HERO Phase 3 Additional Data

- ASCO Oral Presentation
- *New England Journal of Medicine* Publication

June 1, 2020

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Forward-looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements regarding Myovant Sciences' intent, belief, or expectations regarding future events or results and can be identified by words such as "anticipate," "aspire," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. In this presentation, forward-looking statements include, but are not limited to, statements and quotes regarding Myovant Sciences' aspirations to become the leading healthcare company focused on redefining care for women and for men; the characterizations of data from the HERO study; the timing and likelihood of any approvals by the FDA; the timing of data readout regarding the analysis of the secondary endpoint of castration resistance-free survival expected in the third quarter of 2020; the timing of data readout regarding the SPIRIT 1 endometriosis study in June 2020; and the commercial potential for relugolix and relugolix combination tablet in any indication. Myovant Sciences' forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Myovant Sciences cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could materially affect Myovant Sciences' operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the risks and uncertainties listed in Myovant Sciences' filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant Sciences' Annual Report on Form 10-K filed on May 18, 2020, as such risk factors may be amended, supplemented or superseded from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for Myovant Sciences' management to predict all risk factors, nor can Myovant Sciences assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not place undue reliance on the forward-looking statements in this presentation, which speak only as of the date hereof, and, except as required by law, Myovant Sciences undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

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June 1, 2020

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One Pill, Once A Day

Two Distinct Therapeutic Candidates

WOMEN'S HEALTH

Relugolix 40 mg
+ estradiol 1.0 mg
+ norethindrone acetate 0.5 mg*

RELUGOLIX COMBINATION TABLET

Designed for the potential treatment of women with symptomatic uterine fibroids or endometriosis as an alternative to surgery or other invasive procedures.

PROSTATE CANCER

Relugolix 120 mg (following single 360 mg loading dose)*

RELUGOLIX MONOTHERAPY TABLET

Designed with the potential to be the only oral androgen deprivation therapy for men with advanced prostate cancer.

***Relugolix and relugolix combination tablet are investigational drugs that have not been approved for any use**

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Redefining Care.
For Women. For Men. For You.

Uterine Fibroids

- Phase 3 LIBERTY 1 Study — **MAY 2019**
- Phase 3 LIBERTY 2 Study — **JULY 2019**
- LIBERTY One-Year Extension Study — **FEBRUARY 2020**
- European Marketing Authorization Application Submission — **MARCH 2020**
- **NDA Submission** — **MAY 2020**

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Endometriosis

Phase 3
SPIRIT 2 Study
Data

APRIL 2020

Phase 3
SPIRIT 1 Study
Data

JUNE 2020

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Prostate Cancer

Phase 3
HERO Study

✓ **NOVEMBER 2019**

NDA Submission

✓ **APRIL 2020**

ASCO Oral Presentation with Publication in the *New England Journal of Medicine*

✓ **MAY 2020**

Castration Resistance-Free Survival Endpoint

○ **Q3 2020**

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Relugolix for Advanced Prostate Cancer

The First and Only Oral GnRH Receptor Antagonist in Development for Prostate Cancer

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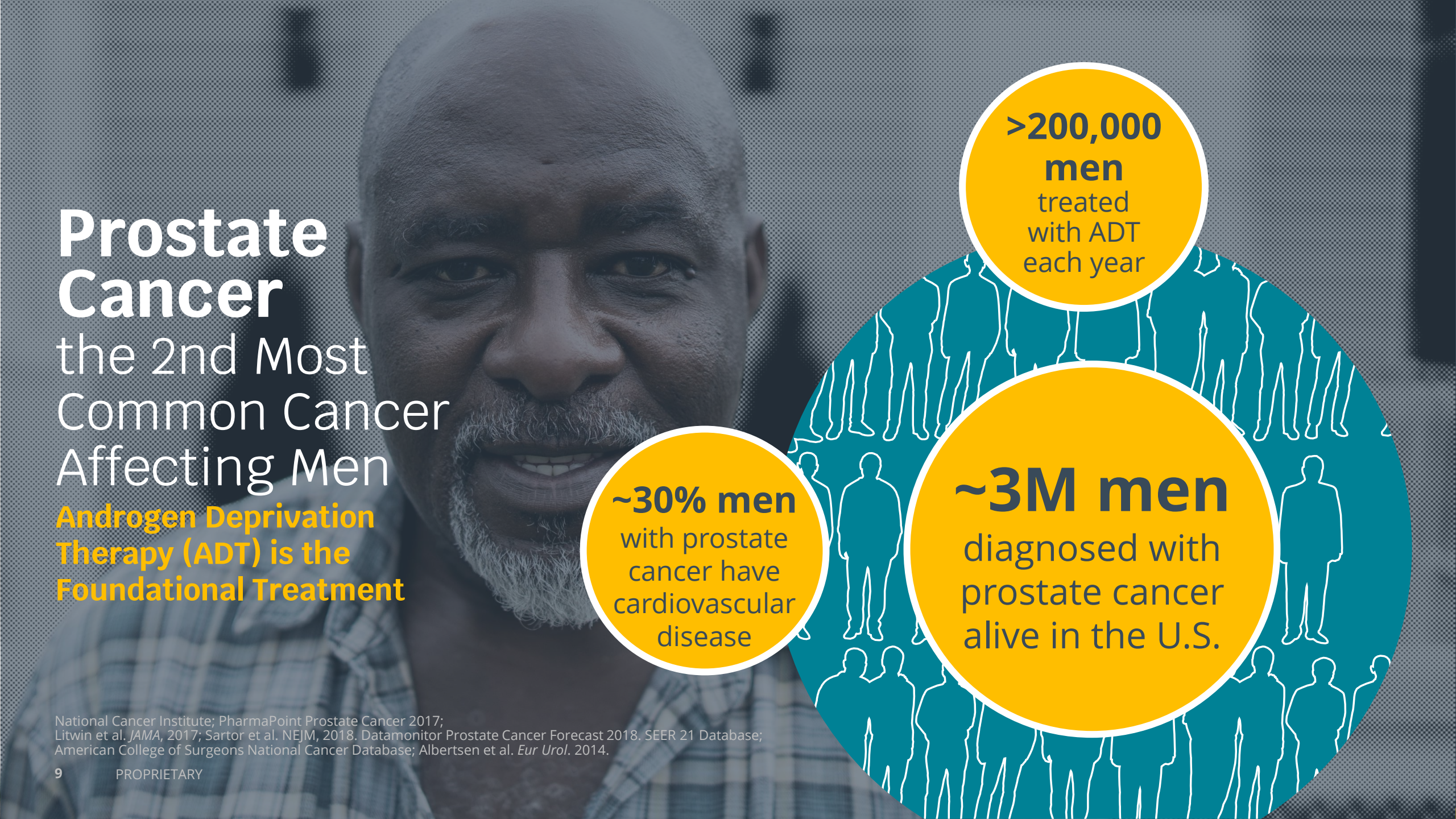
Prostate Cancer the 2nd Most Common Cancer Affecting Men

