# Real World Utilization of Androgen Deprivation Therapy Among Urology Practices: Characterizing Initiation and Transition to Relugolix for Patients with Prostate Cancer (The REAL ADT Transitions Study)

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## Introduction

- Relugolix was FDA approved in December 2020 as the first oral gonadotropin releasing hormone (GnRH) receptor antagonist to treat advanced prostate cancer and became commercially available in January 2021[1-2]
  - The approval was based on the HERO study, a randomized, open label trial involving 934 men requiring at least one year of androgen deprivation therapy (ADT)[3]
  - In the HERO study, patients were randomized (2:1) to receive relugolix 360 mg oral loading dose on the first day, followed by daily oral doses of 120 mg, or leuprolide acetate 22.5 mg injection subcutaneously every 3 months for 48 weeks[3]
    - In this pivotal trial, relugolix demonstrated suppression of testosterone to castrate levels in 96.7% of patients (day 29-48 weeks), which was superior to leuprolide (P<0.0001)
    - A 54% lower risk of major adverse cardiovascular events (MACE), defined as non-fatal myocardial infarction, non-fatal stroke, and death from any cause, was observed for relugolix relative to leuprolide
- Previous studies have documented transitions between injectable GnRH agonists and antagonists
- This study examined the real-world utilization of relugolix during its first year of availability (January – December 2021) and documented transitions between injectable and oral androgen deprivation therapy (ADT)

## Methods

- An observational retrospective analysis was conducted using de-identified electronic medical records
- PPS Analytics Electronic Medical Record (EMR) data from 536,539 patients representing 89 community urology practices in the United States were analyzed
- Patients with at least one record for ADT in 2021 were included
- Excluded from the analysis were patients whose ADT initiation date could not be determined
- Results were stratified by drug class and initiator status, where new initiators were defined as patients with no exposure to ADT in the prior 180 days
- Analysis of transitions between ADTs included patients with only 1 transition

## Results

- In 2021, 51,735 patients, mean age 73.0 (standard deviation [SD]:8.5) years, were prescribed ADT
  - Most were continuing users (29,867 [57.7%]) and were prescribed a GnRH agonist (46,368 [89.6%])
  - Of these patients, 3,096 were prescribed relugolix



## Results *(continued)*

- Baseline characteristics for patients prescribed relugolix are shown in **Table 1**
  - Mean ages (SD) were 72.3 (8.6), 73.2 (8.7), and 71.2 (10.4) years in the only relugolix, transition to relugolix, and transition from relugolix groups, respectively
  - Patients transitioned to relugolix from another ADT were more likely to have metastatic disease (51.1%) than patients who received only relugolix (29.6%) and those who transitioned from relugolix to another ADT (33.7%)

### Table 1. Baseline Characteristics

| Patient Characteristics | Only Relugolix N = 1855 | Transition *to* Relugolix from another ADT n = 881 | Transition *from* Relugolix to another ADT n = 205 |
|---|---|---|---|
| **Demographic** | | | |
| **Age, mean (SD) in years** | 72.3 (8.6) | 73.2 (8.7) | 71.2 (10.4) |
| **Race/Ethnicity, n (%)** | | | |
| Black/African American | 287 (15.5%) | 117 (13.3%) | 37 (18.0%) |
| White/Caucasian | 1229 (66.3%) | 605 (68.7%) | 126 (61.5%) |
| Others/Missing | 339 (18.3%) | 159 (18.0%) | 42 (20.5%) |
| **Insurer Type, n (%)** | | | |
| Commercial | 907 (48.9%) | 392 (44.5%) | 110 (53.7%) |
| Medicare | 948 (51.1%) | 489 (55.5%) | 95 (46.3%) |
| **Clinical** | | | |
| **Radiation Therapy in 2021, n (%)** | 871 (47.0%) | 364 (41.3%) | 101 (49.3%) |
| **Metastatic Disease,* n (%)** | 549 (29.6%) | 459 (52.1%) | 69 (33.7%) |

* Database has 2 variables, metastatic confirmed and metastatic possible. Both are included in this count.
ADT, androgen deprivation therapy. SD, standard deviation.

