Newsletter

Prostate Cancer 101, Inc.

http://prostatecancer101.org

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The Prostate Cancer Information and Support Group of the Mid-Hudson

FDA Urges Caution with Robotically-Assisted Surgeries for Cancer

Surgical robots continue to be popular in the U.S., including for use in minimally-invasive radical prostatectomies to treat prostate cancer. Hospitals and surgical robot manufacturers continue to aggressively market the machines. However, on February 28, 2019, the U.S. Food and Drug Administration (FDA) released a statement saying that the agency has not evaluated or approved surgical robots for cancer prevention or treatment, and some studies have shown they lead to worse results for patients.*

"The relative benefits and risks of surgery using robotically-assisted surgical devices compared to conventional surgical approaches in cancer treatment have not been established," the safety communication said. The FDA noted that patients and physicians may not be aware that the safety and effectiveness of surgical robots has not yet been established for the prevention or treatment of cancer. The agency evaluates medical technology, but they do not regulate how it is used by medical professionals.

The FDA's evaluation of surgical robots has generally focused on comparing complication rates 30 days after surgeries. However, to evaluate surgical robots for cancer prevention and treatment, the FDA would need to evaluate specific clinical outcomes, such as local cancer recurrence, disease-free survival rates, and overall survival at time periods significantly longer than 30 days.

In a *New York Times* article on March 11, 2019, Roni Caryn Rabin wrote, "Robotic surgery was never approved for mastectomy or any other cancer-related treatment, but that has hardly deterred doctors in the operating suite. The equipment is widely used to operate on patients with various malignancies, from breast cancer to prostate cancer…. Now the Food and Drug Administration has warned that there is no evidence cancer patients receiving robotic procedures live longer than those who have traditional procedures. And some research shows that patients with cervical cancer fare worse."

"We want doctors and patients to be aware of the lack of evidence of safety and effectiveness for these uses so they can make better informed decisions about their cancer treatment and care."

– Terri Cornelison, M.D., Ph.D., assistant director for the health of women in the FDA's Center for Devices and Radiological Health

The FDA noted two studies that showed robotic-assisted surgeries led to worse long-term survival for patients with breast or cervical cancers who had mastectomies or hysterectomies using surgical robots. One of the trials was stopped early because women with cervical cancer who had minimally invasive hysterectomies were four times more likely to have recurrence and six times as likely to die, compared to patients who had underwent traditional hysterectomy.*

Dr. Pedro T. Ramirez, the lead author of this cervical cancer study, told the *New York Times* the trial's findings were especially noteworthy because radical hysterectomies usually cure cervical cancer. It is unclear why the minimally-invasive procedures led to

worse outcomes for cervical cancer patients. Dr. Ramirez suggested it could be that the instruments used in the robotic surgery could cause cancer cells to spread, or that carbon dioxide pumped into the abdomen during robotic and minimally invasive surgery could increase the possibility of cancer cells implanting.

The other study cited by the FDA in their statement found that 9% of women died four years after having minimally invasive surgery for cervical cancer, compared to 5% after traditional open hysterectomy.* Proponents of robotic surgery say that patients could have less pain, less blood loss, and shorter hospitals stays with the procedures. But Dr. Ramirez said in the *New York Times*, "If you tell a patient you may stay in the hospital one or two days longer versus going home the same day, but there is a higher likelihood your cancer is going to come back, what are you going to choose as a patient? Of course, you'll stay in the hospital."

Despite this evidence, many physicians and hospitals continue to recommend robotic surgery. However, as reported in Barron's and CBS News, some hospitals, including Dr. Ramirez's department at the University of Texas MD Anderson Cancer Center and Johns Hopkins Medicine in Maryland have stopped performing minimally-invasive surgery (including robot-assisted surgery) for cervical cancer, and instead have switched back to traditional open hysterectomies.

- See "Robotic Surgery Heightens Risk of Death for Cervical Cancer Patients" in the Winter 2018 QUEST and visit www.drcatalona.com for links to additional news coverage of this topic.
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Dr. Catalona's Opinion: For prostate cancer, we don't have long-term comparative data between open and robotic-assisted radical prostatectomies. With robotic prostatectomy, the surgeon has no sense of touch, and suturing is more difficult. This leads to more use of electrocautery, risking thermal damage to the nerves responsible for erections and to other structures, and I question whether the cancer is consistently completely removed as well.