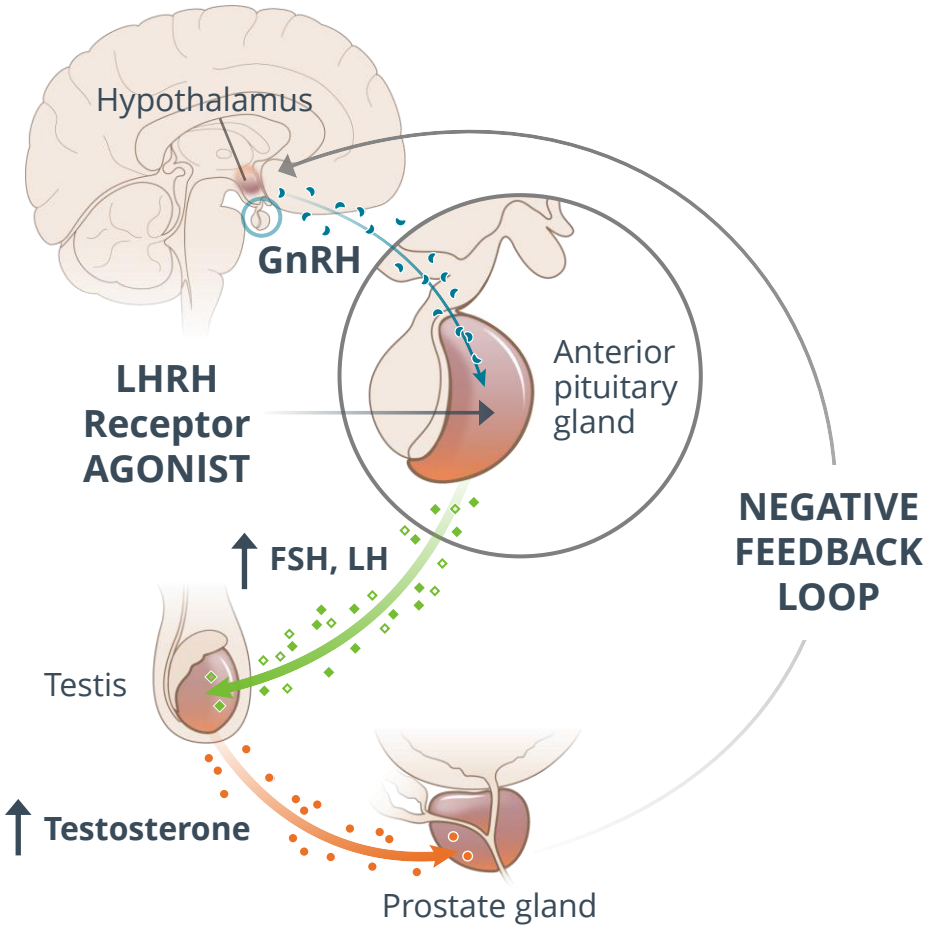
Androgen Deprivation Therapy (ADT) is the Foundational Treatment

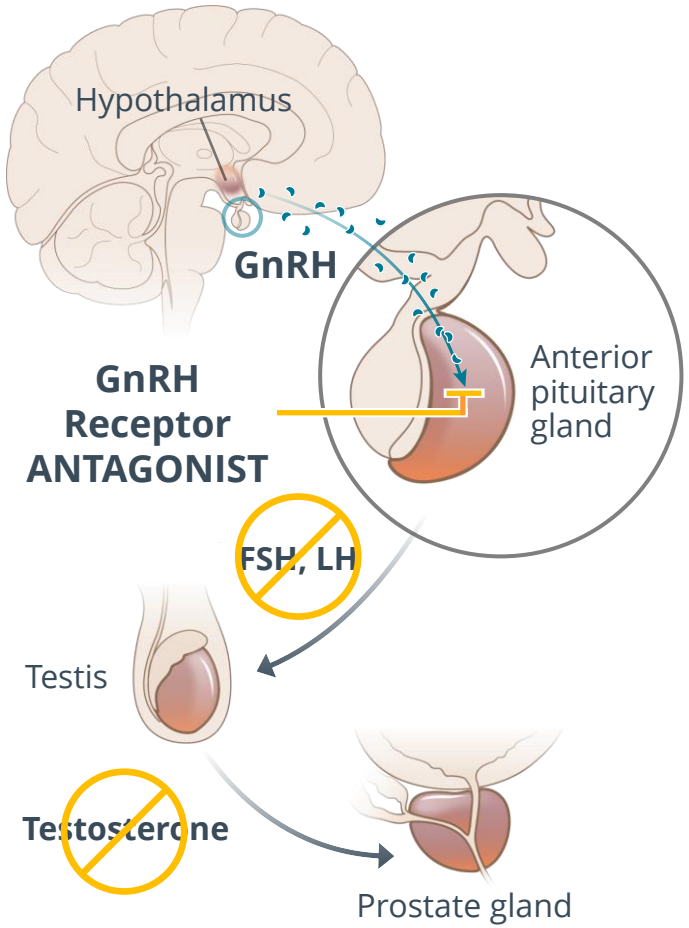


National Cancer Institute; PharmaPoint Prostate Cancer 2017;
Litwin et al. *JAMA*, 2017; Sartor et al. NEJM, 2018. Datamonitor Prostate Cancer Forecast 2018. SEER 21 Database;
American College of Surgeons National Cancer Database; Albertsen et al. *Eur Urol*. 2014.

Androgen Deprivation Therapy

Mechanisms of Testosterone Suppression





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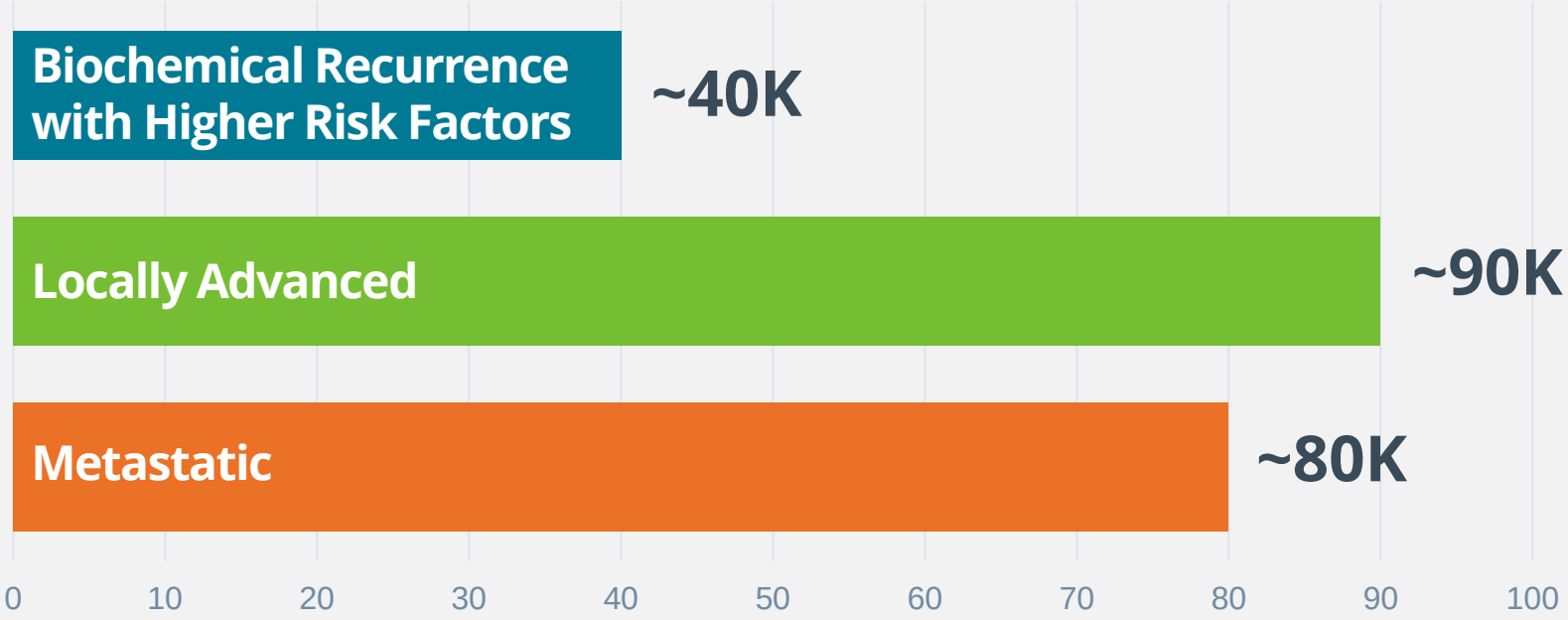
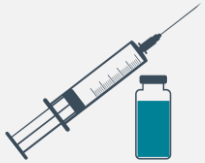
Relugolix Has Potential to Benefit Broad Spectrum of Men with Advanced Prostate Cancer

~210,000 men with prostate cancer were treated with androgen deprivation therapy in 2018



Current Standard of Care



Injectable

Clinical Flare

Weeks to reduce PSA; Months for testosterone recovery

SEER 21 Database; American College of Surgeons National Cancer Database; Clinton. *Expert Opinion on Pharmacotherapy*, 2017.

