ORGOVYX™
(relugolix) 120 mg tablets

THE ONLY ORAL ANDROGEN DEPRIVATION THERAPY

for advanced prostate cancer[1,2]

Bottle and pill not shown at actual size. Actual pill size: 10.7 mm x 7.5 mm x 5.2 mm.[3]

ORGOVYX helps you treat patients with one pill, once a day*

*After initial loading dose of 3 pills.

INDICATION

ORGOVYX is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

QT/QTc Interval Prolongation: Androgen deprivation therapy, such as ORGOVYX may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

This is not an actual patient.

TABLE OF CONTENTS

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A DIFFERENT ANDROGEN DEPRIVATION THERAPY OPTION IS NEEDED

LHRH AGONISTS CAUSE AN INITIAL **TESTOSTERONE SURGE**[4]

- **May exacerbate clinical symptoms** in some patients
- **May require additional agents** to prevent symptoms due to testosterone surge, which might be a challenge for patients already taking multiple medicines
- The testosterone surge **delays onset** of testosterone suppression

PATIENTS WITH PROSTATE CANCER MAY BE AT HIGH RISK FOR CARDIOVASCULAR DISEASE AND **LHRH AGONISTS CARRY A WARNING FOR INCREASED RISK OF CERTAIN CARDIOVASCULAR DISEASES**[5-7]

- In a recent study, **69% of men with prostate cancer** were at high cardiovascular disease risk*
- In this same study, 58% of men were current or former **smokers**, 45% had **hypertension**, 31% had a **BMI ≥30 kg/m²**, and 22% had **known cardiovascular disease**
- LHRH agonists carry warnings for **increased risk of diabetes and certain cardiovascular diseases** (heart attack, sudden cardiac death, and stroke)

ANDROGEN DEPRIVATION THERAPY INJECTIONS CAN BE A BURDEN FOR SOME PATIENTS[8,9]

- Some patients may **prefer an oral option**
- Some patients find **injection appointments inconvenient**
- **Testosterone recovery can be slow** for depot formulations if treatment discontinuation is needed

INJECTION DELAYS CAN NEGATIVELY IMPACT TESTOSTERONE SUPPRESSION[10]

- In a recent retrospective analysis of US clinical data, **84% of LHRH agonist injections were late**, including 60% >1 week late and 29% >2 weeks late
- Delays can lead to **testosterone above castrate levels**

BMI=body mass index; LHRH=luteinizing hormone–releasing hormone.
*Framingham risk score consistent with high cardiovascular risk (≥15).

ASSESS CARDIOVASCULAR RISK IN YOUR PATIENTS WHEN CONSIDERING ANDROGEN DEPRIVATION THERAPY

ADVANCED PROSTATE CANCER SPANS MULTIPLE CLINICAL DISEASE STATES

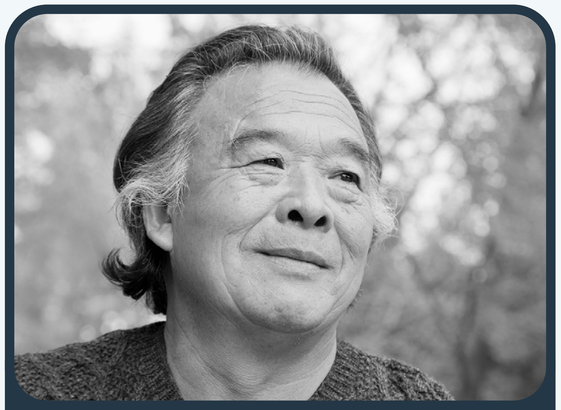
Advanced prostate cancer includes patients with locally advanced disease, patients with biochemical recurrence, and patients with metastatic disease[13,14]

LOCALLY ADVANCED PROSTATE CANCER[13]

- Prostate cancer that extends outside the prostate capsule, which can include nearby tissues and/or regional lymph nodes

BIOCHEMICAL RECURRENCE[13]

- Patients with rising PSA after local therapy (treatment with surgery or radiation)



METASTATIC HORMONE-SENSITIVE PROSTATE CANCER[13]

- Metastatic disease that has either not yet been treated with androgen deprivation therapy or is still responsive to androgen deprivation therapy. This can include:
  - — Patients with newly diagnosed metastatic disease
  - — Patients with primary progressive disease

CASTRATION-RESISTANT PROSTATE CANCER[13,14]

- Prostate cancer that progresses despite androgen deprivation therapy and castrate levels of testosterone <50 ng/dL, including:
  - — Patients with nonmetastatic disease
  - — Patients with metastatic disease

These are not actual patients.

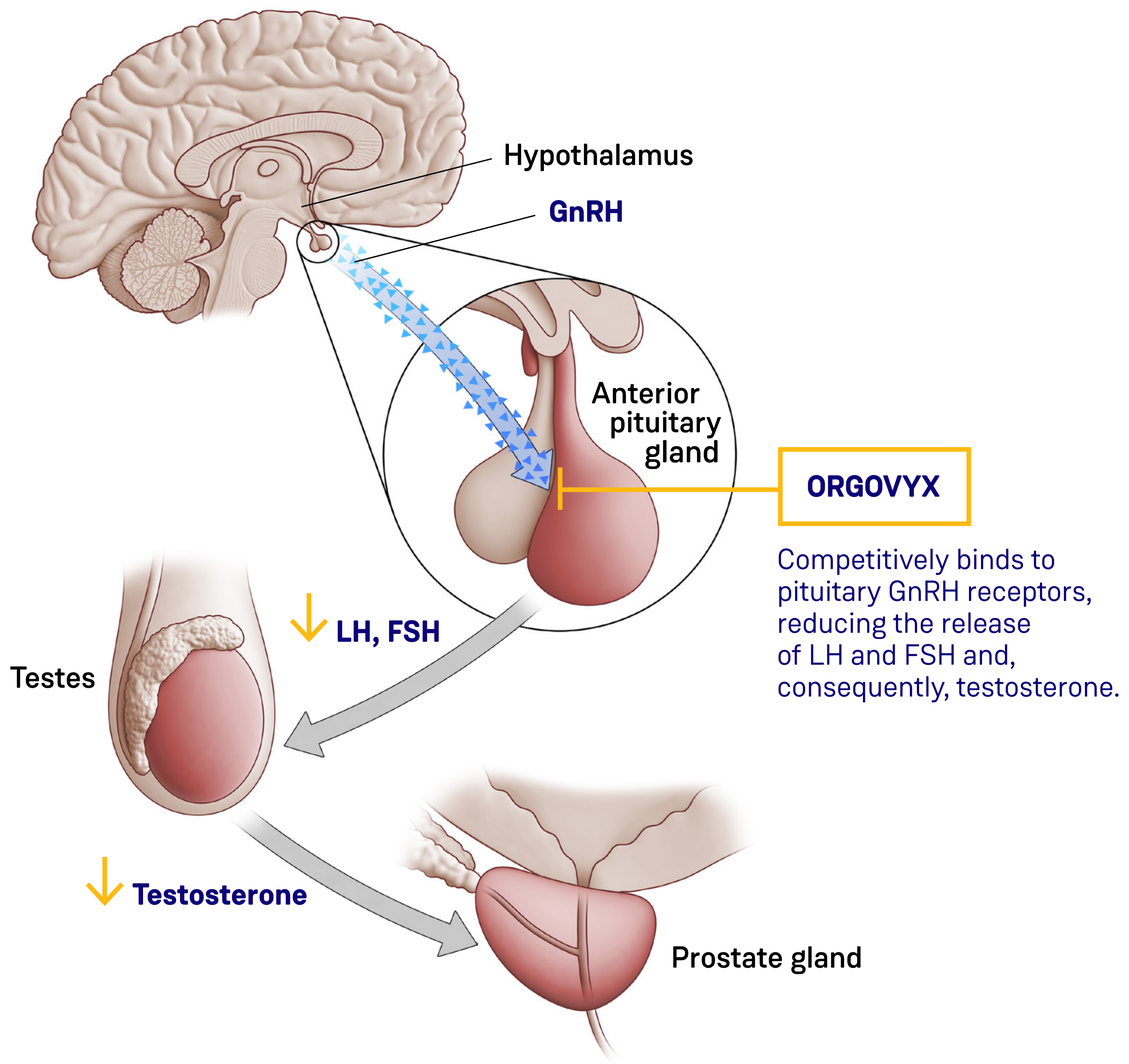
ANDROGEN DEPRIVATION THERAPY IS THE FOUNDATION OF TREATMENT FOR ADVANCED PROSTATE CANCER[8]

PSA=prostate-specific antigen.