Source URL: http://drcatalona.com/quest/spring-2019/article4.html

A to Z list of Cancer Drugs

https://www.cancer.gov/about-cancer/treatment/drugs?cid=eb_govdel

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Annual Report to the Nation: Overall cancer mortality continues to decline; Special section on adults ages 20 to 49 shows higher cancer incidence and mortality for women than men

The latest Annual Report to the Nation on the Status of Cancer finds that, for all cancer sites combined, cancer death rates continued to decline in men, women, and children in the United States from 1999 to 2016. Overall cancer incidence rates, or rates of new cancers, decreased in men from 2008 to 2015, after increasing from 1999 to 2008, and were stable in women from 1999 to 2015. In a special section of the report, researchers looked at cancer rates and trends in adults ages 20 to 49.

The annual report is a collaborative effort among the National Cancer Institute (NCI), part of the National Institutes of Health; the Centers for Disease Control and Prevention (CDC); the American Cancer Society (ACS); and the North American Association of Central Cancer Registries (NAACCR). The report appeared in the *Journal of the National Cancer Institute* on May 30, 2019.

"We are encouraged by the fact that this year's report continues to show declining cancer mortality for men, women, and children, as well as other indicators of progress," said Betsy A. Kohler, executive director of NAACCR. "There are also several findings that highlight the importance of continued research and cancer prevention efforts."

The special section shows a different picture for cancer incidence and mortality among men and women ages 20 to 49 than among people of all ages. In the main report, from 2011 to 2015, the average annual incidence rate for all cancer sites combined was about 1.2 times higher among men than among women, and from 2012 to 2016, the average annual death rate among men (all ages) was 1.4 times the rate among women. However, when the researchers looked only at men and women ages 20 to 49, they found that both incidence and death rates were higher among women.

The authors reported that, in the 20–49 age group from 2011 to 2015, the average annual incidence rate for all invasive cancers was 115.3 (per 100,000 people) among men, compared with 203.3 among women, with cancer incidence rates decreasing an average of 0.7% per year among men and increasing an average of 1.3% per year among women. During the period from 2012 to 2016, the average annual cancer death rate was 22.8 (per 100,000 people) among men and 27.1 among women in this age group.

The most common cancers and their incidence rates among women ages 20 to 49 were breast (73.2 per 100,000 people), thyroid (28.4), and melanoma of the skin (14.1), with breast cancer incidence far exceeding the incidence of any other cancer. The most common cancers among men ages 20 to 49 were colon and rectum (13.1), testis (10.7), and melanoma of the skin (9.8).

"The greater cancer burden among women than men ages 20 to 49 was a striking finding of this study," said Elizabeth Ward, Ph.D., lead author of the study and a consultant at NAACCR. "The high burden of breast cancer relative to other cancers in this age group reinforces the importance of research on prevention, early detection, and treatment of breast cancer in younger women."

In studying this age group, the authors also found that, from 2012 to 2016, death rates decreased 2.3% per year among men and 1.7% per year among women.

"It is important to recognize that cancer mortality rates are declining in the 20-to-49-year -old age group, and that the rates of decline among women in this age group are faster than those in older women," said Douglas R. Lowy, M.D.,

acting director of NCI.

The authors also reported in the special section that the incidence rates of in situ breast cancer and nonmalignant central nervous system tumors among women and men ages 20 to 49 are substantial. They wrote that some of the most frequent malignant and nonmalignant tumors that occur in this age group may be associated with considerable long-term and late effects related to the disease or its treatment. The authors conclude that access to timely and high-quality treatment and survivorship care is important to improve health outcomes and quality of life for younger adults diagnosed with cancer.

This year's report found that, among all ages combined, existing incidence and mortality trends for most types of cancer continue. Rates of new cases and deaths from lung, bladder, and larynx cancers continue to decrease as a result of long-term declines in tobacco smoking. In contrast, rates of new cases of cancers related to excess weight and physical inactivity—including uterine, postmenopausal breast, and colorectal (only in young adults)—have been increasing in recent decades.

Several notable changes in trends were observed in the report. After decades of increasing incidence, thyroid cancer incidence rates in women stabilized from 2013 to 2015. The authors wrote that this could be due to changes in diagnostic processes related to revisions in American Thyroid Association management guidelines for small thyroid nodules.

The report also shows rapid declines in death rates for melanoma of the skin in recent years. Death rates, which had been stable in men and decreasing slightly in women, showed an 8.5% decline per year from 2014 to 2016 in men and a 6.3% decline per year from 2013 to 2016 in women.

"The declines seen in mortality for melanoma of the skin are likely the result of the introduction of new therapies, including immune checkpoint inhibitors, that have improved survival for patients diagnosed with advanced melanoma," said J. Leonard Lichtenfeld, M.D., M.A.C.P., interim chief medical officer of ACS. "This rapid change shows us how important it is to continue working to find effective treatments for all kinds of cancer."