***Relugolix is an investigational drug that has not been FDA approved for use; these are aspirational statements**

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Neal Shore, MD, FACS

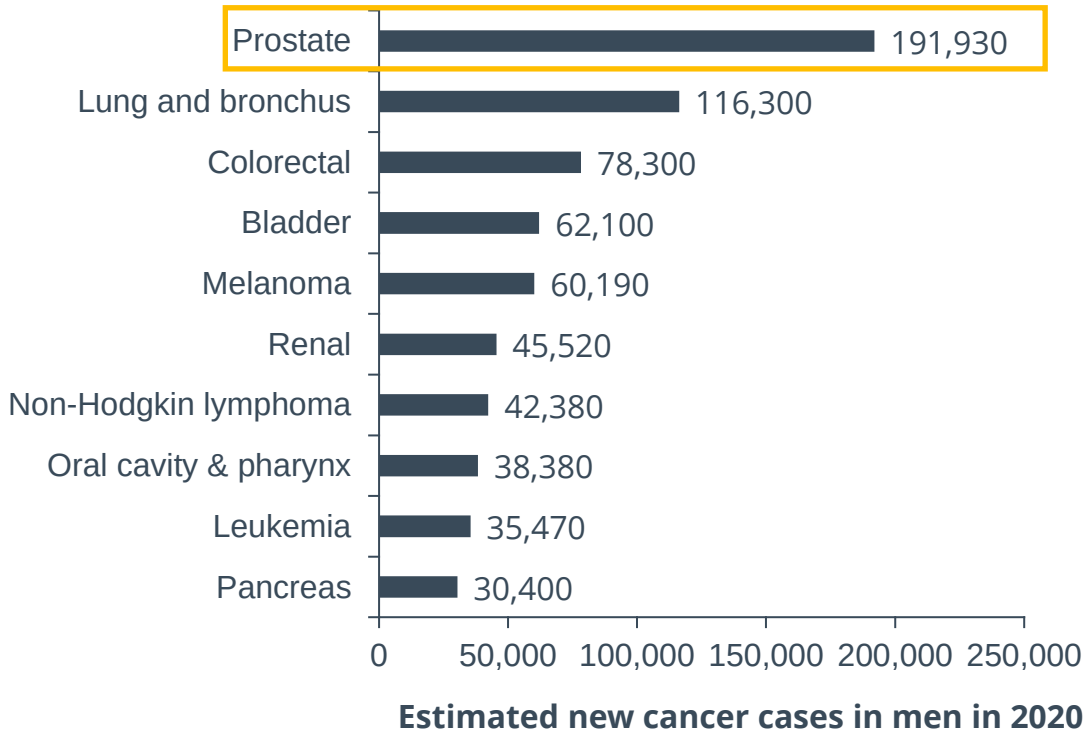
Medical Director at the Carolina Urologic Research Center

HERO Steering Committee Member

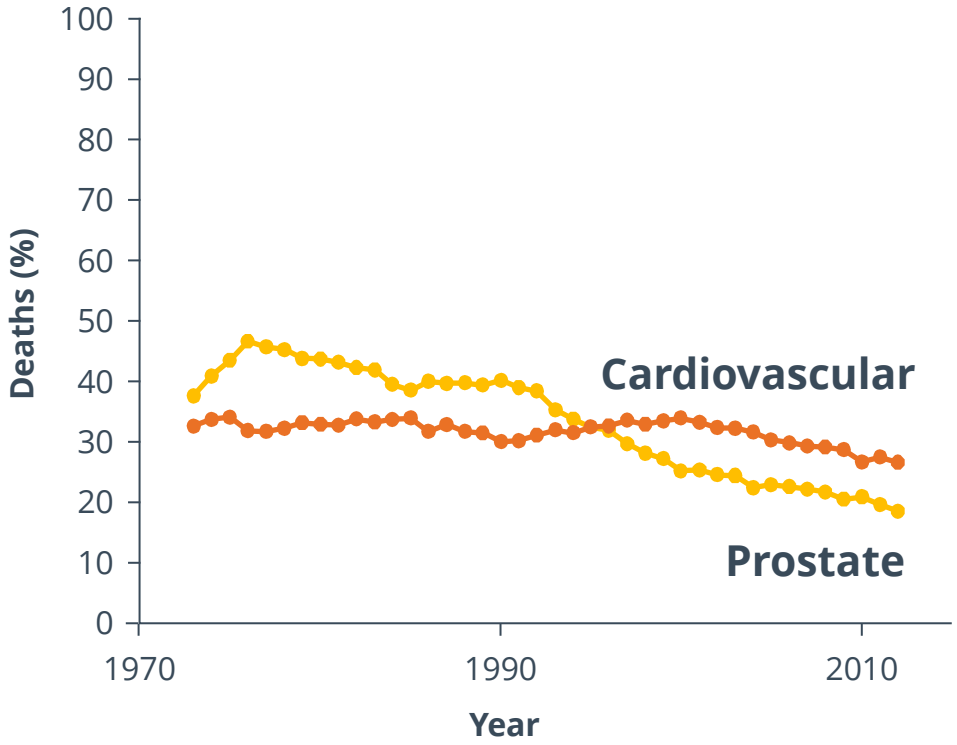
Financial Disclosures: AbbVie, Amgen, Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Dendreon, Fergene, Ferring, Janssen, Merck, MDxHealth, Nymox, Pfizer, Genzyme, Tolmar

Incidence and Burden of Advanced Prostate Cancer

Prostate cancer is the most common cancer diagnosis* and second most common cause of cancer death in US men[1]



Cardiovascular mortality is the leading cause of death in men with prostate cancer[2,3]



*Projected incidence. Estimates are rounded to the nearest 10 and exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Ranking is based on modelled projections and may differ from the most recent observed data.

[1]Siegel RL, et al. *CA Cancer J Clin*. 2020;70:7–30; [2]Thomsen FB, et al. *Eur Urol*. 2017;72(6):920-8; [3]Sturgeon KM, et al. *Eur Heart J*. 2019;Nov 25:40(48):3889-3897.

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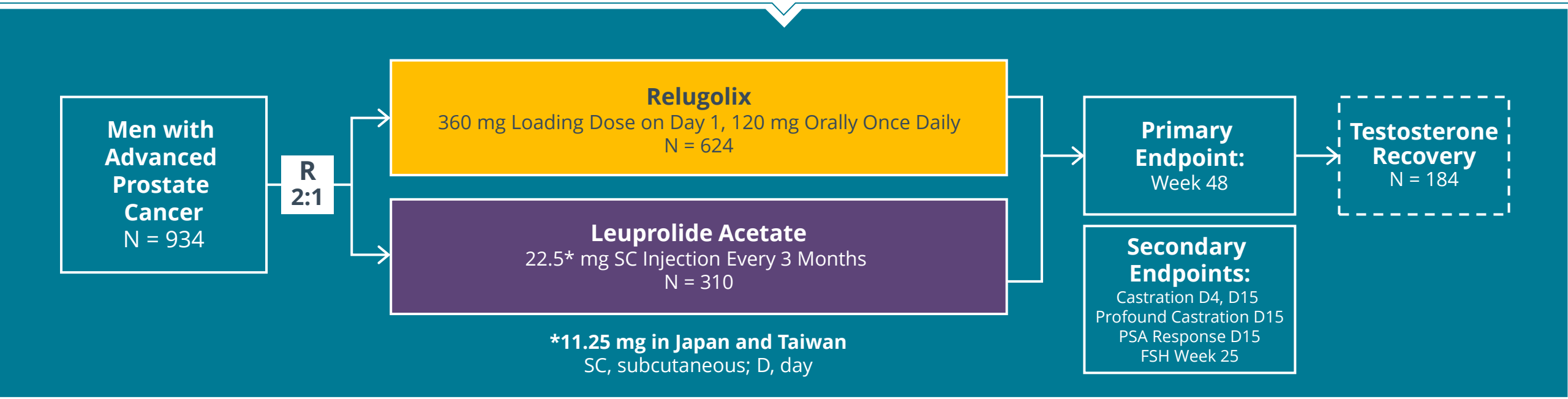
Phase 3 HERO Study Design

