DIVE INTO THE ORGOVYX® DATA

NEW

Pr ORGOVYX® (relugolix) 120 mg tablets

ORGOVYX® (relugolix tablets, 120 mg) is indicated for the treatment of adult patients with advanced prostate cancer.[1]

THE FIRST AND ONLY ORAL ADT INDICATED IN ADVANCED PROSTATE CANCER*[2]

*Comparative clinical significance has not been established.

CONVENIENT, ONCE-DAILY DOSING WITH ORGOVYX®

Day 1	 **3 x 120 mg** (loading dose)
Every day after that	 **1 x 120 mg**

Treatment is usually continued upon development of nmCRPC or mCRPC.

Adapted from the Product Monograph.[1]

DOSING CONSIDERATIONS

- ORGOVYX® does not cause an increase in testosterone concentrations (clinical flare).
  - Therefore, it is not necessary to add an anti-androgen as mitigation to avoid the clinical flare after initiation of therapy.
- ORGOVYX® can be taken with or without food.
- Take ORGOVYX® at approximately the same time each day.
- Instruct patients to swallow tablets whole and not to crush or chew tablets.

For complete dosing and administration instructions, please refer to the ORGOVYX® Product Monograph.

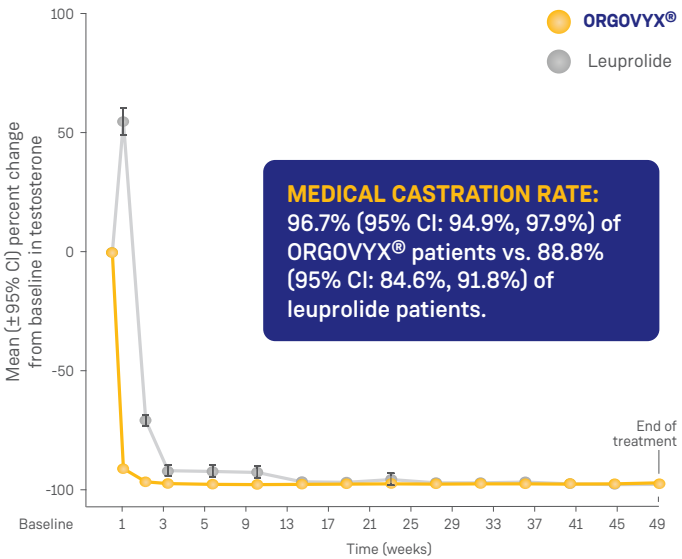
ADT: androgen deprivation therapy;
ECG: electrocardiogram; nmCRPC: nonmetastatic castration-resistant prostate cancer; P-gp: P-glycoprotein; mCRPC: metastatic castration-resistant prostate cancer

ORGOVYX® (relugolix) 120 mg tablets

EFFICACY DATA FROM HERO, AN OPEN-LABEL STUDY OF ORGOVYX® IN ADVANCED PROSTATE CANCER PATIENTS

MEDICAL CASTRATION RATE (DEFINED AS ACHIEVING AND MAINTAINING TESTOSTERONE SUPPRESSION < 50 ng/dL) FROM DAY 29 THROUGH WEEK 48 (PRIMARY ENDPOINT)†,1

Mean percent change from baseline in testosterone concentration



Evaluable patients, n

ORGOVYX®	605	599	606	599	594	588	587	584	580	569	561	557	554	547
Leuprolide	292	293	295	294	293	289	291	283	275	275	274	268	263	257

Adapted from the Product Monograph.[1]

CI: confidence interval

†HERO: A Phase 3, multinational, randomized, open-label, parallel-group study comparing ORGOVYX® (n=622) to leuprolide (n=308) in adult men with androgen-sensitive advanced prostate cancer requiring at least 1 year of ADT. Patients were randomized 2:1 to receive ORGOVYX® (120 mg once daily after a single oral loading dose of 360 mg) or leuprolide acetate (22.5 mg [or 11.25 mg in Japan or Taiwan]) injection subcutaneously every 3 months. Leuprolide acetate 11.25 mg is a dosage regimen that is not recommended for this indication in Canada. The primary efficacy outcome measure was medical castration rate, defined as achieving and maintaining serum testosterone suppression to castrate levels (< 50 ng/dL) by Day 29 through 48 weeks of treatment.[3]

