



## What do these results mean for individuals with high-risk localized or locally advanced prostate cancer?

- Treatment with apalutamide alongside standard hormone therapy before and after prostate surgery helps to shrink aggressive prostate cancer before surgery, reduce the risk of the cancer spreading or coming back, and improve long-term outcomes



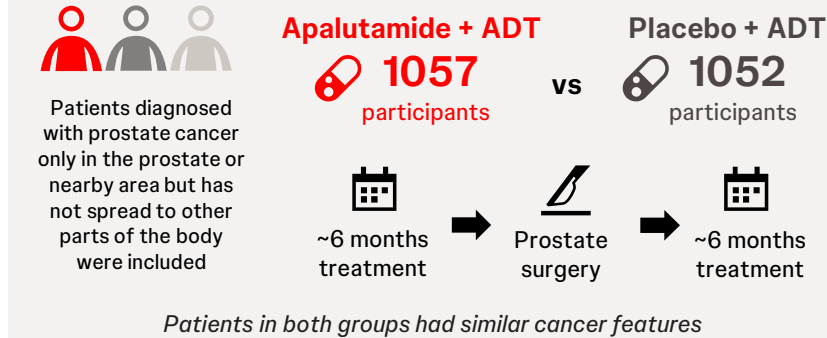
### What was the purpose of this study?

- Researchers wanted to see if adding apalutamide to standard hormone reduction therapy (ADT) before and after prostate surgery can improve outcomes for patients with high-risk localized or locally advanced prostate cancer



### Who was in the study and how was it carried out?

- The PROTEUS study (NCT03767244) was carried out by randomly assigning patients to one of two groups: one group received apalutamide plus ADT and the other received a placebo plus ADT
- Both groups were treated for around (~) 6 months before prostate removal surgery (to shrink the tumor before surgery) and ~6 months after surgery (to help prevent the cancer from returning)



#### Primary objectives:

- To evaluate whether apalutamide can 1) eliminate or shrink the cancer before surgery and 2) reduce the risk of the cancer spreading

#### Other key secondary objectives:

- How long patients stay free from signs that the cancer has come back, spread, or caused death
- How long until patients need another prostate cancer treatment
- Safety



**61.7 months** Median time patients continue study follow-up visits after starting treatment

# Perioperative apalutamide in high-risk localized prostate cancer

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## What were the results?

### Treatment with apalutamide + ADT before and after surgery improved cancer outcomes and increased the chances of a successful surgery compared with placebo + ADT



~9x

Increased percentage of patients having **no cancer or only a very small amount of cancer** detected in the prostate **at time of surgery** (≤5 mm)



20%

Decreased risk of **cancer spreading** to other parts of the body or death



29%

Decreased risk of **cancer returning** to the prostate, spreading to other parts of the body, or death



35%

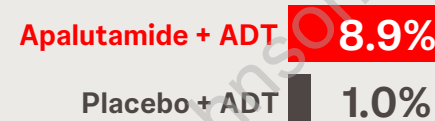
Decreased risk of receiving a **subsequent treatment** for prostate cancer



3.6%

Increased percentage of patients with **no evidence of prostate cancer 4 years** after treatment

Percentage of patients with a treatment response detected at time of surgery



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### Side effects with apalutamide + ADT were generally not difficult to treat and consistent with those observed in previous studies

Percentage of patients that experienced side effects over one year of treatment were similar in both groups, except for rash

Percentage of patients who experienced at least one severe side effect related to treatment (Grade 3 or above)

27.5%

Apalutamide + ADT

18.9%

Placebo + ADT

Higher rates of severe side effects in the apalutamide + ADT group were mainly due to more rash, which was graded by percentage of body surface affected, regardless of symptoms

Percentage of patients who reduced their dose because of side effects related to their treatment was low in both groups

11.2%

Apalutamide + ADT

2.3%

Placebo + ADT

### Glossary of terms

<b>ADT</b>	Androgen deprivation therapy, a treatment that lowers male hormones (like testosterone) to slow or stop prostate cancer growth.	<b>Grade</b>	A grading system from 1 to 5 used to describe the severity of a side effect. Side effects graded 1 or 2 are considered mild to moderate. Side effects graded 3 or above are considered serious and need immediate medical attention.	<b>Localized prostate cancer</b>	Prostate cancer that is only inside the prostate and has not spread to other parts of the body.
<b>Locally advanced prostate cancer</b>	Prostate cancer that has spread only to a nearby area but not to distant parts of the body.	<b>Median</b>	The middle number in a sequence of numbers ordered from lowest to highest.		