Clinical trial of **ARV-766**, a PROTAC androgen receptor degrader, in men with **metastatic castration-resistant prostate cancer**

This summary contains information from the scientific poster:

A phase 2 expansion study of ARV-766, a PROTAC androgen receptor degrader, in metastatic castration-resistant prostate cancer

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What is prostate cancer?

**Prostate cancer** is cancer of the prostate gland. **Male hormones (androgens)**, including testosterone, **stimulate cancer growth by binding androgen receptors** on prostate cancer cells

- **Castration-sensitive** prostate cancer is cancer that is controlled by keeping the testosterone level low (called the castrate level)

- **Castration-resistant** prostate cancer is cancer that is still growing even when the testosterone levels are at or below the castrate level

**Metastatic** prostate cancer is cancer that started in the prostate gland and has spread to other parts of the body

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What are the different types of treatments for metastatic prostate cancer?

- **Androgen-deprivation therapies** reduce the levels of androgens (that is, testosterone) made in the testicles. This may slow or stop the growth of castration-sensitive cancer

- Other hormone therapies, called **novel hormonal therapies**, work by either blocking testosterone production or by blocking the activity of testosterone on cancer cells. This may slow or stop cancer growth

- **Chemotherapy** is a treatment that damages cancer cells

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What is ARV-766?

ARV-766 is a drug that is being evaluated as a treatment for metastatic prostate cancer. It is a **PROteolysis TArgeting Chimera (PROTAC) androgen receptor degrader**

- PROTAC protein degraders are designed to bind specific proteins of interest in cells, which causes those proteins to be **marked for elimination** by a natural protein disposal system in the body

- ARV-766 works by **causing androgen receptors to be eliminated**, which blocks the activity of androgens and could potentially stop prostate tumors from growing or cause the tumors to shrink

The first part of a **clinical study** in men with metastatic castration-resistant prostate cancer evaluated the **safety and side effects of different doses of ARV-766**

- This information was used to select the doses of ARV-766 that would be evaluated in subsequent studies
This summary describes the second part of the clinical study.

Researchers are testing 2 doses of ARV-766 in men with metastatic castration-resistant prostate cancer whose cancer got worse during treatment with novel hormonal therapies.

The main aims of this study are to evaluate:
- If ARV-766 can cause tumors to stop growing or shrink
- If ARV-766 can lower prostate-specific antigen levels
- The side effects men who take ARV-766 may experience

WHO CAN PARTICIPATE IN THE STUDY?
- Adult men with metastatic castration-resistant prostate cancer who also
  - Were previously treated with 1–3 novel hormonal therapies
  - Had their cancer get worse during treatment with novel hormonal therapies
  - Are currently being treated with androgen-deprivation therapy or had their testicles removed
  - Are physically healthy and able to do regular daily activities

WHO CANNOT PARTICIPATE IN THE STUDY?
- Men who receive certain types of cancer treatments in the 2–6 weeks before the study treatment is scheduled to start
- Men who are treated with radiation in the 4 weeks before the study treatment is scheduled to start
- Men who have received a certain amount of radiation treatment to their bone marrow
- Men who were previously treated with more than 2 chemotherapy regimens

WHAT IS THE TREATMENT?
- Men will be assigned at random to receive 1 of 2 doses of ARV-766
- ARV-766 will be taken as pills by mouth every day

WHAT WILL BE MEASURED IN THE STUDY?
- Tumor size will be measured by scans to evaluate if ARV-766 treatment has any effect on slowing tumor growth or shrinking tumors
- The levels of prostate-specific antigen in the blood will be measured to see if they are reduced in men taking ARV-766
- The side effects experienced by men taking ARV-766
  - This includes any symptoms felt by the men who volunteer in the study, signs observed in the men by the investigators, or abnormalities that are detected in their blood samples

Who sponsored this study?
This study is sponsored by Arvinas Androgen Receptor, Inc.

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Where can I find more information?
For more information on this study, visit https://clinicaltrials.gov/ct2/about-studies/find

For more information on clinical studies in general, please visit https://www.clinicaltrials.gov/ct2/about-studies/learn

Prostate-specific antigen, or PSA, is a protein produced by prostate cancer cells as well as by normal prostate cells. The blood level of PSA is often elevated in men with prostate cancer and testing is used to monitor the progression of prostate cancer. If a man’s PSA level begins to rise after prostate cancer treatment, it may be the first sign that the cancer is getting worse/coming back.