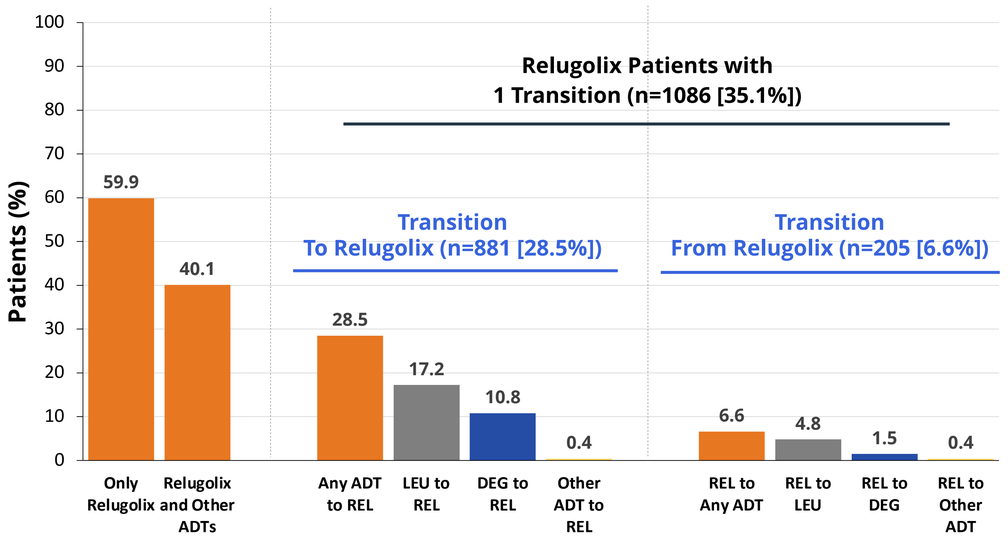
- Over a third of the patients prescribed relugolix (1241 [40.1]%) had exposure to at least one injectable ADT in 2021 (**Table 2** and **Figure 1**)
- Relugolix transitions to and from other ADTs are summarized in **Figure 1**
- Overall, 28.5% transitioned to relugolix; 534 (17.2%) from leuprolide and 335 (10.8% from degarelix)
- Conversely, 148 (4.8%) patients transitioned from relugolix to leuprolide and and 46 (1.5%) to degarelix

### Table 2. Relugolix Utilization, ADT Transitions and Mean Prescriptions

| 2021 | Patient Count | Patient % | Mean # Relugolix Prescriptions |
|---|---|---|---|
| **Patients on relugolix** | 3096 | | |
| Patients treated only with relugolix (no ADT Transition) | 1855 | 59.9% | **2.95** |
| Patients treated with relugolix and other ADTs (pre or post) | 1241 | 40.1% | |
| With 1 transition | 1086 | 35.1% | |
| **From other ADTs to relugolix** | 881 | 28.5% | |
| Leuprolide to relugolix | 534 | 17.2% | **3.2** |
| Degarelix to relugolix | 335 | 10.8% | **3.54** |
| Other ADT to relugolix | 12 | 0.4% | **2.5** |
| **From relugolix to other ADTs** | 205 | 6.6% | |
| Relugolix to leuprolide | 148 | 4.8% | **1.41** |
| Relugolix to degarelix | 46 | 1.5% | **1.95** |
| Relugolix to others | 11 | 0.4% | **1.82** |
| With > 1 transition between products | 155 | | |

ADT, androgen deprivation therapy.

### Figure 1. Relugolix Utilization and ADT Transitions




ADT, androgen deprivation therapy. DEG, degarelix. LEU, leuprolide. REL, relugolix.

## Conclusions

- This descriptive analysis of the first year of novel oral GnRH receptor antagonist availability showed that most relugolix utilization was observed in patients who were new to ADT in 2021
- Patients transitioning to relugolix from another ADT were more likely to have metastatic disease than patients who received only relugolix or those who transitioned from relugolix to another ADT
- The most frequent transitions were from leuprolide to relugolix

### References / Acknowledgements

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