A multinational Phase 3 randomized, open-label, parallel group study to evaluate the safety and efficacy of relugolix in men with advanced prostate cancer

Primary Endpoint
Sustained castration through 48 weeks (< 50 ng/dL)



Key Eligibility Criteria

Inclusion	Exclusion
Confirmed advanced prostate cancer • Biochemical or clinical relapse • Metastatic disease • Advanced localized disease	Chemotherapy or surgical therapy expected within 2 months of initiating ADT
Requiring ≥ 1 year of ADT	Previous ADT for >18 months or previous systemic cytotoxic therapy for prostate cancer
Serum testosterone ≥ 150 ng/dL	Active liver disease
Serum PSA > 2.0 ng/mL	Significant cardiac conditions • Heart attack or stroke in previous 6 months • Arrhythmias • Uncontrolled hypertension
ECOG Score 0/1	

ADT = androgen deprivation therapy; PSA = prostate-specific antigen; ECOG = Eastern Cooperation Oncology Group.

Patient Demographics

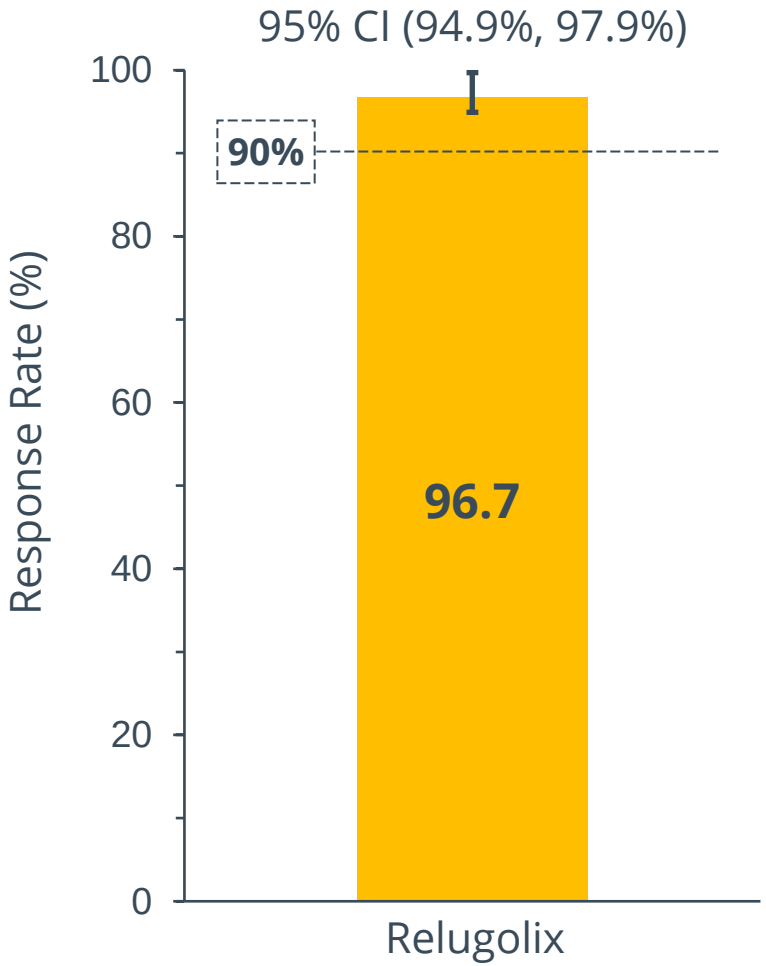
	Relugolix, N = 622	Leuprolide, N = 308
Age (Years)		
≤ 75	71.4%	71.4%
Median (Range)	72.0 (48, 91)	71.0 (47, 97)
Race		
White	69.8%	65.6%
Asian	20.4%	23.1%
Other	5.0%	6.2%
Black or African American	4.8%	5.2%
Geographic Region		
Europe	39.7%	39.6%
North America	29.3%	28.2%
Asia Pacific	25.6%	26.0%
South America	5.5%	6.2%

Clinical Characteristics

	Relugolix, N = 622	Leuprolide, N = 308
Clinical Disease State Presentation (%)		
Biochemical (PSA relapse)	49.7%	51.3%
Newly diagnosed androgen-sensitive metastatic disease	22.7%	22.7%
Advanced localized disease	27.7%	26.0%
Prostate-Specific Antigen (PSA) Level		
Median – ng/dL	11.7	9.4
Testosterone Level		
Median – ng/dL	415.8	395.9
Total Cardiovascular Risk Factors (%)	**91.6%**	**94.2%**
Lifestyle risk factors[1]	67.8%	65.6%
Cardiovascular or cerebrovascular risk factors[2]	78.5%	82.5%
History of MACE[3]	13.5%	14.6%

[1]Includes current/past smoker, heavy alcohol use, and body mass index > 30 kg/m2; [2]Cardiovascular or cerebrovascular-risk factors including: hypertension, dyslipidemia, diabetes, prior history of myocardial infarction or cardiovascular disease, prior history of stroke, transient ischemic attack or cerebral hemorrhage, peripheral arterial disease, heart failure, etc. [3]Search criteria include myocardial infarction, central nervous system hemorrhages, and cerebrovascular conditions. MACE = major adverse cardiovascular event.

Achieved Primary Endpoint



96.7% of men met responder criteria

Sustained testosterone suppression to castrate levels (< 50 ng/dl) with lower bound of 95% CI > 90%