ABOUT ORGOVYX

ORGOVYX is the only oral once-a-day GnRH receptor antagonist for advanced prostate cancer[1,2]

ORGOVYX MECHANISM OF ACTION[1,4]



- **Targeted GnRH receptor antagonist mechanism of action:** reduces the release of LH and FSH and, consequently, testosterone
- **No initial testosterone surge:** avoids potential worsening of clinical symptoms due to surge

FSH=follicle-stimulating hormone; GnRH=gonadotropin-releasing hormone; LH=luteinizing hormone.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Embryo-Fetal Toxicity: The safety and efficacy of ORGOVYX have not been established in females. Based on findings in animals and mechanism of action, ORGOVYX can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of ORGOVYX

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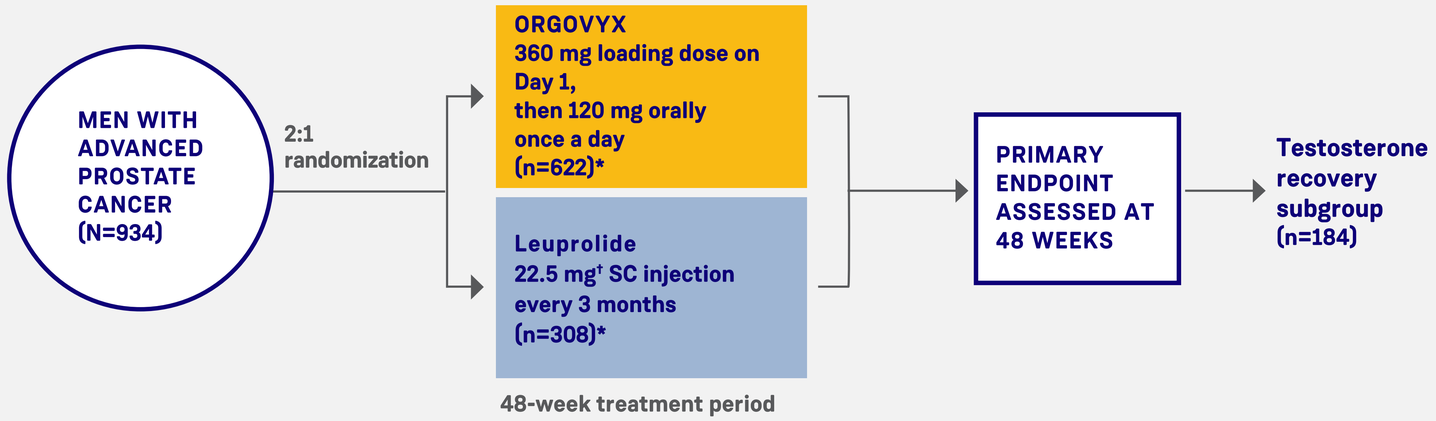
HERO STUDY DESIGN

The efficacy and safety of ORGOVYX were evaluated in a multinational, phase 3, randomized, open-label, parallel-group study[1,2]



*Two patients in each arm did not receive the study treatment and were not included.
†The dosage of leuprolide was 11.25 mg in Japan and Taiwan, per local guidelines, and is not recommended for this indication in the United States.

PRIMARY ENDPOINT[1]:

- Sustained testosterone suppression rate, defined as achieving and maintaining serum testosterone concentrations to <50 ng/dL by Day 29 through 48 weeks of treatment

KEY SECONDARY ENDPOINTS[1,2]:

- Testosterone suppression rates on Day 4 and Day 15 (defined as testosterone concentrations <50 ng/dL)
- PSA response rate on Day 15 (>50% decrease from baseline), confirmed on Day 29
- Profound testosterone suppression rate on Day 15 (defined as testosterone concentrations <20 ng/dL)

TESTOSTERONE RECOVERY SUBSTUDY[2]:

- Cumulative probability of testosterone recovery to 280 ng/dL at the 90-day follow-up in 184 patients who completed 48 weeks of treatment and who did not receive subsequent androgen deprivation therapy for at least 90 days after discontinuation‡

SC=subcutaneous.
‡These data were to be reported in the final analysis; however, for the primary analysis, this endpoint was analyzed for exploratory purposes without formal testing.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Laboratory Testing: Therapy with ORGOVYX results in suppression of the pituitary gonadal system. Results of diagnostic tests of the pituitary gonadotropic and gonadal functions conducted during and after ORGOVYX may be affected. The therapeutic effect of ORGOVYX should be monitored by measuring serum concentrations of prostate-specific antigen (PSA) periodically. If PSA increases, serum concentrations of testosterone should be measured.

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PATIENT ENROLLMENT

HERO enrolled patients across different clinical disease presentations of advanced prostate cancer[1]

KEY INCLUSION CRITERIA[1,2]

- **Men ≥18 years of age** with confirmed adenocarcinoma of the prostate
- **Requiring at least 1 year of continuous androgen deprivation therapy** with 1 of the following clinical disease presentations:
  - — Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent
  - — Newly diagnosed androgen-sensitive metastatic disease
  - — Advanced localized disease unlikely to be cured by local primary intervention with curative intent
- Serum testosterone ≥150 ng/dL
- Serum PSA >2.0 ng/mL*
- ECOG score 0/1

KEY EXCLUSION CRITERIA[2,15]

- **Patients likely to require chemotherapy or surgical therapy** for symptomatic disease management within 2 months of initiating androgen deprivation therapy
- **Previously received GnRH analog** or other form of androgen deprivation therapy for >18 months total duration
  - — If androgen deprivation therapy was received for ≤18 months total duration, then patients must have completed treatment >3 months prior to baseline, or at least as long as the dosing interval of the depot formulation received
- **Significant cardiovascular risk conditions**
  - — Myocardial infarction or thromboembolic events within 6 months
  - — Arrhythmias
  - — Uncontrolled hypertension

ECOG=Eastern Cooperative Oncology Group.
*When applicable, post radical prostatectomy of >0.2 ng/mL or post radiotherapy, cryotherapy, or high-frequency ultrasound >2.0 ng/mL above the postinterventional nadir.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Serious adverse reactions occurred in 12% of patients receiving ORGOVYX. Serious adverse reactions in ≥0.5% of patients included myocardial infarction (0.8%), acute kidney injury (0.6%), arrhythmia (0.6%), hemorrhage (0.6%), and urinary tract infection (0.5%). Fatal adverse reactions occurred in 0.8% of patients receiving ORGOVYX including metastatic lung cancer (0.3%), myocardial infarction (0.3%), and acute kidney injury (0.2%). Fatal and non-fatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX.

