



# RESULTS FROM PHASE 3 HERO TRIAL FOR ADVANCED PROSTATE CANCER

November 19, 2019

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# RELUGOLIX FOR ADVANCED PROSTATE CANCER

THE ONLY ORAL GNRH  
RECEPTOR ANTAGONIST  
IN DEVELOPMENT FOR  
PROSTATE CANCER

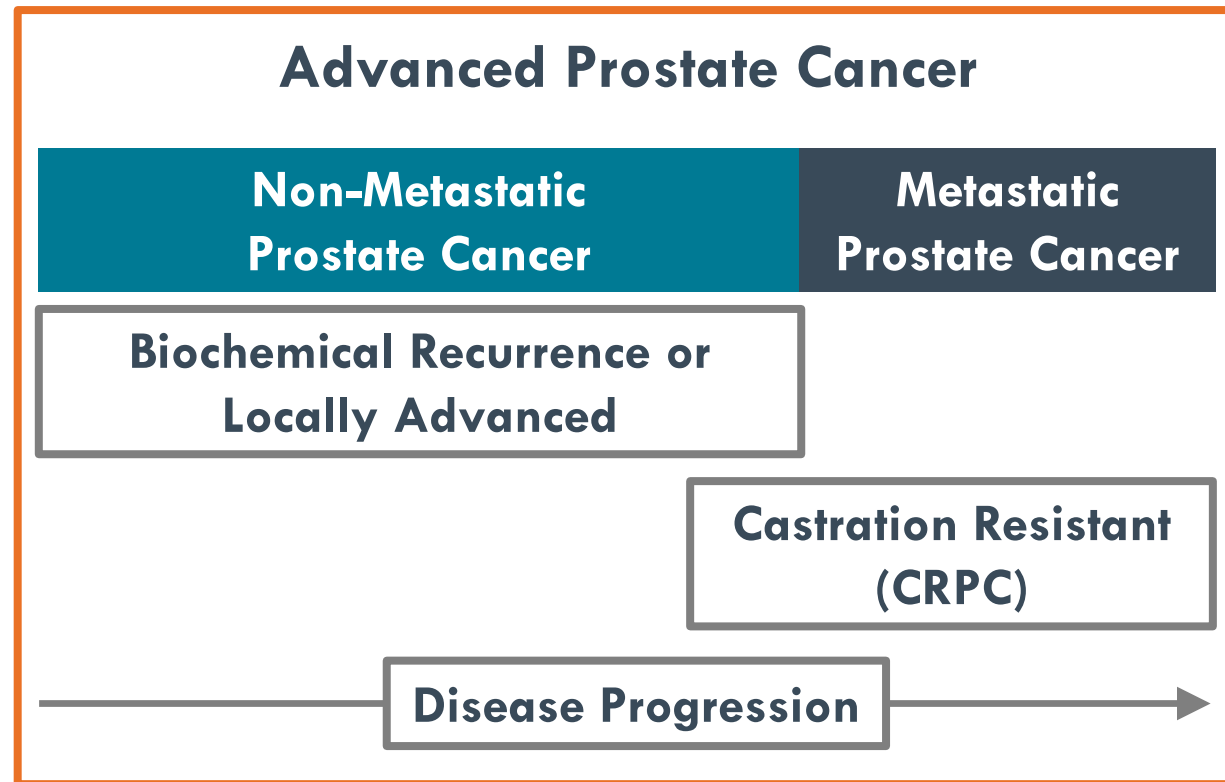
NOVEMBER 19, 2019



# PROSTATE CANCER

## THE 2ND MOST COMMON CANCER AFFECTING MEN

- ~**3M** men currently living with prostate cancer in the US
- **170K** expected to be newly diagnosed in 2019
- >95% of prostate cancers are driven by testosterone
- Therapies that target this pathway are used across the continuum of advanced prostate cancer






### RELUGOLIX TARGET INDICATION

# RELUGOLIX HAS POTENTIAL TO BENEFIT BROAD SPECTRUM OF MEN WITH PROSTATE CANCER

## 2018 Prevalence of GnRH-Treated Prostate Cancer Patients



## GnRH Agonist Mechanism of Action Has Challenges

-  Initially raises testosterone, worsening symptoms (clinical flare)
-  Takes weeks to reduce PSA; months for testosterone recovery
-  All agonists are injectable