CI = Confidence Interval

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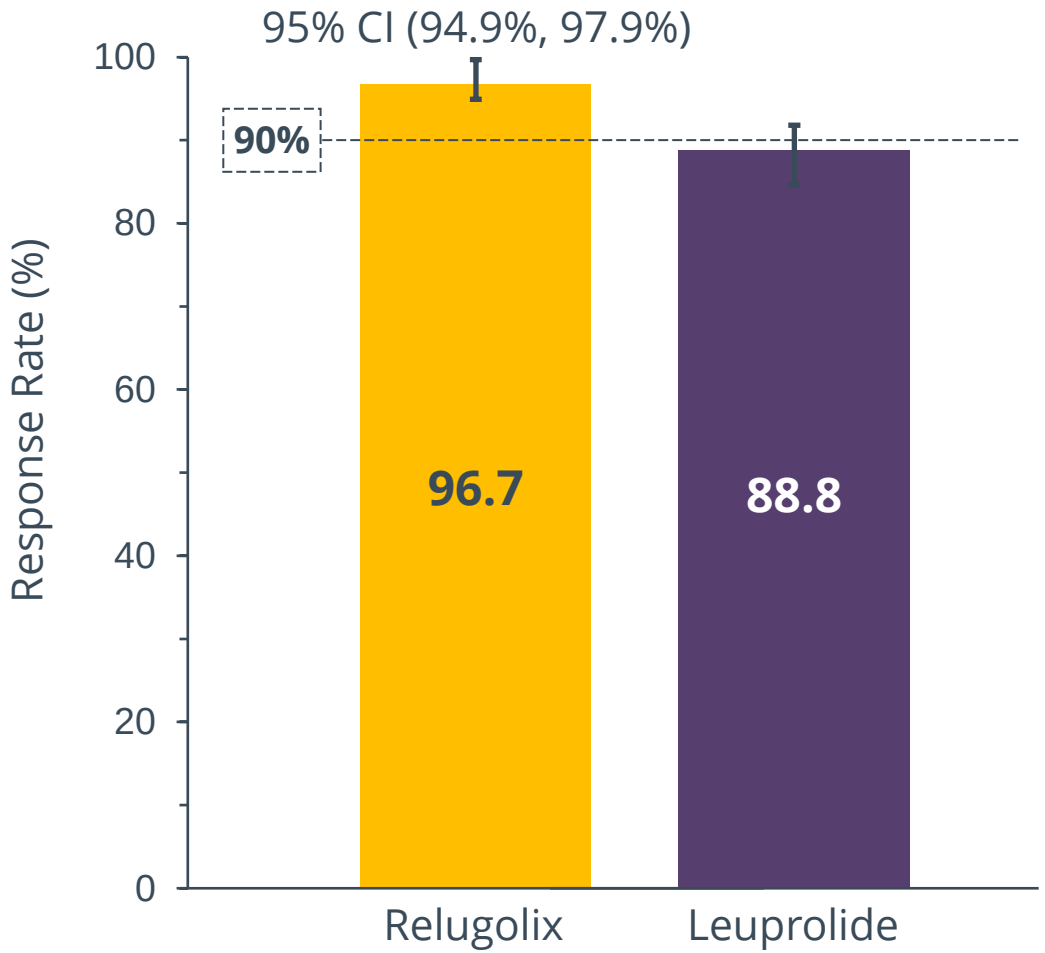
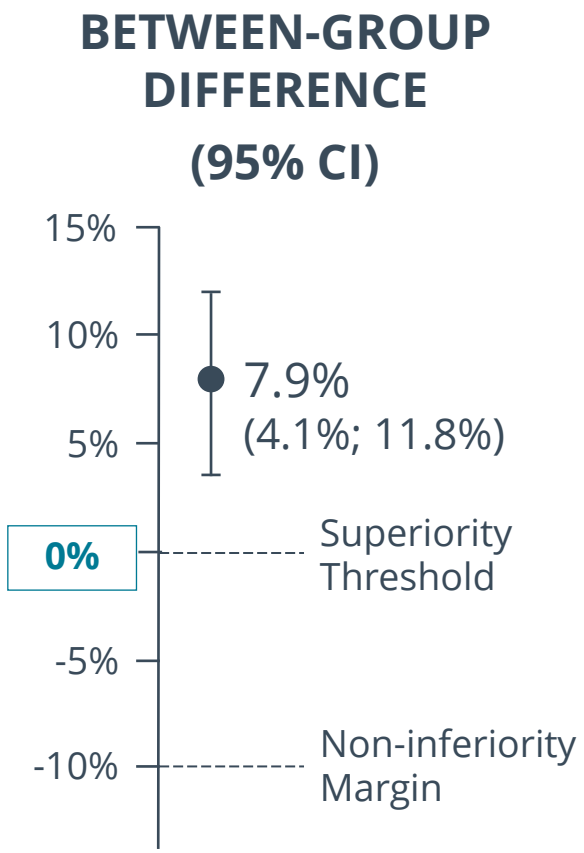
Achieved First Key Secondary Endpoint





Oral relugolix achieved superiority to injectable leuprolide

Difference in sustained testosterone suppression to castrate levels (lower bound 95% CI > 0%)

CI = Confidence Interval

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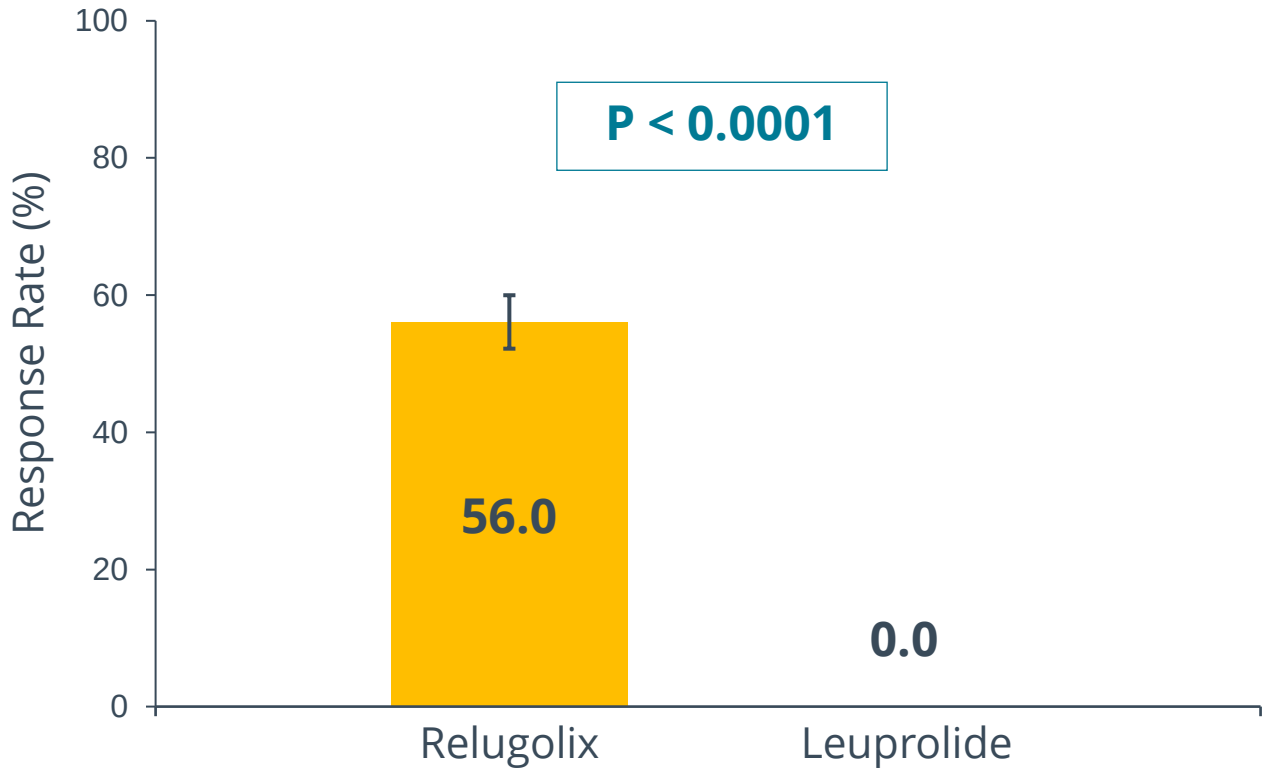
Achieved Additional Key Secondary Endpoints