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PATIENT POPULATION

Baseline characteristics were well balanced between treatment arms[2]

SELECT BASELINE CHARACTERISTICS[2,15]	ORGOVYX (n=622)	Leuprolide (n=308)
Age		
≤75 years	**71.4%**	**71.4%**
Median age (range), years	**72 (48-91)**	**71 (47-97)**
Race		
White	**69.8%**	**65.6%**
Asian	**20.4%**	**23.1%**
Black or African American	**4.8%**	**5.2%**
Other	**5.0%**	**6.2%**
Clinical Disease Presentation		
Evidence of biochemical or clinical relapse after local primary intervention with curative intent*	**49.7%**	**51.3%**
Newly diagnosed androgen-sensitive metastatic disease	**22.7%**	**22.7%**
Advanced localized disease not suitable for primary surgical intervention with curative intent	**27.7%**	**26.0%**
Mean testosterone level, ng/dL (±SD)	**436.1 (±159.0)**	**410.0 (±149.1)**
Mean PSA level, ng/mL (±SD)	**104.2 (±416)**	**68.6 (±244)**
ECOG performance status†		
0	**88.1%**	**88.0%**
1	**11.9%**	**11.7%**
3‡	**-**	**0.3%**
Previous androgen deprivation therapy	**13.0%**	**9.7%**
Cardiovascular Risk Factors§	**91.6%**	**94.2%**
Lifestyle risk factors‖	**67.8%**	**65.6%**
Cardiovascular or cerebrovascular risk factors¶	**78.5%**	**82.5%**
History of major adverse cardiovascular events#	**13.5%**	**14.6%**

CARDIOVASCULAR RISK FACTORS AT BASELINE[2]:

- *80%* **of patients had cardiovascular or cerebrovascular risk factors** such as diabetes or hypertension
- *67%* **of patients had lifestyle risk factors** such as a history of smoking or obesity
- *14%* **of patients had a history of myocardial infarction or stroke**

*Biochemical relapse was defined by a rising PSA level.
†ECOG performance status ranges from 0 to 5, with higher scores reflecting greater disability.
‡One patient in the leuprolide group had a surgical vascular procedure on his leg and was given an ECOG score of 3 at screening because of the use of crutches. By the baseline Day 1 visit, the patient no longer used crutches, and his ECOG score had improved to 0.
§Patients with multiple risk factors were counted only once.
‖Included current/past tobacco smoking, heavy alcohol use, and a BMI >30 kg/m^2.
¶Included hypertension; dyslipidemia; diabetes; a history of myocardial infarction or cardiovascular disease; a history of stroke, transient ischemic attack, or cerebral hemorrhage; peripheral arterial disease; atrial fibrillation and other arrhythmias; heart valve disease; chronic obstructive pulmonary disease; chronic kidney disease; chronic liver disease; carotid artery stenosis or occlusion; venous thromboembolic events; and heart failure.
#Search criteria included “myocardial infarction” (broad standardized MedDRA query) and “central nervous system hemorrhages and cerebrovascular conditions” (broad standardized MedDRA query).

MedDRA=Medical Dictionary for Regulatory Activities; SD=standard deviation.

IMPORTANT SAFETY INFORMATION (cont’d)

Adverse Reactions (cont’d)

Most common adverse reactions (≥10%) and laboratory abnormalities (≥15%) in patients receiving ORGOVYX were hot flush (54%), glucose increased (44%), triglycerides increased (35%), musculoskeletal pain (30%), hemoglobin decreased (28%), alanine aminotransferase increased (27%), fatigue (26%), aspartate aminotransferase increased (18%), constipation (12%), and diarrhea (12%).

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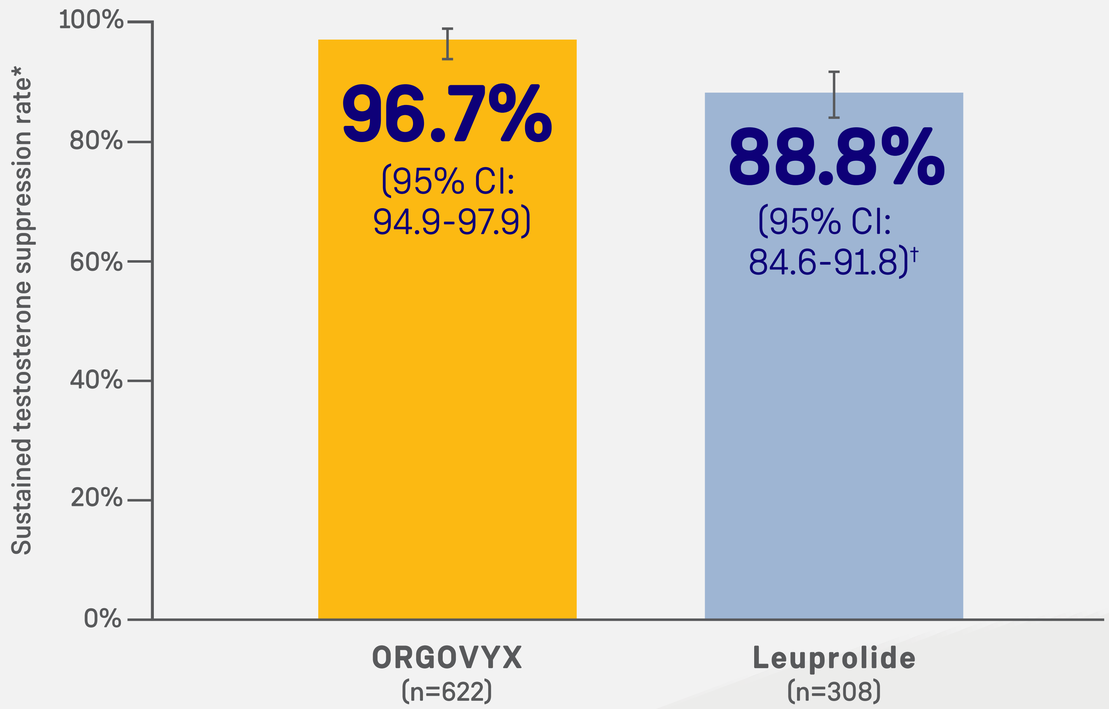
ORGOVYX™ (relugolix) 120 mg tablets

SUSTAINED TESTOSTERONE SUPPRESSION TO <50 NG/DL

ORGOVYX achieved sustained testosterone suppression in 97% of men[1]

- **97% of men** achieved and maintained testosterone suppression to <50 ng/dL from Day 29 through Week 48 with ORGOVYX vs 89% of men with leuprolide

PRIMARY ENDPOINT: SUSTAINED TESTOSTERONE SUPPRESSION RATE (TESTOSTERONE LEVELS <50 ng/dL FROM DAY 29 THROUGH WEEK 48)[1]



CI=confidence interval.
*Kaplan-Meier estimates within each group.
†The testosterone suppression rate of the subgroup of patients receiving leuprolide 22.5 mg (n=264) was 88.0% (95% CI: 83.4-91.4).

THINK ORAL ORGOVYX FOR ANDROGEN DEPRIVATION THERAPY

IMPORTANT SAFETY INFORMATION (cont'd)

Drug Interactions

Co-administration of ORGOVYX with a P-gp inhibitor increases the area under the curve (AUC) and maximum concentration (C_{max}) of ORGOVYX, which may increase the risk of adverse reactions associated with ORGOVYX. Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions. Treatment with ORGOVYX may be interrupted for up to 2 weeks for a short course of treatment with certain P-gp inhibitors. If treatment with ORGOVYX is interrupted for more than 7 days, resume administration of ORGOVYX with a 360 mg loading dose on the first day, followed by 120 mg once daily.