Sources: 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 approved for any use; these are aspirational statements

# POSITIVE STUDY RESULTS

**NDA SUBMISSION  
EXPECTED Q2 2020**

- ✓ **Primary endpoint achieved**
  - Relugolix 96.7% sustained testosterone suppression rate through 48 weeks (95% CI: 94.9%, 97.9%)
- ✓ **All 6 tested key secondary endpoints achieved**
  - 5/5 endpoints tested for superiority to leuprolide achieved (all  $p < 0.0001$ )
  - Relugolix non-inferior to leuprolide on sustained testosterone suppression (96.7% vs. 88.8%)
- ✓ **Predictable pharmacodynamics**
  - No testosterone flare after initiation of therapy
  - Mean testosterone returned to normal levels within 90 days
- ✓ **Safety profile consistent with mechanism of action**
  - Rate of CV events lower than leuprolide

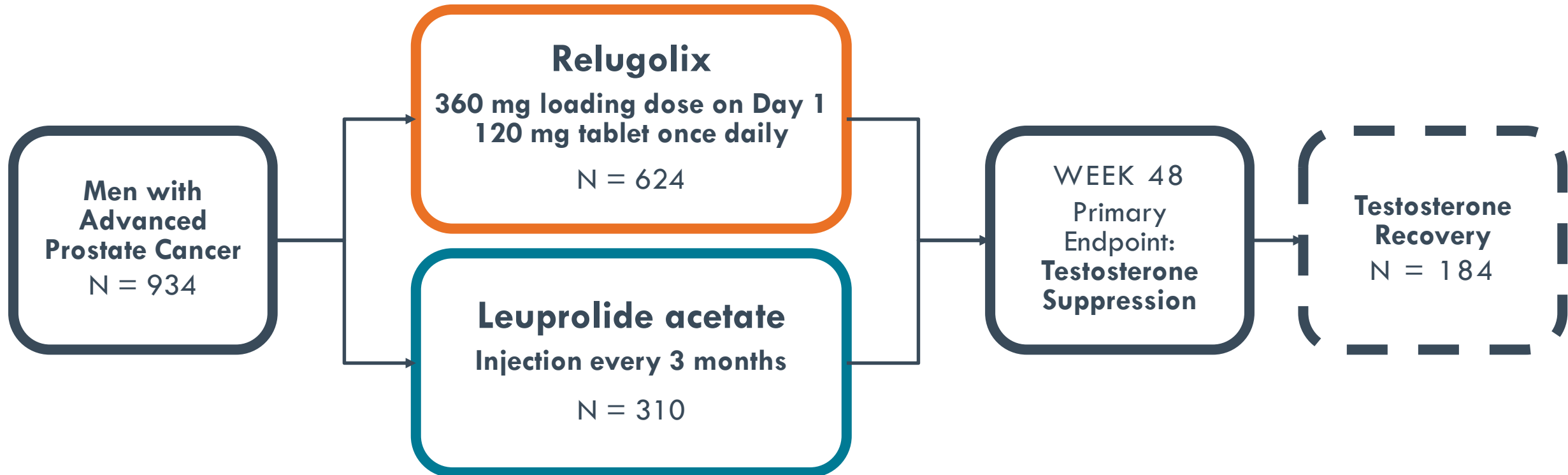
# PHASE 3 STUDY DESIGN

## POPULATION

Men with advanced prostate cancer who require androgen deprivation therapy for hormone-sensitive disease

## PRIMARY ENDPOINT

Sustained testosterone suppression through 48 weeks (< 50 ng/dL)



# HERO PRIMARY ENDPOINTS

## US Primary Endpoint

**Sustained testosterone suppression to castrate levels:**  
Lower bound of 95% CI  $\geq$  90% in relugolix

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## Ex-US Primary & US Key Secondary Endpoint