Other notable findings about cancer mortality from the report include that from 2012 to 2016:

- Overall death rates decreased 1.8% per year in men and 1.4% per year in women.
- Among men, death rates decreased for 10 of the 19 most common cancers but increased for 6 cancers, with the steepest increases for liver cancer, oral cavity and pharynx cancer, and non-melanoma skin cancer.

Among women, death rates decreased for 13 of the 20 most common cancers, including the 3 most common cancers (lung and bronchus, breast, and colorectal), but increased for 5 cancer types, with the steepest increases for cancers of the uterus and liver.

For cancer incidence, from 2011 to 2015:

- Incidence rates for all cancers combined were stable in women and decreased 2.1% per year in men.
- Among men, rates of new cancers decreased for 8 of the 17 most common cancers, increased for 7 cancers, and were stable for 2 cancers.

Among women, rates of new cancers decreased for 6 of the 18 most common cancers, increased for 9 cancers, and were stable for 3 cancers.

The report also shows continuing racial and ethnic disparities in cancer mortality and incidence. When data for people of all ages were combined and compared by sex, across racial and ethnic groups, black men and black women had the highest cancer death rates, both for all cancer sites combined and for about half of the most common cancers in men and women. Black men and white women had the highest overall cancer incidence rates, and Asian/Pacific Islander men and women had the lowest overall rates. Non-Hispanic men and women had higher overall incidence rates than Hispanic men and women.

"Major declines overall in cancer mortality point in the right direction, yet significant differences remain in cancer cases and deaths based on gender, ethnicity, and race," said CDC Director Robert R. Redfield, M.D. "A better understanding of these discrepancies improves cancer diagnosis and recovery for all patients and is vital to our public health mission."

For more about the report, see: https://seer.cancer.gov/report_to_nation/

About the North American Association of Central Cancer Registries (NAACCR): The North American Association of Central Cancer Registries, Inc., is a professional organization that develops and promotes uniform data standards for cancer registration; provides education and training; certifies population-based registries; aggregates and publishes data from central cancer registries; and promotes the use of cancer surveillance data and systems for cancer control and epidemiologic research, public health programs, and patient care to reduce the burden of cancer in North America. For more, see naaccr.orgExit Disclaimer.

About the National Cancer Institute (NCI): NCI leads the National Cancer Program and NIH's efforts to dramatically reduce the prevalence of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers. For more information about cancer, please visit the NCI website at cancer.gov or call NCI's contact center, the Cancer Information Service, at 1-800-4-CANCER (1-800-422-6237).

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit nih.gov.

About the Centers of Disease Control and Prevention (CDC): CDC works 24/7 protecting America's health, safety, and security. Whether diseases start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

About the American Cancer Society (ACS): ACS is a global grassroots force of 1.5 million volunteers dedicated to saving lives, celebrating lives, and leading the fight for a world without cancer. From breakthrough research, to free lodging near treatment, a 24/7/365 live helpline, free rides to treatment, and convening powerful activists to create awareness and impact, the Society is attacking cancer from every angle. For more information, go to www.cancer.orgExit Disclaimer.

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Xtandi, Zytiga Better for African-Americans Than Whites With Advanced Prostate Cancer, Research Finds

March 4, 2019 Marisa Wexler

African-Americans with metastatic castration-resistant prostate cancer live longer after treatment with the androgen inhibitors Zytiga (abiraterone acetate) or Xtandi (enzalutamide) than white men, a new study reports.

Historically, African-Americans diagnosed with prostate cancer have had worse survival outcomes than whites. The reasons for this are complex and likely involve a number of interconnected factors, from socioeconomic inequalities to genetic differences.

Yet, a new study suggests this disparity isn't present when comparing African-American and white men treated with Zytiga (by Janssen Oncology), or Xtandi (by Pfizer and Astellas). In fact, the opposite may be true. Both of these medicines target the production of androgens, which are hormones that often help drive prostate cancer growth.

The research was presented at the 2019 Genitourinary Cancers Symposium, a meeting of the American Society of Clinical Oncology (ASCO), under the title, "Overall survival by race in chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) patients treated with abiraterone acetate or enzalutamide."

The study retrospectively analyzed nearly 3,000 patients — about two-thirds of whom were white and one-third African American — with metastatic castration-resistant prostate cancer who had not received any prior chemotherapy for their condition.

Patients were treated for prostate cancer with either Zytiga or Xtandi from April 2013 to March 2018, and followed up with for an average of a year-and-a-half. The data from these patients was retrieved from the U.S. Veterans Health Administration database, and treatment outcomes were compared.

