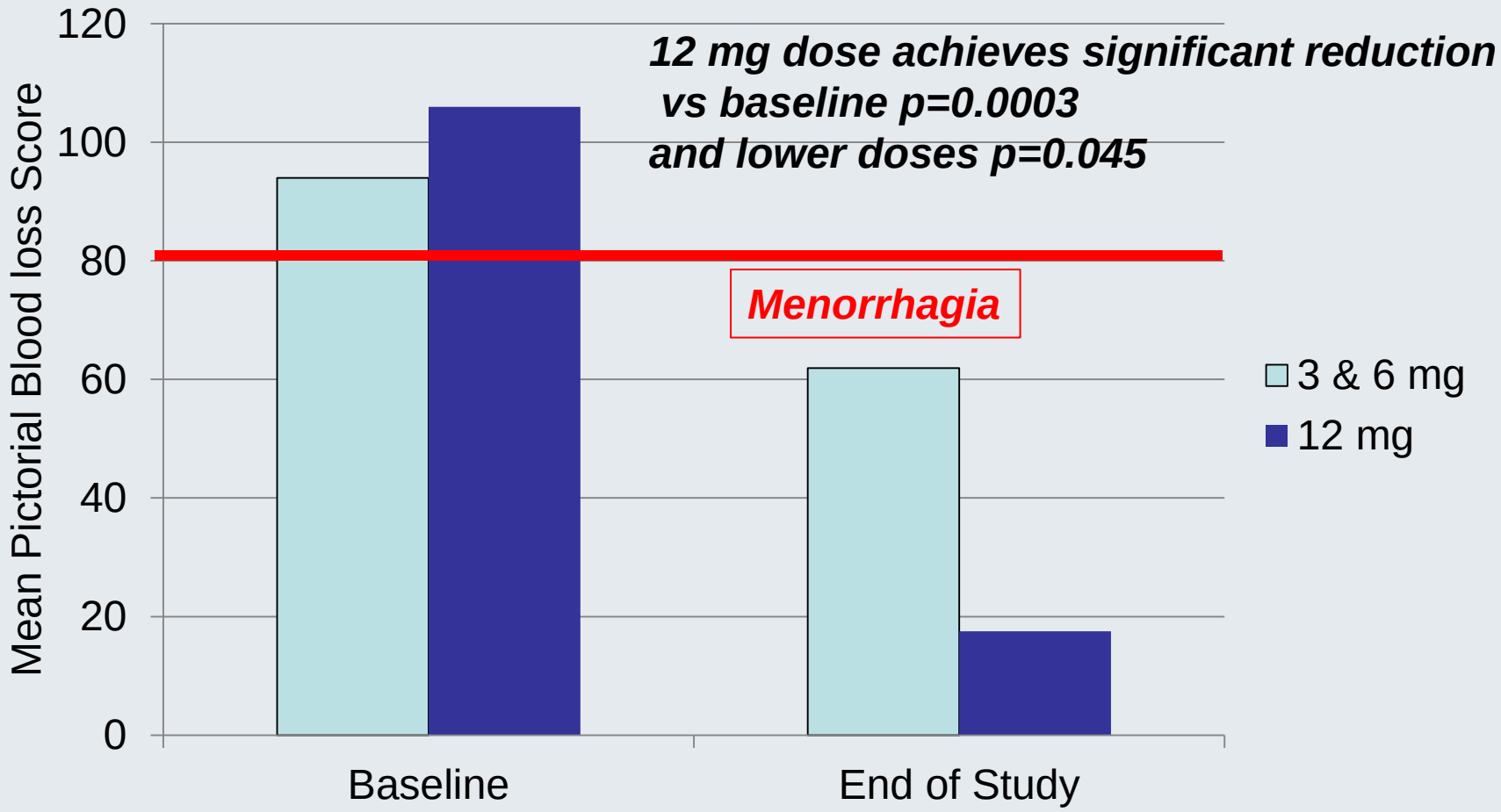
Clot Scoring

Clot Size	Dime (1 ml)	Penny (3 ml)	Quarter (5ml)	Total score
Number				

Wyatt et al. Fertil Steril 2001; 76:125-131

Vaginal Proellex Update

12 mg Dose Achieves Significant Improvement in Vaginal Bleeding



UFSQOL Symptom Severity Questions

1. Heavy bleeding during your menstrual period
2. Passing blood clots during your menstrual period
3. Fluctuation in the duration of your menstrual period compared to your previous cycle
4. Fluctuation in the length of your monthly cycle compared to your previous cycles
5. Feeling tightness or pressure in your pelvic area
6. Frequent urination during the daytime hours
7. Frequent nighttime urination
8. Feeling fatigued