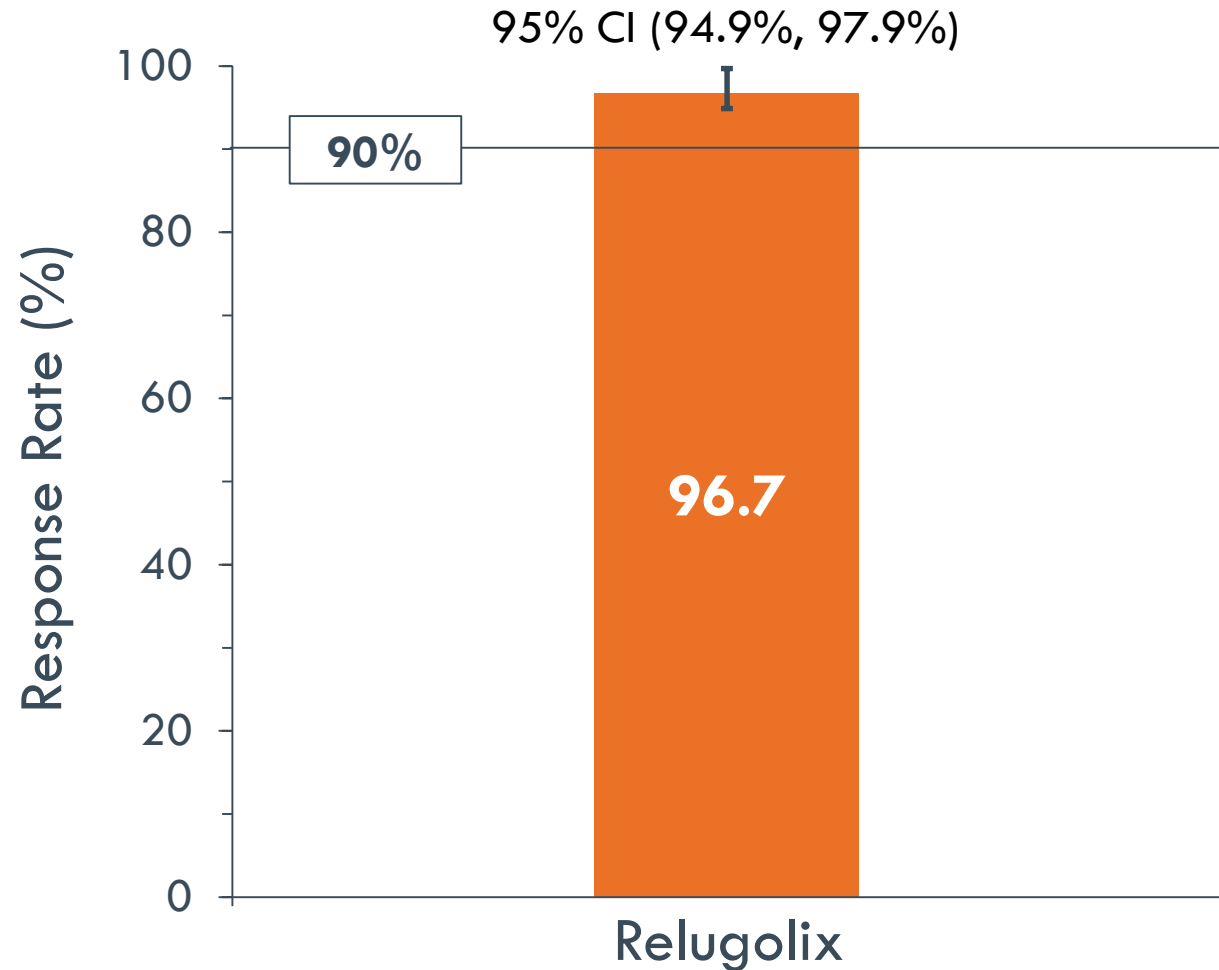
**Sustained testosterone suppression to castrate levels:**  
Non-inferiority relugolix vs. leuprolide



# ACHIEVED US PRIMARY ENDPOINT

**SUSTAINED  
TESTOSTERONE  
SUPPRESSION TO  
CASTRATE LEVELS  
( $< 50$  ng/dL) WITH  
LOWER BOUND OF  
95% CI  $\geq 90\%$**