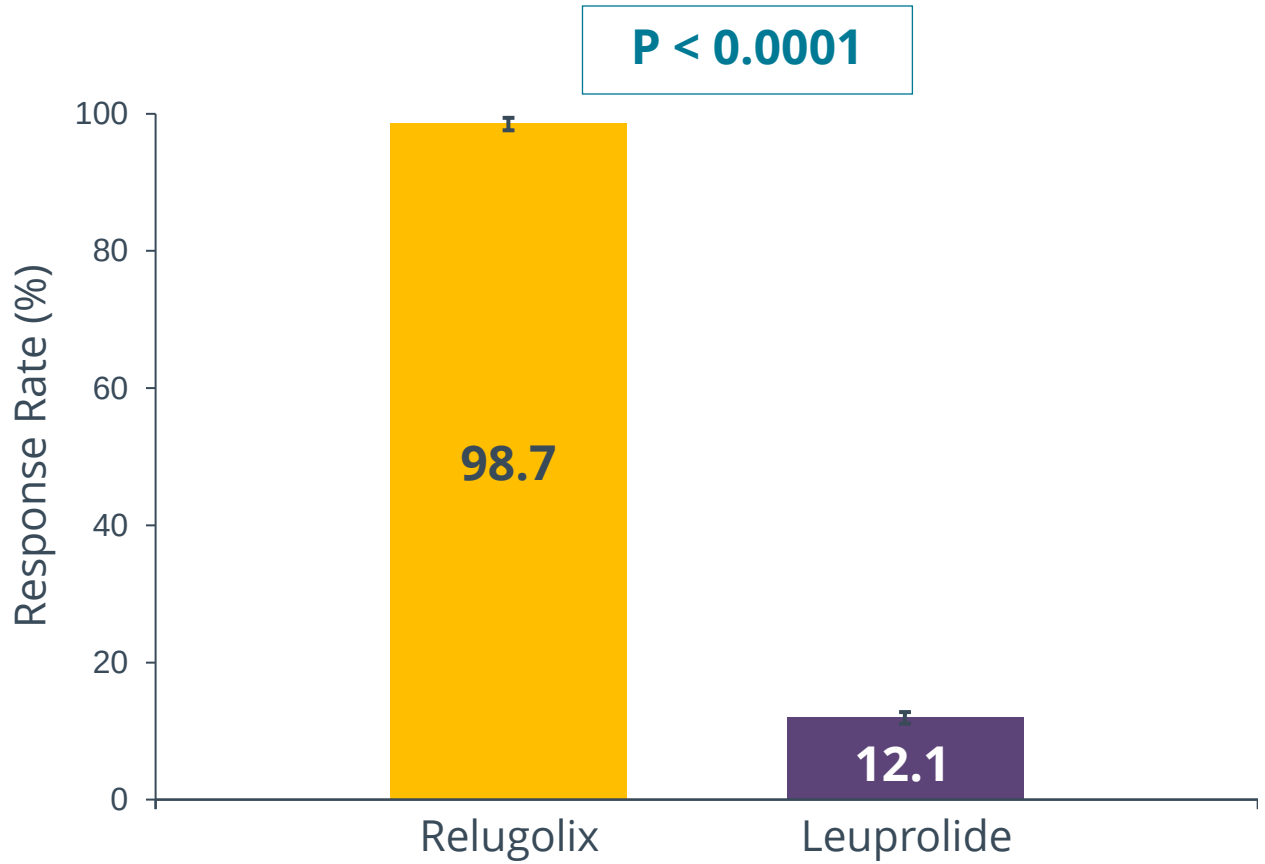
Secondary Endpoints (alpha-protected)	p-value
Cumulative probability of **testosterone suppression to < 50 ng/dL on Day 4**	
Cumulative probability of **testosterone suppression to < 50 ng/dL on Day 15**	
Cumulative probability of **profound testosterone suppression to < 20 ng/dL on Day 15**	**p < 0.0001**
Proportion of patients with **PSA response at Day 15** followed with confirmation at Day 29	
Mean of **FSH level at** end of **Week 24 — IU/L**	

FSH, follicle-stimulating hormone; PSA, prostate-specific antigen; IU, international unit.

Relugolix Achieved Testosterone Suppression to Castrate Levels in Majority of Men at Day 4

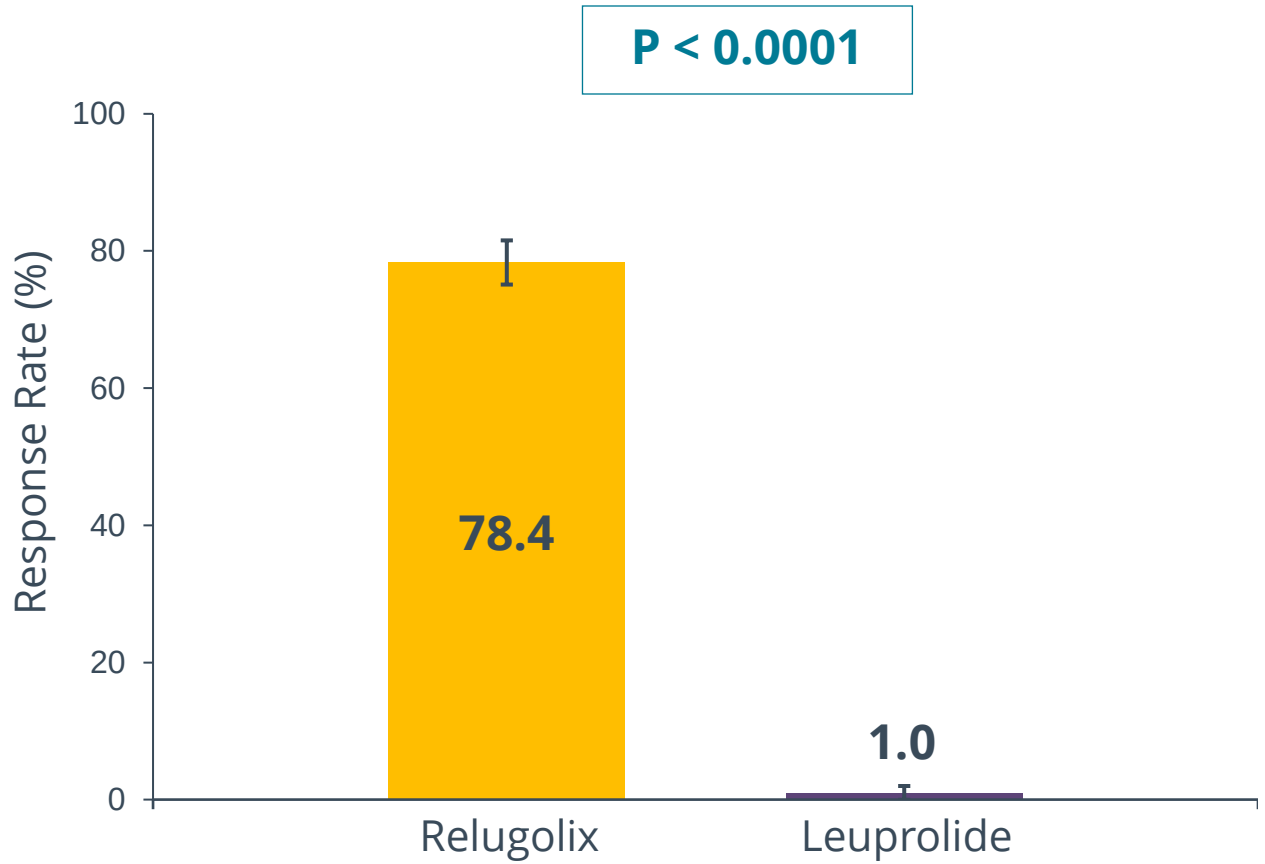


Relugolix Achieved Testosterone Suppression to Castrate Levels in Almost All Men at Day 15

