All the men who participated experienced medical problems.*** PSA (prostate-specific antigen) is produced by the prostate, and PSA blood level is often elevated in men with prostate cancer. The level of PSA could have been caused by a study treatment, or by another medicine the participant was taking.

Who took part in this study?

DNA contains genetic information that regulates activity inside cancer cells. If cancer cells cannot repair their DNA, they will die. **This is often due to a faulty BRCA gene, but can also be due to faults in other DNA repair pathways.**

Talazoparib (TALA for short) is an investigational medicine (a medicine that is being tested) in combination with Enzalutamide (ENZA for short) to treat men with metastatic (advanced) castration-resistant prostate cancer (CRPC). CRPC is a type of prostate cancer that has not responded to treatment and will continue to grow, even with treatment. In certain cases, prostate cancer may not respond to treatment and will continue to grow. In this initial portion of the study, men with CRPC will receive either TALA with ENZA or ENZA alone, depending on the dose of TALA prescribed.

Nineteen men with mCRPC took part in this initial portion of a larger clinical study, which will look at 872 men in total. The researchers will use the lower dose of TALA + ENZA on its own. The researchers also looked at other specific medical problems. Seven men in group 1 experienced these medical problems. The most common medical problem was low levels of healthy red blood cells (anemia).

In the first part of this ongoing study, all 19 men experienced medical problems.*** The most common medical problem was anemia. In group 2, Pfizer reviewed the initial data and halved the dose of TALA for the rest of the men with mCRPC. The safety of TALA + ENZA was low levels of healthy red blood cells (anemia). The effects of adding talazoparib to ENZA were well-tolerated in men with mCRPC. ENZA is an approved chemotherapy treatment for men with mCRPC. It is known as chemical castration. Cazafem, in combination with ENZA, may help TALA to better prevent DNA repair mechanisms.

In this initial portion of a larger study, men with mCRPC who have PSA levels rising and who have not had previous PSA therapy will be eligible to participate. Participants may have received previous chemotherapy or hormone therapy but not a previous PSA therapy. The researchers believe that this study will help determine the most suitable dose of TALA + ENZA to use in combination with ENZA for men with mCRPC.

Who sponsored this study?

Pfizer would like to thank all of the men who took part in this study.

Phone (United States): +1 212-733-2323

235 East 42nd Street NY, 10041-0937

Pfizer Inc. 1

Further information

For more information on this study, please visit:

https://clinicaltrials.gov/ct2/show/NCT03485149

For more information on clinical studies in general, please visit:

https://clinicaltrials.gov/how/learn/studyTeam

https://www.fda.gov/medical-devices/how-do-i-know-if-a-medical-device-is-approved

Additional information about Pfizer Inc. and clinical studies are available at:

https://clinicaltrials.gov/ct2/show/NCT03485149

The clinical trial summary was written for Pfizer by Abstract Plain Language Writing Support Milena Wagner PhD and Peijia Jessica Yuan PhD, Buddhist Tzu Chi Foundation. The summary was reviewed by Pfizer. As the summary is a translation of the original, some differences may exist. **Please note that this summary only contains information from the full scientific summary.**

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