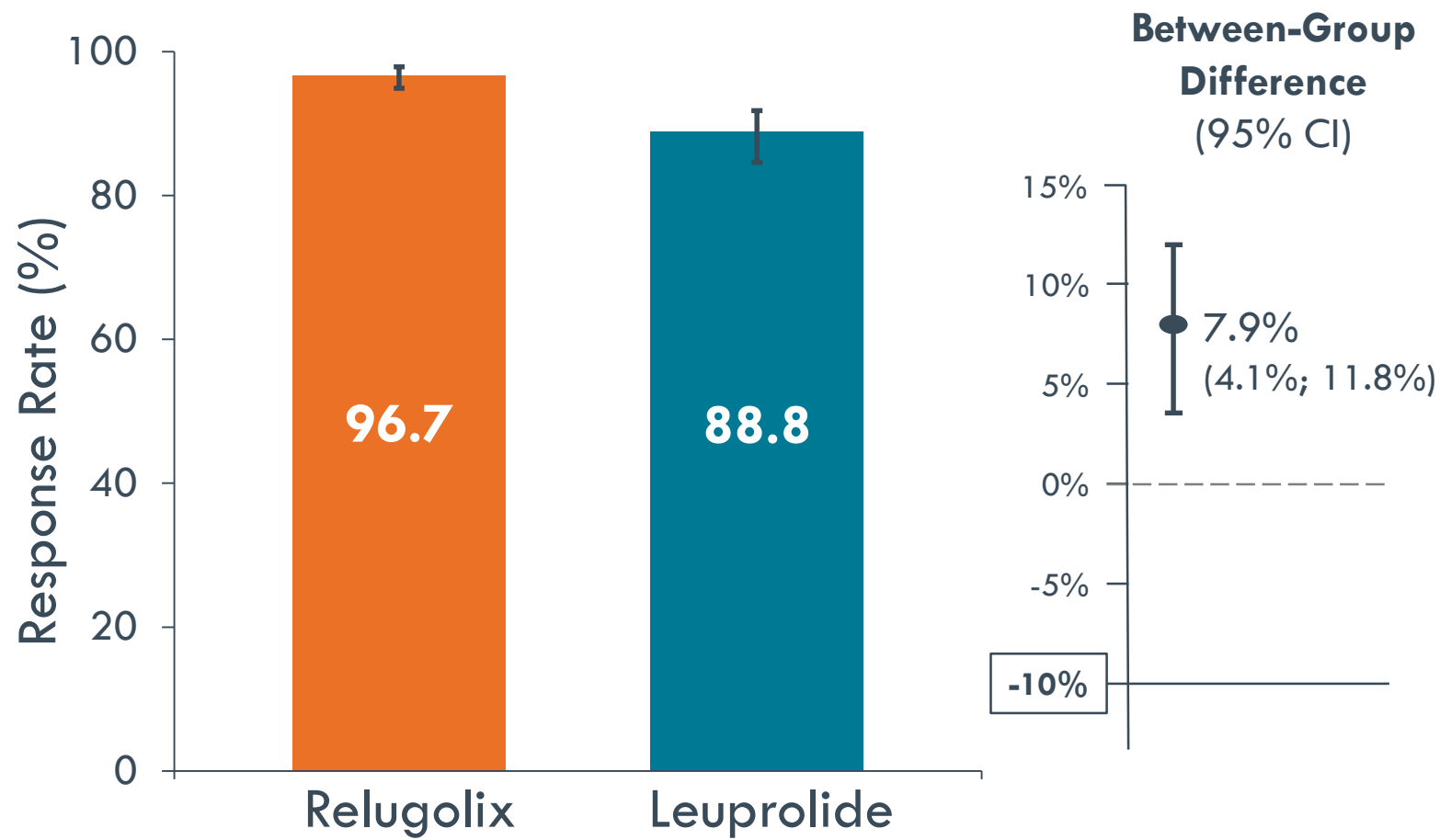
## 96.7% OF MEN MET RESPONDER CRITERIA



# ACHIEVED EX-US PRIMARY ENDPOINT

DIFFERENCE IN SUSTAINED TESTOSTERONE SUPPRESSION TO CASTRATE LEVELS (LOWER BOUND 95% CI > -10%)