UFSQOL Scoring (Symptom Severity)

Each question can be scored as follows:

Not at all	*A little bit*	*Some-what*	*A great deal*	*A very great deal*
1	*2*	*3*	*4*	*5*

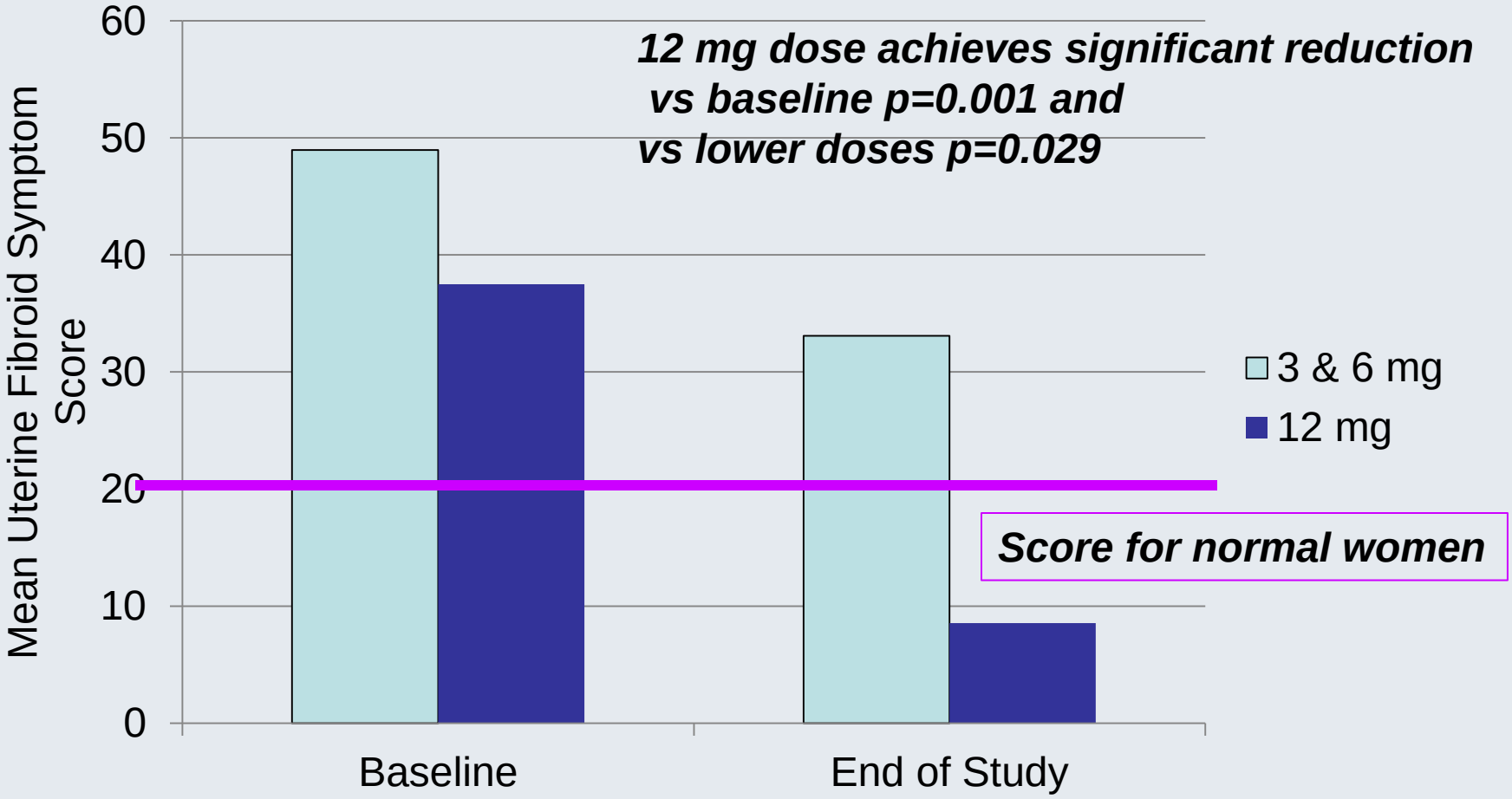
Sum Item Values: ***Questions 1-8***
Lowest and Highest Possible Scores; ***8, 40***
Possible Raw Score Range: ***32***