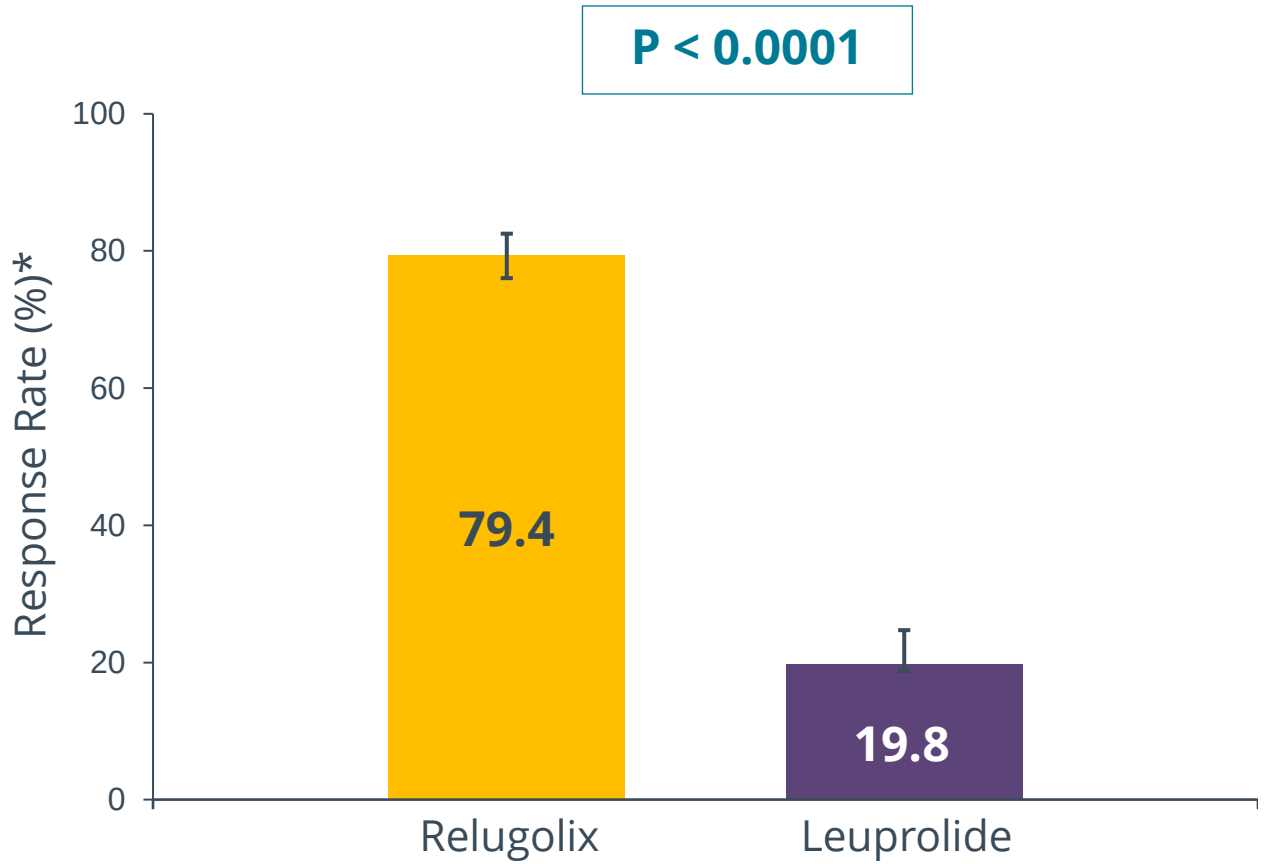


Relugolix Achieved Testosterone Suppression to Profound Castrate Levels in Majority by Day 15

Profound Castration (T < 20 ng/dL)



Relugolix Achieved PSA Response Rate in Majority of Men at Day 15



PSA = Prostate-specific antigen
* ≥ 50% reduction in PSA from baseline at Day 15 and confirmed at Day 29

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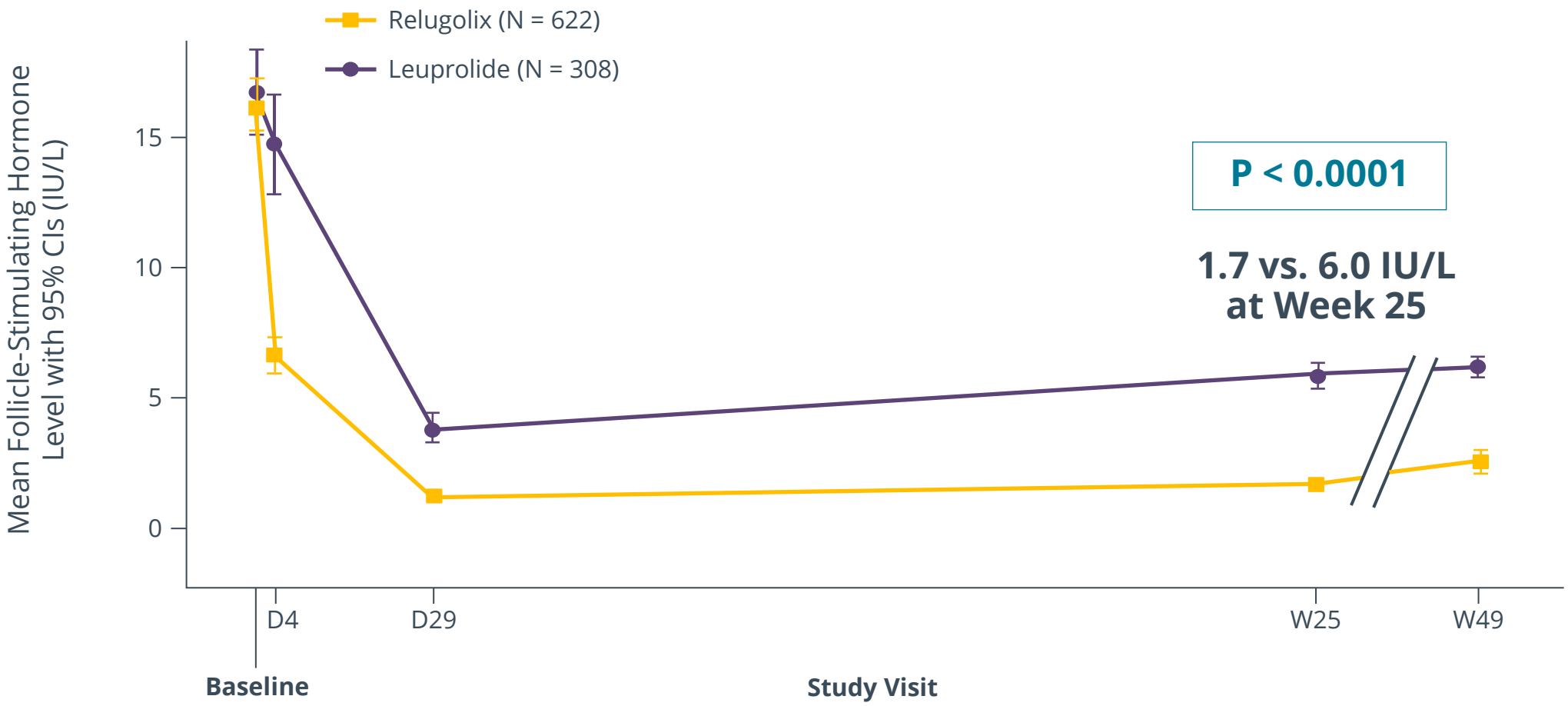
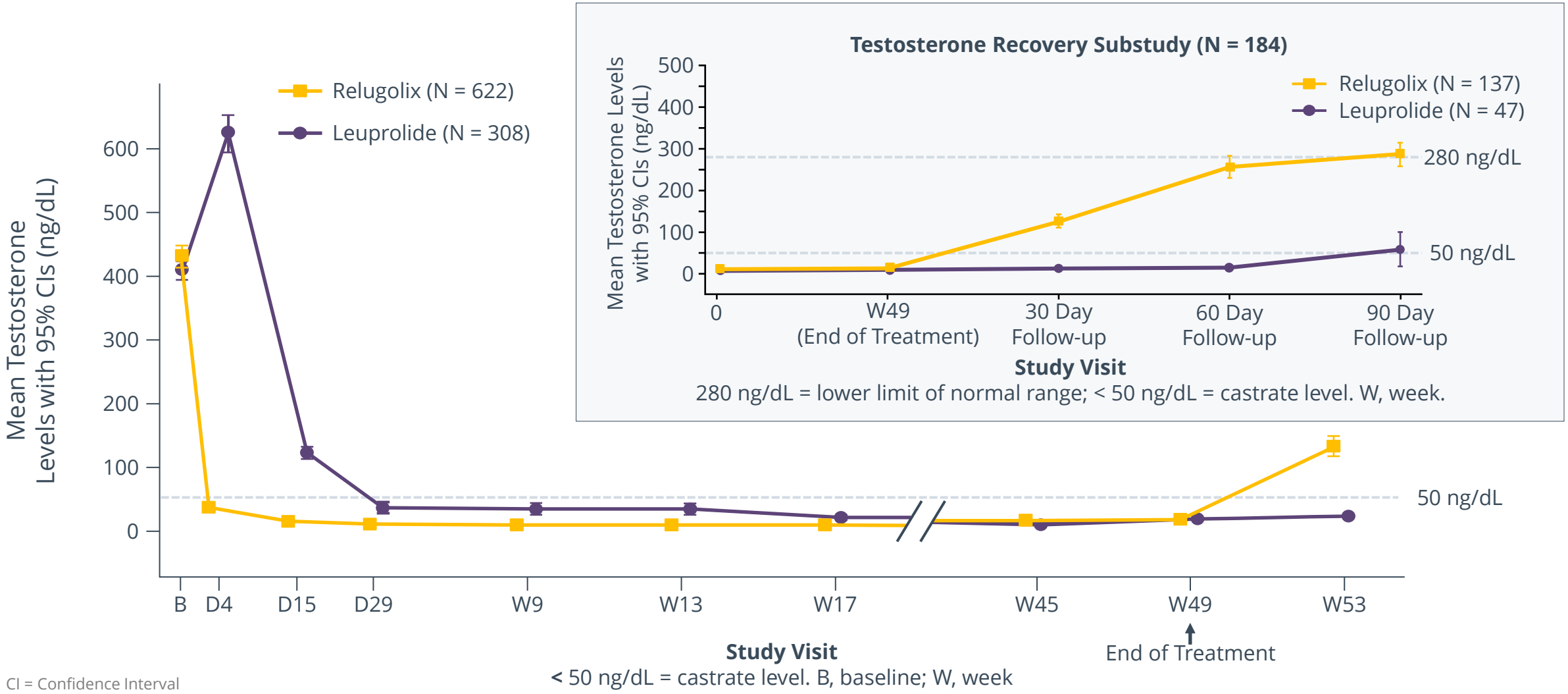
Relugolix Achieved Greater FSH Suppression Than Leuprolide At Week 25