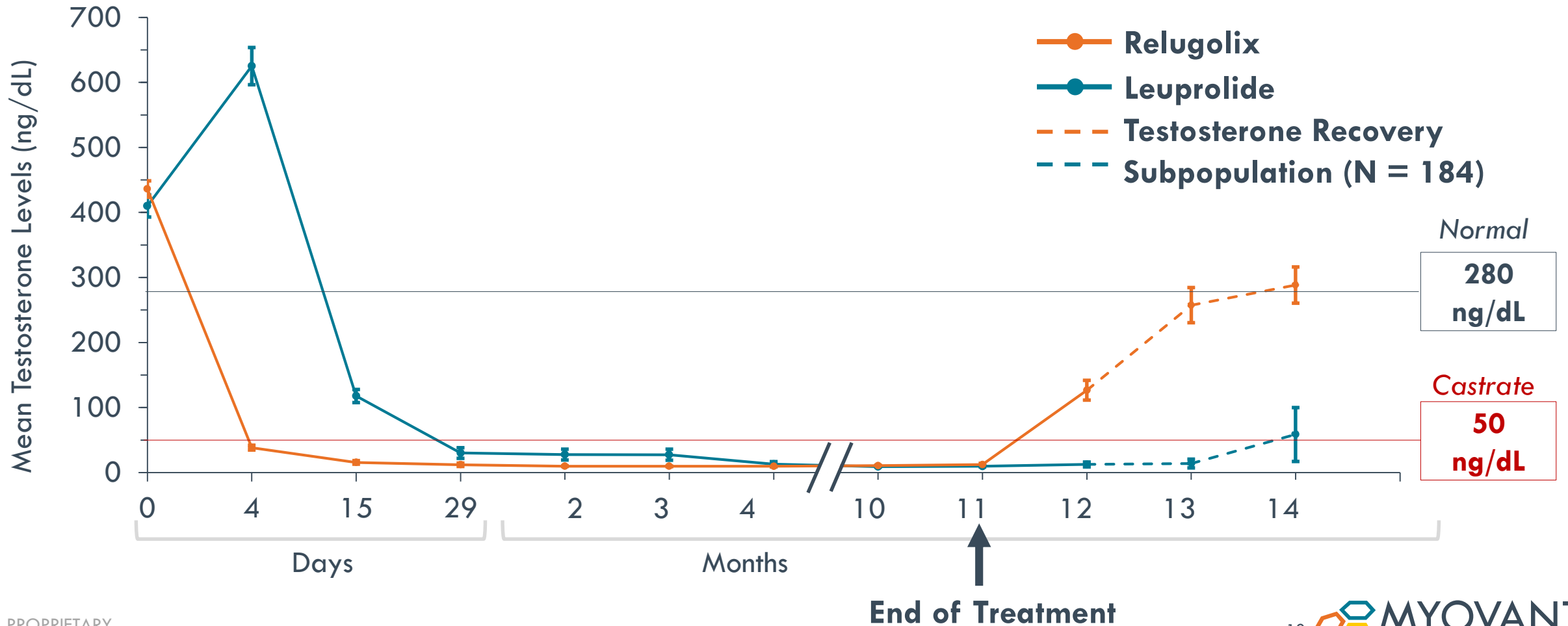
## ORAL RELUGOLIX ACHIEVED NON-INFERIORITY TO INJECTABLE LEUPROLIDE



# SUPERIOR TO LEUPROLIDE IN FIVE KEY SECONDARY ENDPOINTS

Key Secondary Endpoints	Definitions	P-Value
<b>TESTOSTERONE SUPPRESSION</b>	Testosterone suppression to castrate levels (< 50 ng/dL) at Day 4	<b>P &lt; 0.0001</b>
	Testosterone suppression to castrate levels (< 50 ng/dL) at Day 15	
	Testosterone suppression to profound castrate levels (< 20 ng/dL) at Day 15	
<b>PSA RESPONSE</b>	Confirmed PSA response rate (> 50% reduction from baseline at Day 15)	
<b>FSH LEVEL</b>	Mean FSH level (IU/L) at Week 24	