Formula for Transformation of Symptom Severity Raw Scores

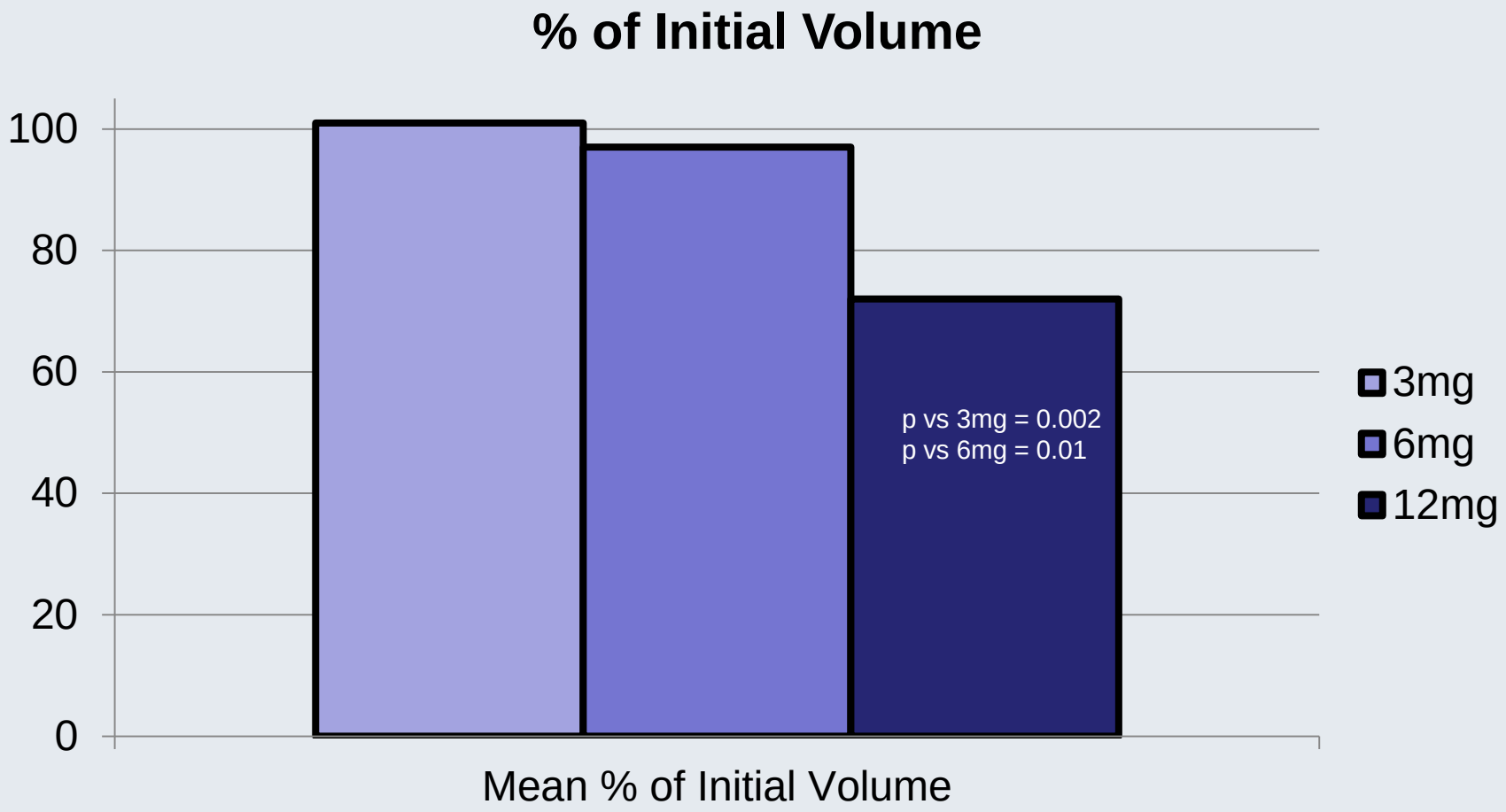
$$\text{Transformed Score} = \frac{(\text{Actual raw score} - \text{lowest possible raw score}) \times 100}{\text{Possible raw score range}}$$

Vaginal Proellex Update

12 mg Dose Achieves Significant Improvement in Symptom Scores



Fibroid Volume Significantly Reduced at end of 4 Month Study @ 12 mg



Financial Summary

- **Cash and equivalents** (as of 12/31/12, unaudited) ~ $24.2M
- **Cash burn** = 2012 = ~$14 M
- **Cash runway** = Mid 2014 (projected)
- **17.2 MM shares outstanding**
  - **Warrants outstanding = 1.75MM Series A (Purchased in unit deal @$2.46) + 1.57MM Series B (@$2.49 with cashless exercise provision)**
  - **Forced warrant strike at $8/share converts B warrants**

Projected 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
• 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