CUMULATIVE PROBABILITY OF TESTOSTERONE SUPPRESSION ON DAY 15†,1

Secondary endpoint

	ORGOVYX®	Leuprolide
Testosterone suppression prior to Day 15 dose (< 50 ng/dL)	**98.7%** of ORGOVYX® patients (n=622)	**12.1%** of leuprolide patients (n=308)
Testosterone suppression prior to Day 15 dose (< 20 ng/dL)	**78.4%** of ORGOVYX® patients (n=622)	**1.0%** of leuprolide patients (n=308)

Adapted from the Product Monograph.[1]

DESCRIPTIVE ANALYSIS: CUMULATIVE PROBABILITY OF TESTOSTERONE RECOVERY (> 280 ng/dL) (n=184)1

- Evaluated in a subset of patients who completed 48 weeks of treatment and were not offered alternative ADT upon completion for at least 90 days after discontinuation of either arm.

ORGOVYX®	Leuprolide
53.93% of ORGOVYX® patients	**3.23%** of leuprolide patients

Adapted from the Product Monograph.[1]

COMPARISON OF SELECT TREATMENT OPTIONS IN ADVANCED PROSTATE CANCER[1,4-6]

Product	ORGOVYX® (relugolix)	LUPRON® DEPOT (leuprolide acetate)	ELIGARD® (leuprolide acetate)	FIRMAGON® (degarelix)
Therapeutic classification	GnRH receptor antagonist	GnRH analog	LHRH analog	GnRH receptor antagonist
Mode of administration	Oral	Intramuscular injection	Subcutaneous injection	Subcutaneous injection
Dosing	**Day 1:** 3 x 120 mg (loading dose) **Every day after:** 1 x 120 mg	7.5 mg every month OR 22.5 mg every 3 months OR 30 mg every 4 months	7.5 mg every month OR 22.5 mg every 3 months OR 30 mg every 4 months OR 45 mg every 6 months	**Starting dose:** 240 mg given as 2 injections of 120 mg (concentration of 40 mg/mL) **Monthly maintenance dose:** 80 mg given as 1 injection (concentration of 20 mg/mL)

Data from separate product monographs; comparative clinical significance has not been proven.

GnRH: gonadotropin-releasing hormone; LHRH: luteinizing hormone-releasing hormone

SAFETY INFORMATION[1]

Clinical use:

Safety and efficacy have not been established in pediatrics (< 18 years of age).

Most serious warnings and precautions:

- **QT prolongation**

Relevant warnings and precautions:

- Co-administration with an oral P-gp inhibitor or a combined P-gp and strong cytochrome P450 (CYP) 3A inducer
- ADT can prolong the QT interval
- Therapy results in suppression of the pituitary gonadal system
- Tests of pituitary gonadotropic and gonadal functions conducted during and after therapy may be affected
- Monitor prostate-specific antigen (PSA) levels; if PSA increases, measure serum testosterone concentrations
- Consider periodic monitoring of ECG and serum electrolyte levels for those at risk for QTc prolongation and electrolyte abnormality
- Risk of decreased bone density with use of GnRH receptor agonist or antagonist
- Men and women of reproductive potential should use contraception during treatment and for 2 weeks after the last dose
- May impair fertility in males of reproductive potential

For more information:

Consult the Product Monograph at https://www.ca.sumitomo-pharma.com/assets/files/monographs/orgovyx.pdf for important information relating to adverse reactions, drug interactions, and dosing that has not been discussed in this piece. The Product Monograph is also available by calling 1-866-260-6291.

VISIT ORGOVYX.CA FOR MORE INFORMATION!

References: 1. ORGOVYX® Product Monograph. Sumitomo Pharma Switzerland GmbH. October 30, 2023. **2.** Data on file – first and only. Sumitomo Pharma Canada, Inc. December 6, 2023. **3.** Shore ND et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. *N Engl J Med*. 2020;382(32):2187–2196. **4.** LUPRON® DEPOT Product Monograph. AbbVie Corporation. March 30, 2023. **5.** ELIGARD® Product Monograph. Tolmar International Ltd. September 20, 2023. **6.** FIRMAGON® Product Monograph. Ferring Pharmaceuticals. March 18, 2016.

Sumitomo Pharma