# RELUGOLIX ACHIEVED FASTER ONSET AND OFFSET THAN LEUPROLIDE



# ADDITIONAL PROSTATE CANCER DATA EXPECTED IN Q3 2020

## Cohort

## Endpoints

✓ **Completed  
Data**

**PRIMARY ANALYSIS COHORT**  
N = 934

- Primary endpoint
- Most key secondary endpoints

**Data Expected  
Q3 2020**

**CASTRATION RESISTANCE-  
FREE SURVIVAL COHORT**  
N = 434  
139 additional men with  
metastatic disease

- Castration resistance-free survival

# SUMMARY OF ADVERSE EVENTS

	Relugolix (N = 622)	Leuprolide (N = 308)
Study discontinuation due to an adverse event	3.5%	2.6%
Patients reporting at least 1 adverse event	92.9%	93.5%
Related to study drug	73.6%	68.8%
Grade 3 or above	18.0%	20.5%
Serious	12.2%	15.3%
Major Adverse Cardiovascular Events (MACE)	2.9%	6.2%
Fatal outcome	1.1%	2.9%

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

# ADVERSE EVENTS $\geq 10\%$ IN ANY TREATMENT GROUP

	Relugolix (N = 622)	Leuprolide (N = 308)
Hot flash	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%

## TAKEAWAYS: MAJOR STEPS FORWARD

- ✓ Positive study results for HERO with **96.7%** response rate in primary endpoint
- ✓ All six key secondary endpoints achieved, including **superiority to leuprolide** on rapid suppression of testosterone and PSA
- ✓ Safety profile consistent with mechanism of action with half the rate of cardiovascular events than leuprolide
- ✓ Data support **filings in US, Europe and Japan**; NDA submission expected in Q2 2020
- ✓ HERO data to be submitted for presentation and publication in first half of 2020
- ✓ Castration-resistance free survival data expected Q3 2020



# DR. NEAL SHORE, MD, FACS



**Medical Director**

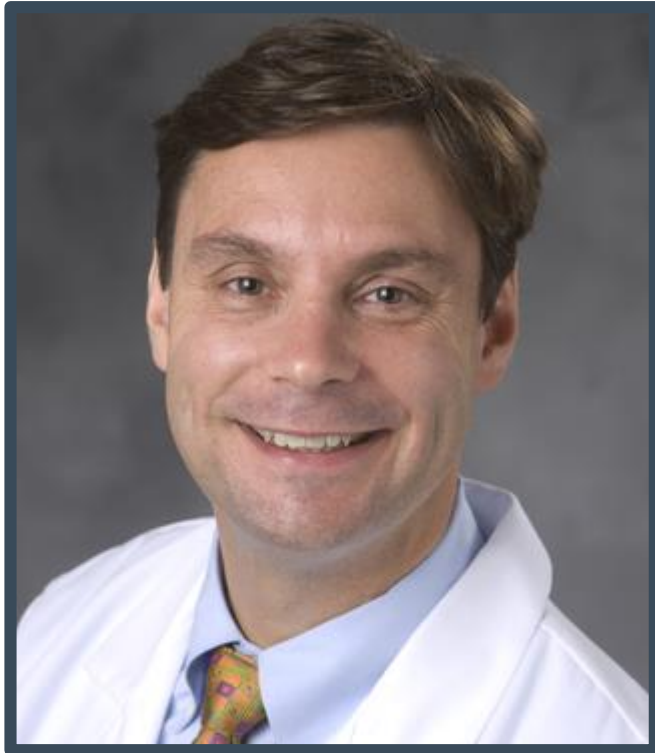
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HERO Investigator**

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**Professor of Medicine and Surgery**  
Duke University School of Medicine

**Medical Oncologist & Director,  
Genitourinary Oncology**  
Duke Cancer Institute

**HERO Steering Committee Member &  
HERO Investigator**

# MYOVANT SCIENCES' UPCOMING MILESTONES

INDICATION	PHASE 1	PHASE 2	PHASE 3	Anticipated Milestones 2019-Q2 2020
Uterine Fibroids				<ul style="list-style-type: none"> <li>• NDA Submission (April 2020)</li> <li>• MAA* Submission (Q1 2020)</li> </ul>
Advanced Prostate Cancer				<ul style="list-style-type: none"> <li>• NDA Filing (Q2 2020)</li> <li>• Castration Resistance-Free Survival Data (Q3 2020)</li> </ul>
Endometriosis				<ul style="list-style-type: none"> <li>• Phase 3 Data (Q1 &amp; Q2 2020)</li> </ul>

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