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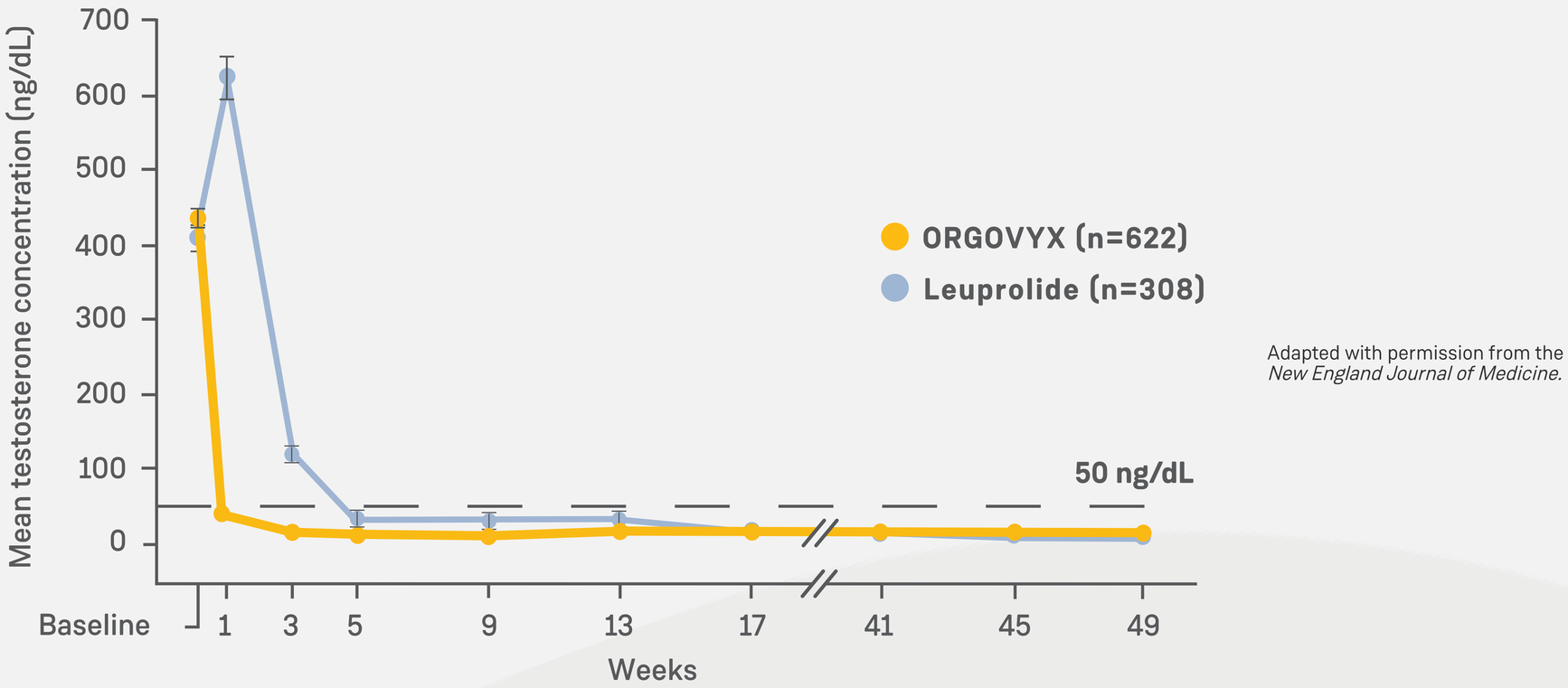
RAPID TESTOSTERONE SUPPRESSION

ORGOVYX suppressed testosterone with no initial surge and sustained suppression throughout the study[1,2]

- **On Day 4:** *56%* of men treated with ORGOVYX achieved testosterone suppression to <50 ng/dL vs 0% of men treated with leuprolide*

MEAN TESTOSTERONE CONCENTRATIONS FROM BASELINE THROUGH WEEK 48[2]



Adapted with permission from the *New England Journal of Medicine.*

- **On Day 15:** *99%* of men treated with ORGOVYX achieved testosterone suppression to <50 ng/dL vs 12% of men treated with leuprolide*

*Kaplan-Meier estimates within each group.

CONSIDER ORAL ORGOVYX FOR PATIENTS WHO NEED RAPID TESTOSTERONE SUPPRESSION

IMPORTANT SAFETY INFORMATION (cont'd)

Drug Interactions (cont'd)

Co-administration of ORGOVYX with a combined P-gp and strong CYP3A inducer decreases the AUC and C_{max} of ORGOVYX, which may reduce the effects of ORGOVYX. Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg once daily.

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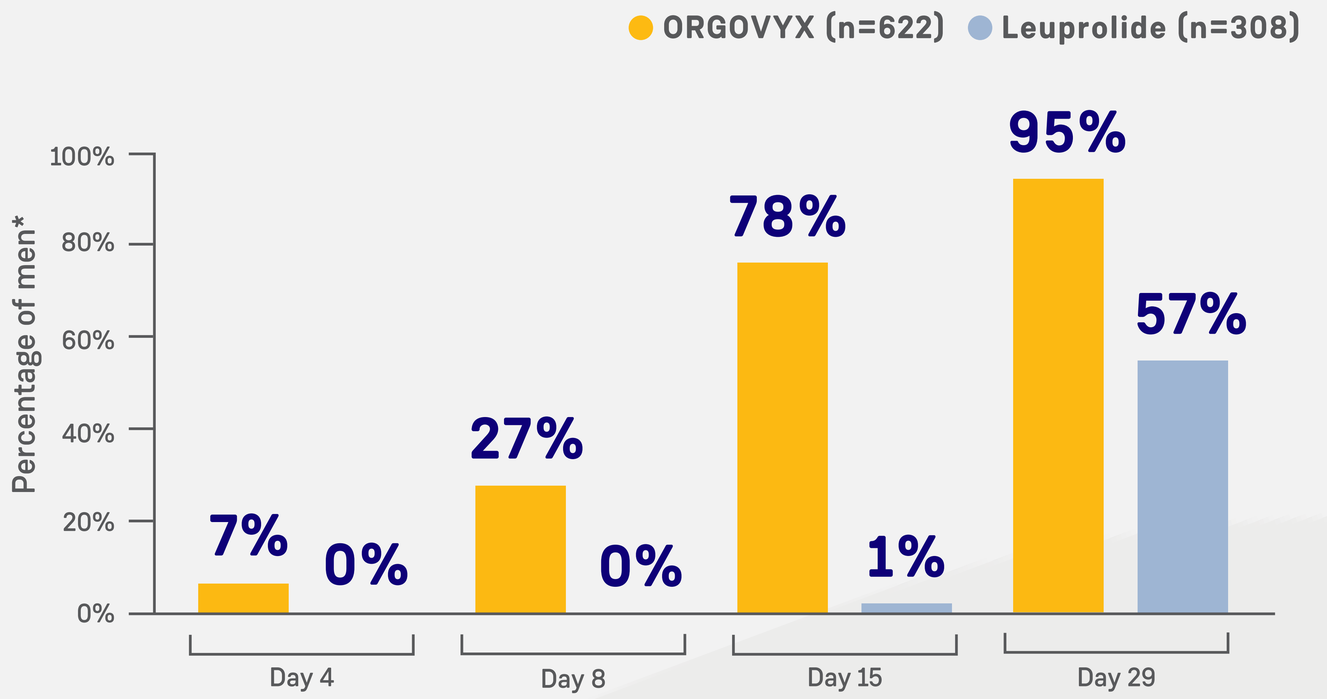
PROFOUND TESTOSTERONE SUPPRESSION TO <20 NG/DL

ORGOVYX achieved profound testosterone suppression, defined as testosterone concentrations <20 ng/dL[1]

- **On Day 15:** 78% of men treated with ORGOVYX achieved profound testosterone suppression to <20 ng/dL vs 1% of men treated with leuprolide*
- **On Day 29:** 95% of men treated with ORGOVYX achieved profound testosterone suppression to <20 ng/dL vs 57% of men treated with leuprolide*

PERCENTAGE OF MEN WITH TESTOSTERONE CONCENTRATIONS <20 ng/dL[1]



*Kaplan-Meier estimates within each group.