Time Course of Testosterone Suppression



CI = Confidence Interval

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Summary of Adverse Events

	Relugolix (N = 622)	Leuprolide (N = 308)
Any Adverse Event	92.9%	93.5%
Related to study drug	73.6%	68.8%
Any Grade 3 or Greater	18.0%	20.5%
Grade 3 or greater related to study drug	3.4%	2.6%
Fatal Adverse Events	1.1%	2.9%

Summary of Adverse Events

	Relugolix (N = 622)	Leuprolide (N = 308)
Hot flush	54.3%	51.6%
Fatigue	21.5%	18.5%
Constipation	12.2%	9.7%
Diarrhea*	12.2%	6.8%
Arthralgia	12.1%	9.1%
Hypertension	7.9%	11.7%

***Adverse events of diarrhea were grade 1 or 2 and did not result in study discontinuation**

Cardiovascular Adverse Events

	Relugolix (N = 622)	Leuprolide (N = 308)
Adverse Cardiovascular Events	3.9%	7.1%
Major Adverse Cardiovascular Events (MACE)	2.9%	6.2%
Ischemic Heart Disease	2.4%	1.6%

History of MACE	Yes		No	
% Men	**Relugolix** 13.5%	**Leuprolide** 14.6%	**Relugolix** 86.5%	**Leuprolide** 85.4%
MACE	3.6%	17.8%	2.8%	4.2%
Odds Ratio Leuprolide vs Relugolix (95% confidence interval)	5.8 (1.5, 23.3)		1.5 (0.7, 3.4)	

MACE = non-fatal myocardial infarction + non-fatal stroke + all-cause mortality

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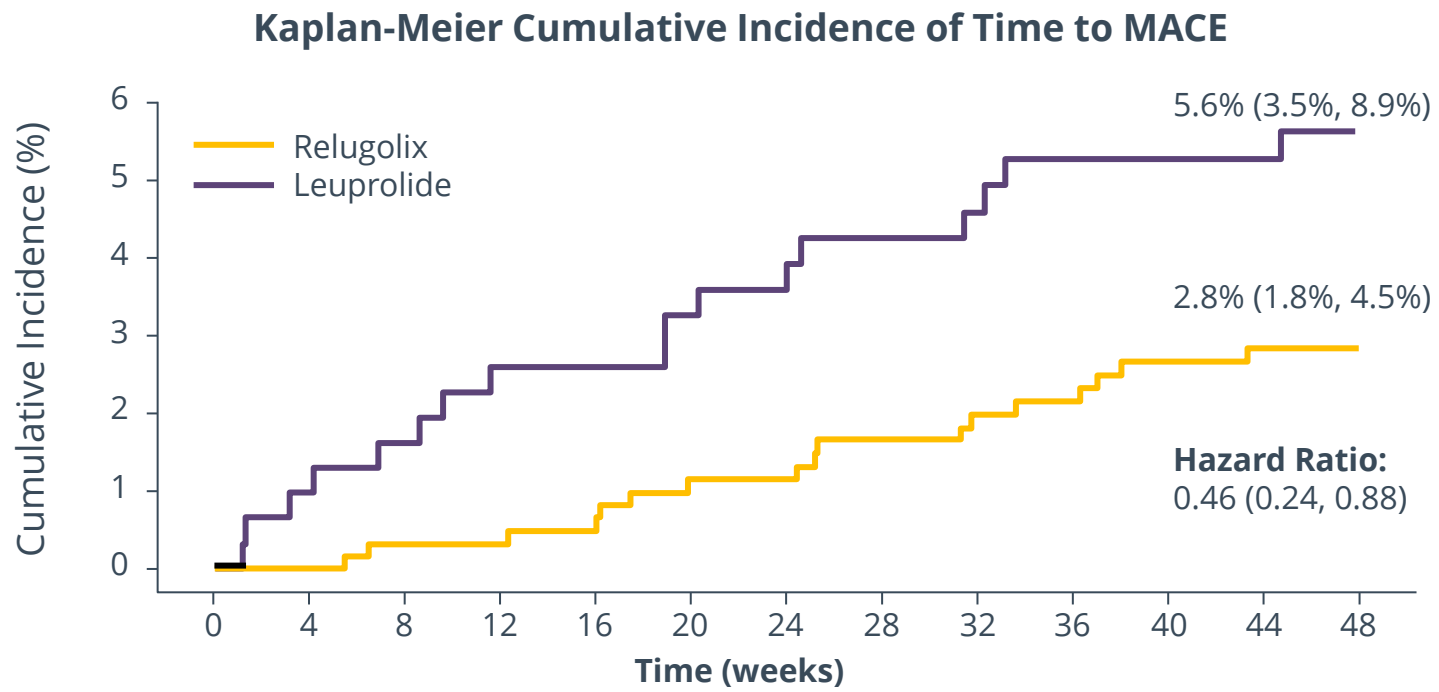
54% Lower Risk Of Major Adverse Cardiovascular Events (MACE) Compared With Leuprolide



No. at Risk													
Relugolix	622	621	616	610	605	596	595	588	582	575	563	559	538
Leuprolide	308	305	303	298	298	293	292	288	281	279	278	269	259

Conclusions

Primary and key secondary endpoints achieved

- 96.7% response rate for men treated with relugolix (sustained castration over 48 weeks)
- Relugolix achieved superiority over leuprolide
  - Sustained castration rates
  - Castration (< 50 ng/dL) and profound castration (< 20 ng/dL) by Day 15
  - PSA response (decrease > 50%) by Day 15
- Proportion of men with testosterone recovery to normal range (54% vs 3%) at 90 days

Relugolix once-daily oral therapy was generally well tolerated

Risk of major adverse cardiovascular events was 54% lower with relugolix compared with leuprolide

Additional Data Expected in Q3 2020

	Cohort	Endpoints
Completed Data	**PRIMARY ANALYSIS COHORT** N = 934	• Primary endpoint • Key secondary endpoints
Data Expected Q3 2020	**CASTRATION RESISTANCE-FREE SURVIVAL COHORT** N = 434 men with metastatic disease	• Confirmed PSA progression using Prostate Cancer Working Group 3 criteria and death

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