



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
EMA/111169/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Orgovyx relugolix

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Orgovyx, intended for the treatment of prostate cancer.

The applicant for this medicinal product is Myovant Sciences Ireland Limited.

Orgovyx will be available as 120 mg film-coated tablets. The active substance of Orgovyx is relugolix, a hormone antagonist (ATC code: L02BX04) that competitively binds to gonadotropin-releasing hormone (GnRH) receptors in the anterior pituitary gland, preventing native GnRH from binding. This reduces the secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), causing a reduction in the production of testosterone from the testes.

The benefits of Orgovyx are a medical castration rate of 96.7% compared with 88.8% in the control arm as observed in a randomised, open-label study in adult men with androgen-sensitive advanced prostate cancer. The most common side effects are hot flushes, musculoskeletal pain, fatigue, diarrhoea and constipation.

The full indication is:

Orgovyx is indicated for the treatment of adult patients with advanced hormone-sensitive prostate cancer.

Orgovyx should be initiated and supervised by specialist physicians experienced in the medical treatment of prostate cancer.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