CHOOSE ORGOVYX FOR EFFECTIVE AND PROFOUND TESTOSTERONE SUPPRESSION TO <20 ng/dL

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

QT/QTc Interval Prolongation: Androgen deprivation therapy, such as ORGOVYX may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

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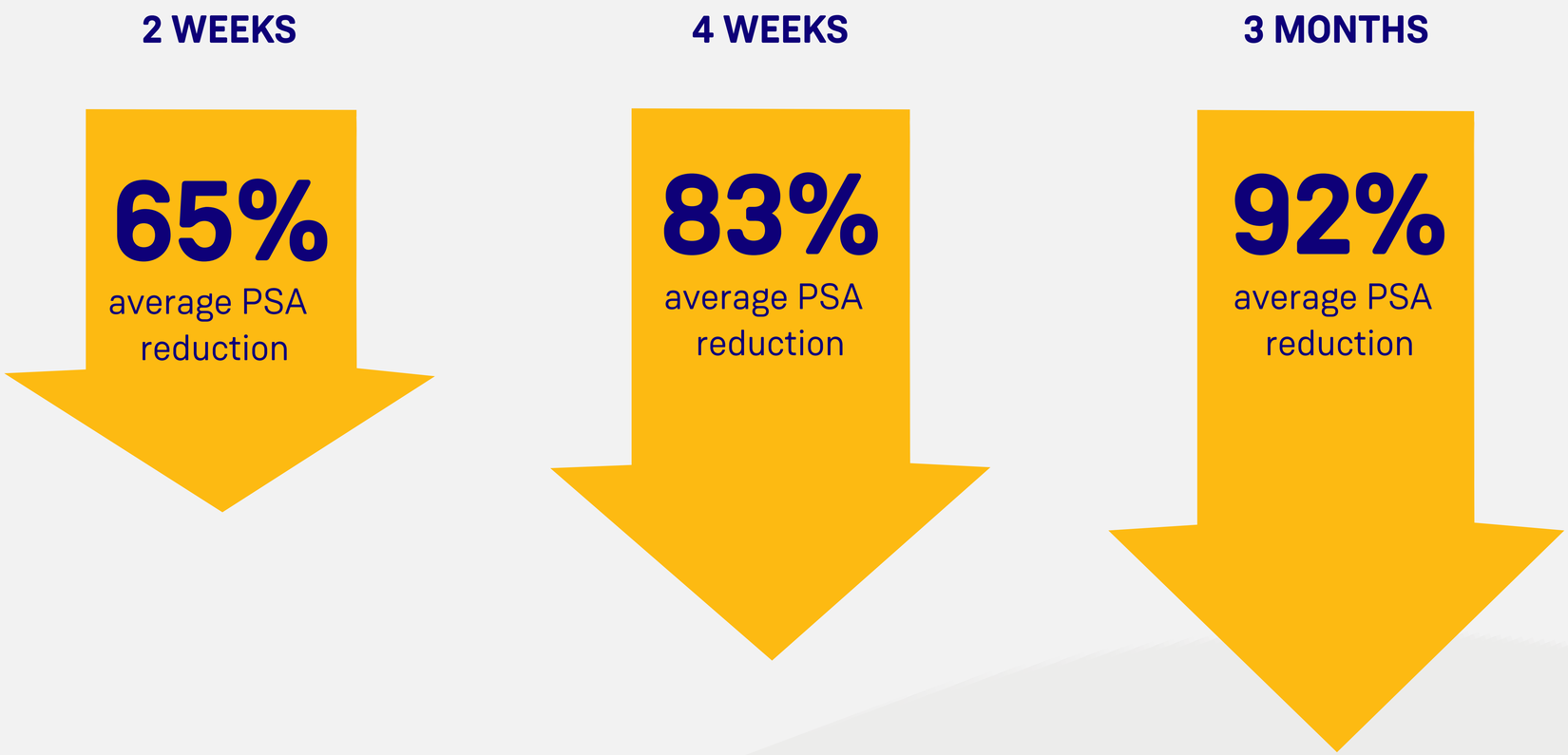
PSA REDUCTION

ORGOVYX lowered PSA levels at 2 weeks and maintained PSA suppression through 48 weeks[1]

ORGOVYX DEMONSTRATED PSA REDUCTIONS FROM BASELINE AVERAGE OF 104.2 ng/mL[2]



PSA results should be interpreted with caution because of the heterogeneity of the patient population studied. No evidence has shown that the rapidity of PSA decline is related to a clinical benefit.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Embryo-Fetal Toxicity: The safety and efficacy of ORGOVYX have not been established in females. Based on findings in animals and mechanism of action, ORGOVYX can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of ORGOVYX

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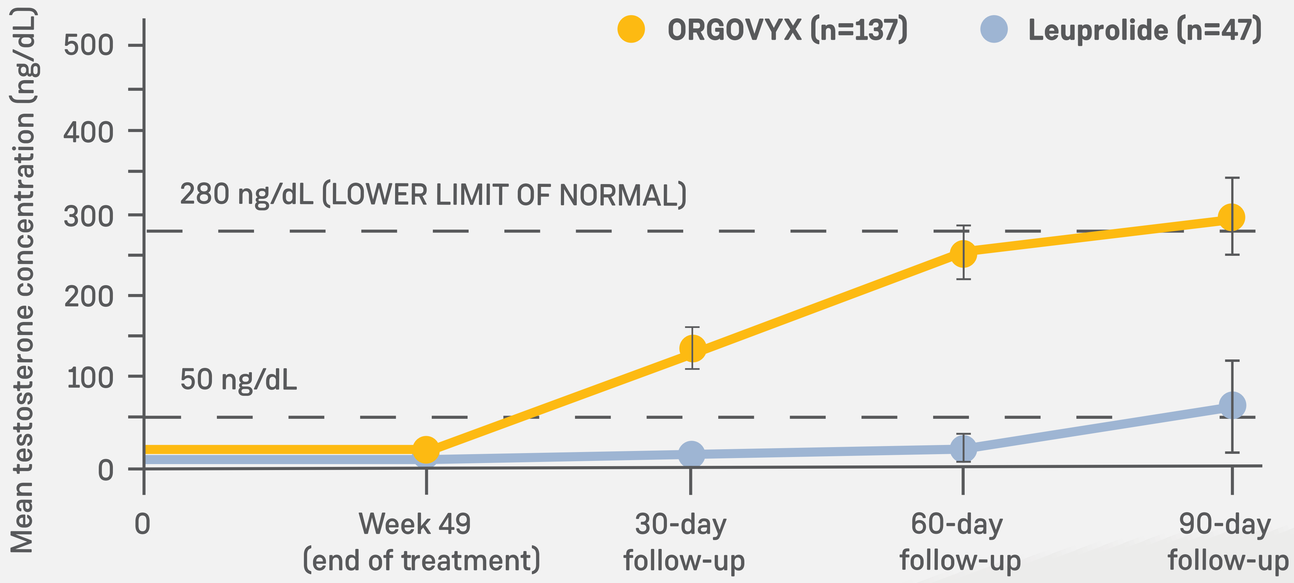
TESTOSTERONE RECOVERY

ORGOVYX testosterone recovery 90 days after discontinuation[1-3]

- Testosterone recovery was evaluated in a substudy of 184 patients who completed 48 weeks of treatment*
- 90 days after treatment discontinuation, *55%* **of 137 men treated with ORGOVYX had their testosterone return** to above the lower limit of the normal range (>280 ng/dL) or baseline values vs 3% of 47 men treated with leuprolide†

TESTOSTERONE CONCENTRATIONS IN TESTOSTERONE RECOVERY SUBSTUDY (N=184)[2]



Adapted with permission from the *New England Journal of Medicine.*

*These data were to be reported in the final analysis; however, for the primary analysis, this endpoint was analyzed for exploratory purposes without formal testing.

†Kaplan-Meier estimates within each group.

CONSIDER ORAL ORGOVYX FOR PATIENTS WHO MAY BENEFIT FROM TESTOSTERONE RECOVERY

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Laboratory Testing: Therapy with ORGOVYX results in suppression of the pituitary gonadal system. Results of diagnostic tests of the pituitary gonadotropic and gonadal functions conducted during and after ORGOVYX may be affected. The therapeutic effect of ORGOVYX should be monitored by measuring serum concentrations of prostate-specific antigen (PSA) periodically. If PSA increases, serum concentrations of testosterone should be measured.

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HERO STUDY ADVERSE EVENTS

ADVERSE EVENTS[1,2]*	ORGOVYX (n=622)		Leuprolide (n=308)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
Any adverse event – n (%)	578 (92.9)	112 (18.0)	288 (93.5)	63 (20.5)
Serious adverse event – n (%)	76 (12.2)	61 (9.8)	47 (15.3)	35 (11.4)
Fatal adverse event – n (%)	7 (1.1)	-	9 (2.9)	-
Major adverse cardiovascular event – n (%)†	18 (2.9)	8 (1.3)	19 (6.2)	4 (1.3)

*Shown are the numbers of patients with an event, rather than the number of events. Adverse events were evaluated with the use of MedDRA, version 22.0, and graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.
†Search criteria included "myocardial infarction" (broad standardized MedDRA query), "central nervous system hemorrhages and cerebrovascular conditions" (broad standardized MedDRA query), and deaths from any cause.

- Major adverse cardiovascular events were defined as nonfatal myocardial infarction, nonfatal stroke, and all-cause death[2]
- In a separate analysis reported in the US Prescribing Information, fatal and nonfatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX. Fatal adverse events, excluding prostate cancer–related deaths, were reported in 0.8% of patients receiving ORGOVYX and 2.3% of patients receiving leuprolide[1,3]

AMONG PATIENTS WHO RECEIVED ORGOVYX, 91% WERE EXPOSED FOR AT LEAST 48 WEEKS[1]

- 99 patients (16%) received concomitant radiotherapy and 17 patients (3%) received concomitant enzalutamide with ORGOVYX
- The most common adverse events during treatment with ORGOVYX (≥10%) in the study were hot flush, musculoskeletal pain, fatigue, constipation, and diarrhea

ADVERSE REACTIONS (≥10%) OF PATIENTS WITH ADVANCED PROSTATE CANCER WHO RECEIVED ORGOVYX IN HERO[1]				
ADVERSE REACTIONS	ORGOVYX (n=622)		Leuprolide (n=308)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
Hot flush	54%	0.6%	52%	0%
Musculoskeletal pain‡	30%	1.1%	29%	1.6%
Fatigue§	26%	0.3%	24%	0%
Diarrhea‖	12%	0.2%	7%	0%
Constipation	12%	0%	10%	0%

‡Includes arthralgia, back pain, pain in extremity, musculoskeletal pain, myalgia, bone pain, neck pain, arthritis, musculoskeletal stiffness, noncardiac chest pain, musculoskeletal chest pain, spinal pain, and musculoskeletal discomfort.
§Includes fatigue and asthenia.
‖Includes diarrhea and colitis.

- Most common laboratory abnormalities (≥15%, all grades) in patients receiving ORGOVYX vs leuprolide were glucose increased (44% vs 54%), triglycerides increased (35% vs 36%), hemoglobin decreased (28% vs 29%), alanine aminotransferase increased (27% vs 28%), and aspartate aminotransferase increased (18% vs 19%)

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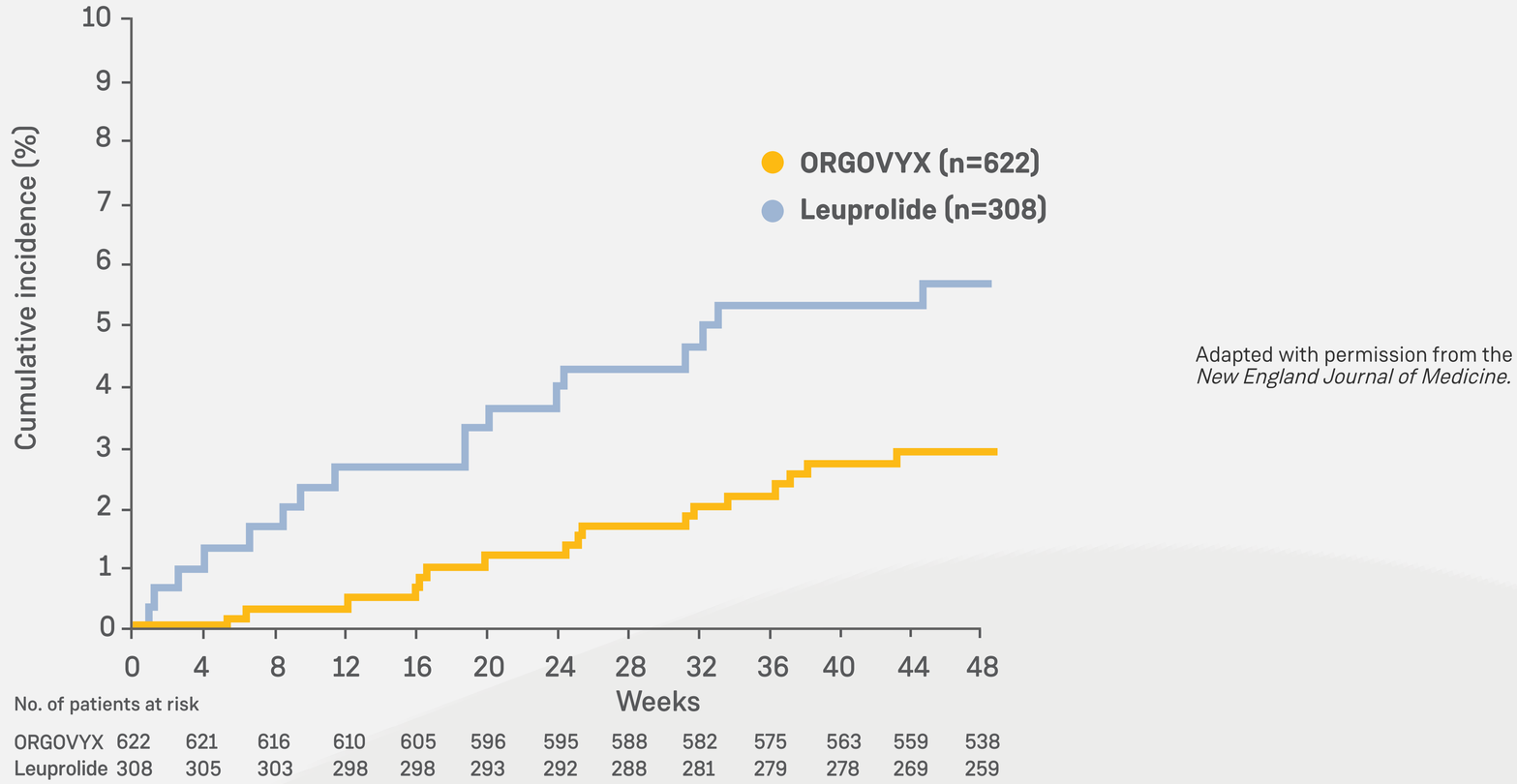
CARDIOVASCULAR EVENT DATA

Cumulative incidence of major adverse cardiovascular events through Week 48 in a post-hoc analysis[2,3]

- Major adverse cardiovascular events were defined as nonfatal myocardial infarction, nonfatal stroke, and all-cause death

CUMULATIVE INCIDENCE OF MAJOR ADVERSE CARDIOVASCULAR EVENTS[2]



Adapted with permission from the *New England Journal of Medicine.*

The incidence of major adverse cardiovascular events was a safety analysis. This was not a prospective efficacy endpoint in the study, the events were not adjudicated, and only descriptive analyses were performed. For these reasons, the FDA did not include the incidence of major adverse cardiovascular events for leuprolide in the label. The clinical benefit of major adverse cardiovascular events for ORGOVYX compared with leuprolide should be interpreted with caution and in this context.

CONSIDER CARDIOVASCULAR RISK FACTORS WHEN CHOOSING AN ANDROGEN DEPRIVATION THERAPY

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

ORGOVYX™ (relugolix) 120 mg tablets

ORAL DOSING

One pill, once a day, fits into men's lives[1,2]

- The only androgen deprivation therapy that offers **convenient, injection-free administration**
- Mean effective half-life of ORGOVYX is 25 hours

FIRST DAY OF TREATMENT
- Take 3 pills
- 360 mg loading dose

EVERY DAY AFTER THAT
- Take 1 pill
- 120 mg daily dose

Pills not shown at actual size. Actual size: 10.7 mm x 7.5 mm x 5.2 mm.[3]

After the initial loading dose, patients take one pill, once a day[1]

Can be taken with or without food

Should be taken around the same time each day

For oral administration only—should be swallowed whole, not crushed or chewed

- In patients treated with GnRH receptor agonists and antagonists for prostate cancer, treatment is usually continued upon development of nonmetastatic or metastatic castration-resistant prostate cancer
- No dosage adjustment required in patients with mild to severe renal impairment or mild or moderate hepatic impairment*
- Advise patients to take a missed dose of ORGOVYX as soon as they remember. If the dose was missed by more than 12 hours, patients should not take the missed dose and resume with the next scheduled dose
- Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first and separate dosing by at least 6 hours. Treatment with ORGOVYX may be interrupted for up to 2 weeks if a short course of treatment with a P-gp inhibitor is required
- If treatment with ORGOVYX is interrupted for more than 7 days, resume administration of ORGOVYX with a 360 mg loading dose on the first day, followed by 120 mg once a day
- Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once a day. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg

PRESCRIBE ONCE-A-DAY ORAL ORGOVYX FOR INJECTION-FREE ADMINISTRATION

*The effect of end-stage renal disease with or without hemodialysis or severe hepatic impairment on the pharmacokinetics of ORGOVYX has not been evaluated.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Serious adverse reactions occurred in 12% of patients receiving ORGOVYX. Serious adverse reactions in ≥0.5% of patients included myocardial infarction (0.8%), acute kidney injury (0.6%), arrhythmia (0.6%), hemorrhage (0.6%), and urinary tract infection (0.5%). Fatal adverse reactions occurred in 0.8% of patients receiving ORGOVYX including metastatic lung cancer (0.3%), myocardial infarction (0.3%), and acute kidney injury (0.2%). Fatal and non-fatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

ORGOVYX™ (relugolix) 120 mg tablets

PATIENT SUPPORT

Support to help your patients get started and stay on track

We are dedicated to providing your patients with ongoing support to help them start and continue taking ORGOVYX as prescribed. We know how important it is for patients to stay on track while on treatment. We're here to help.

Reimbursement Support

We can help assist your patients with access challenges. This includes **benefits investigation** on patients' insurance coverage, **prior authorization** through CoverMyMeds®, and **appeals support**

ORGOVYX Free Trial Program

Eligible patients who are new to ORGOVYX **get up to a 2-month supply** of medication at no cost*

Financial Assistance

We offer options to help your eligible patients afford their treatment, including **copay assistance** for commercially insured patients for as little as $10 per month*

ORGOVYX Bridge Program

Eligible commercially insured patients who are experiencing coverage issues can receive **ORGOVYX at no cost for a limited period of time***

Nurse Support

We are here to support your enrolled patients with check-in calls to help answer their questions about treatment

ORGOVYX Education

We provide **educational resources** to support your patients **throughout their treatment**

*Please see page 20 for the full Terms and Conditions for the ORGOVYX Free Trial Program, ORGOVYX Copay Assistance Program, and ORGOVYX Bridge Program.

ORGOVYX™ SUPPORT PROGRAM

For more information, call toll free 1-833-ORGOVYX (1-833-674-6899), Monday-Friday, 8 AM-8 PM ET or visit orgovyxhcp.com

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

ORGOVYX™ (relugolix) 120 mg tablets

ORAL ORGOVYX FOR ANDROGEN DEPRIVATION THERAPY IN ADVANCED PROSTATE CANCER[1,2]

- **ONCE-A-DAY ORAL DOSING** for injection-free administration
- **SUSTAINED EFFECTIVE SUPPRESSION** of testosterone in **97%** of men
  - Achieved and maintained testosterone suppression to <50 ng/dL from Day 29 through Week 48
- **RAPIDLY SUPPRESSED TESTOSTERONE** with no surge
  - On Day 4, **56%** of men achieved testosterone suppression to <50 ng/dL
- **TESTOSTERONE RECOVERY** 90 days after discontinuation
  - In a substudy, **55%** of 137 men who received ORGOVYX had their testosterone return to above the lower limit of the normal range (>280 ng/dL) or baseline values
- Safety profile includes the evaluation of **MAJOR ADVERSE CARDIOVASCULAR EVENTS**
- The **MOST COMMON ADVERSE EVENTS** during treatment with ORGOVYX (≥10%) in the study were hot flush, musculoskeletal pain, fatigue, constipation, and diarrhea

Bottle and pill not shown at actual size. Actual pill size: 10.7 mm x 7.5 mm x 5.2 mm.[3]

THINK ORAL ORGOVYX WHEN CHOOSING ANDROGEN DEPRIVATION THERAPY FOR YOUR PATIENTS

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

Most common adverse reactions (≥10%) and laboratory abnormalities (≥15%) in patients receiving ORGOVYX were hot flush (54%), glucose increased (44%), triglycerides increased (35%), musculoskeletal pain (30%), hemoglobin decreased (28%), alanine aminotransferase increased (27%), fatigue (26%), aspartate aminotransferase increased (18%), constipation (12%), and diarrhea (12%).

INDICATION

ORGOVYX is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

ORGOVYX™ (relugolix) 120 mg tablets

IMPORTANT SAFETY INFORMATION

INDICATION

ORGOVYX is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

QT/QTc Interval Prolongation: Androgen deprivation therapy, such as ORGOVYX may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

Embryo-Fetal Toxicity: The safety and efficacy of ORGOVYX have not been established in females. Based on findings in animals and mechanism of action, ORGOVYX can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of ORGOVYX

Laboratory Testing: Therapy with ORGOVYX results in suppression of the pituitary gonadal system. Results of diagnostic tests of the pituitary gonadotropic and gonadal functions conducted during and after ORGOVYX may be affected. The therapeutic effect of ORGOVYX should be monitored by measuring serum concentrations of prostate-specific antigen (PSA) periodically. If PSA increases, serum concentrations of testosterone should be measured.

Adverse Reactions

Serious adverse reactions occurred in 12% of patients receiving ORGOVYX. Serious adverse reactions in ≥0.5% of patients included myocardial infarction (0.8%), acute kidney injury (0.6%), arrhythmia (0.6%), hemorrhage (0.6%), and urinary tract infection (0.5%). Fatal adverse reactions occurred in 0.8% of patients receiving ORGOVYX including metastatic lung cancer (0.3%), myocardial infarction (0.3%), and acute kidney injury (0.2%). Fatal and non-fatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX.

Most common adverse reactions (≥10%) and laboratory abnormalities (≥15%) in patients receiving ORGOVYX were hot flush (54%), glucose increased (44%), triglycerides increased (35%), musculoskeletal pain (30%), hemoglobin decreased (28%), alanine aminotransferase increased (27%), fatigue (26%), aspartate aminotransferase increased (18%), constipation (12%), and diarrhea (12%).

Drug Interactions

Co-administration of ORGOVYX with a P-gp inhibitor increases the area under the curve (AUC) and maximum concentration (C_{max}) of ORGOVYX, which may increase the risk of adverse reactions associated with ORGOVYX. Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions. Treatment with ORGOVYX may be interrupted for up to 2 weeks for a short course of treatment with certain P-gp inhibitors. If treatment with ORGOVYX is interrupted for more than 7 days, resume administration of ORGOVYX with a 360 mg loading dose on the first day, followed by 120 mg once daily.

Co-administration of ORGOVYX with a combined P-gp and strong CYP3A inducer decreases the AUC and C_{max} of ORGOVYX, which may reduce the effects of ORGOVYX. Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg once daily.

Please see full Prescribing Information for ORGOVYX.

ORGOVYX™ (relugolix) 120 mg tablets

ORGOVYX Free Trial Program Terms and Conditions

The ORGOVYX Free Trial Program (FTP) provides an up to 2-month supply of ORGOVYX at no cost to patients who meet FTP eligibility requirements and who agree to the FTP terms and conditions by submitting a signed FTP enrollment form. (i) FTP is a free trial offer, intended solely to allow new patients to try ORGOVYX and to determine with their healthcare provider whether ORGOVYX is right for them. There is no obligation to continue use of ORGOVYX after the free trial has been completed; (ii) to be eligible, patient must: (1) reside in the United States or Puerto Rico and (2) be a new patient not currently using ORGOVYX or who previously received ORGOVYX through the FTP; (iii) ORGOVYX supplied through the FTP will be dispensed only through a pharmacy designated by Myovant Sciences up to the limits above; (iv) product may only be delivered to the patient's home address (no P.O. boxes) or the prescribing healthcare provider's office; (v) it is unlawful for any person to sell, purchase, trade, barter or export ORGOVYX supplied through the FTP or make an offer to do so; (vi) ORGOVYX supplied through the FTP may not be billed (in whole or part, directly or indirectly) to any patient or third-party payer, including Medicare, Medicaid and commercial insurance plans; (vii) Myovant Sciences reserves the right to change or discontinue the FTP at any time without notice; (viii) the FTP is not health insurance; (ix) the FTP is not a discount, rebate, coupon, cost-sharing program or other form of financial assistance and no portion of the value of the FTP product may count as a patient out-of-pocket expense under any health insurance program; (x) ORGOVYX supplied free of charge through the FTP is not contingent on continued use of ORGOVYX. To continue a patient on therapy, a separate prescription must be written by the healthcare provider; (xi) the FTP is void where prohibited by law and where use is prohibited by the patient's insurance provider.

ORGOVYX Copay Assistance Program Terms and Conditions

The ORGOVYX Copay Assistance Program ("Program") is for eligible patients with commercial prescription insurance for ORGOVYX. The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. Patient must be a resident of the U.S., Puerto Rico, or U.S. Territories. This Program is void where prohibited by state law. Certain rules and restrictions apply. This card is not insurance. This offer cannot be combined with any other coupon, free trial, discount, prescription savings card, or other offer. Patient and participating pharmacists agree not to seek reimbursement for all or any part of the benefit received by the patient through this Program. Patient and participating pharmacists agree to report the receipt of Program benefits to any insurer or other third party who pays for or reimburses any part of the prescription filled using the Card, as may be required by such insurer or third party. Myovant reserves the right to revoke, rescind, or amend this offer without notice. The Program has no control over the decisions made by, and does not guarantee support from, independent third parties.

ORGOVYX Bridge Program Terms and Conditions

The ORGOVYX Bridge Program ("Program") provides ORGOVYX at no cost for a limited period (up to 4 months) to eligible, commercially-insured patients whose insurance coverage is delayed or who experience a temporary lapse in coverage. This Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government insurance, or any state patient or pharmaceutical assistance program. Prescribers must complete the Bridge prescription on the start form. By participating, patient acknowledges intent to pursue insurance coverage for ORGOVYX with their health care provider. Program requires the submission of a request for coverage within 9 months post-Program initiation in order to remain eligible. Patients will receive their maintenance drug supply each month for up to 12 months or until they receive insurance coverage approval, whichever occurs earlier. Program is not available to patients who are uninsured or where prohibited by law. Patients may be asked to reverify insurance coverage status during the course of the Program. Patient and participating prescribers agree not to seek reimbursement for all or any part of the benefit received by the patient through this Program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Myovant Sciences reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

References: 1. ORGOVYX (relugolix) [prescribing information]. Brisbane, CA: Myovant Sciences, Inc.; 2020. **2.** Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. *N Engl J Med*. 2020;382(23): 2187-2196 and supplementary material, available online. **3.** Data on file. Myovant Sciences, Inc. **4.** Reyes C, Groshel C, Given R. Androgen deprivation therapy. In: Trabulsi EJ, Lallas CD, Lizardi-Calvaresi AE, eds. *Chemotherapy and Immunotherapy in Urologic Oncology: A Guide for the Advanced Practice Provider*. Springer International Publishing; 2021:77-92. **5.** US Food and Drug Administration. FDA drug safety communication: update to ongoing safety review of GnRH agonists and notification to manufacturers of GnRH agonists to add new safety information to labeling regarding increased risk of diabetes and certain cardiovascular diseases. October 20, 2010. Accessed October 6, 2020. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-update-ongoing-safety-review-gnrh-agonists-and-notification. **6.** Davis MK, Rajala JL, Tyldesley S, Pickles T, Virani S. The prevalence of cardiac risk factors in men with localized prostate cancer undergoing androgen deprivation therapy in British Columbia, Canada. *J Oncol*. 2015;2015:820403. **7.** Leong DP, Fradet V, Shayegan B, et al. Cardiovascular risk in men with prostate cancer: insights from the RADICAL PC study. *J Urol*. 2020;203(6):1109-1116. **8.** Crawford ED, Heidenreich A, Lawrentschuk N, et al. Androgen-targeted therapy in men with prostate cancer: evolving practice and future considerations. *Prostate Cancer Prostatic Dis*. 2019;22(1):24-38. **9.** Nascimento B, Miranda EP, Jenkins LC, Benfante N, Schofield EA, Mulhall JP. Testosterone recovery profiles after cessation of androgen deprivation therapy for prostate cancer. *J Sex Med*. 2019;16(6):872-879. **10.** Crawford ED, Twardowski PW, Concepcion RS, et al. The impact of late luteinizing hormone-releasing hormone agonist dosing on testosterone suppression in patients with prostate cancer: an analysis of United States clinical data. *J Urol*. 2020;203(4):743-750. **13.** Lowrance WT, Breau RH, Chou R, et al. Advanced prostate cancer: AUA/ASTRO/SUO guideline part I. *J Urol*. 2021;205:(1)14-21. **14.** Lowrance WT, Breau RH, Chou R, et al. Advanced prostate cancer: AUA/ASTRO/SUO guideline part II. *J Urol*. 2021;205:(1)22-29. **15.** Shore ND, Saad F, Cookson MS, et al. HERO phase 3 trial: results comparing relugolix, an oral GnRH receptor antagonist, versus leuprolide acetate for advanced prostate cancer. Presented at: American Society of Clinical Oncology Virtual Scientific Program; May 29-June 2, 2020; virtual. Abstract 5602.

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