There were some differences between both racial groups: African-Americans were more likely to have high blood pressure, type 2 diabetes, and liver problems.

The average overall survival for African-Americans was 30 months, whereas the average overall survival for whites was only 26 months. This represented a 12% higher chance of survival among African-Americans than for whites, which increased even further (to 17%) even when other factors, such as age and other health issues, were taken into account.

"We don't really know why this is occurring, but it is definitely something that demands further research," Megan Ann McNamara, one of the researchers, said in a press release.

Conceivably, this difference in treatment outcome could be genetic — for example, variants in androgen-related genes that are more common in African-American men that make their tumors more likely to respond to treatments that target this pathway. But significant research will need to be done to confirm this association and to determine what its cause might be.

Source: https://prostatecancernewstoday.com/2019/03/04/blacks-outlive-whites-taking-xtandi-zytiga-advanced-prostate-cance/?utm_source=Prostate+Cancer&utm_campaign=70278695e8-RSS_MONDAY_EMAIL_CAMPAIGN&utm_medium=email&utm_term=0_a6d9c27ca8-70278695e8-71812337

Prostate Cancer Prevention and Finasteride: A Conversation with NCI's Dr. Howard Parnes

Recent research findings have provided important information about the use of finasteride and prostate cancer risk. In 2003, results from the Prostate Cancer Prevention Trial (PCPT)—an NCI-funded randomized clinical trial with nearly 19,000 participants—showed that men aged 55 and older who used the drug finasteride daily for 7 years had a substantially reduced risk of developing prostate cancerExit Disclaimer.

However, the trial results also raised the possibility that finasteride might increase the risk of high-grade (potentially more aggressive) prostate cancer. This finding led the Food and Drug Administration (FDA) to place a black box warning on the drug's label about the potential risk of high-grade prostate cancer.

Subsequent analyses of the PCPT suggested that the observed increase in high-grade prostate cancer in men who received finasteride could be explained, at least in part, by improved detection of these cancers caused by the drug itself. Study findings published in January 2019 showed that PCPT participants who took finasteride did not appear to have a higher risk of dying from prostate cancer than those who took a placebo.

In this interview, Howard Parnes, M.D., of NCI's Division of Cancer Prevention and a PCPT investigator, talks about the findings from these subsequent studies and what they mean for the use of finasteride today.

What was the rationale for testing finasteride as a way to prevent prostate cancer?

Finasteride blocks the activity of an enzyme called 5-alpha reductase. This enzyme converts the hormone testosterone into dihydrotestosterone, which is the most potent androgen in the prostate.

Interestingly, men born with a deficiency of 5-alpha reductase, a rare genetic condition, have undetectable levels of PSA and do not get prostate cancer. So, it made sense that finasteride, already approved for the treatment of male pattern baldness and benign prostatic hyperplasia (BPH), might also reduce the risk of developing prostate cancer.

There was a 25% relative reduction in prostate cancer risk in PCPT. Were you surprised by the large reduction?

The finding that finasteride decreased the 7-year period prevalence of prostate cancer by 25% was actually very much in-line with our expectations.
A more surprising finding was the unexpectedly high overall prevalence of prostate cancer, which was about 25% in men in the placebo group and about 18% in men receiving finasteride. This was due to two factors.

First, all men in the trial underwent annual PSA screening. And, second, about one-third of study participants agreed to have a research biopsy performed at the end of the 7-year study despite having had PSA scores on their annual screens that were consistently below 4 ng/dl, which is the usual PSA threshold for recommending a prostate biopsy.
In fact, these end-of-study biopsies accounted for about half of all the prostate cancers diagnosed in the PCPT. This observation, in particular, provides important insight into the problem of overdiagnosis, which refers to the diagnosis of prostate cancers not destined to become clinically evident during a man's lifetime.

What about the increased risk of high-grade cancer finding? Does the January 2019 study on prostate cancer-specific survival end the de-

bate about that finding?

You are referring to the fact that, despite nearly 20 years of follow-up, we did not see an increase in prostate cancer mortality among men who took finasteride.

Howard Parnes, M.D.
NCI Division of Cancer Prevention

Due to the relatively small number of men who died from prostate cancer on both study arms, these findings probably won't end the debate. But I feel they go a long way toward alleviating concerns regarding the potential of this drug to increase the risk of lethal prostate cancer.

So how do you explain the increased risk of high-grade disease reported in 2003?

There are two mechanisms by which we believe finasteride enhances the detection of high-grade cancer on prostate biopsy. First, finasteride is known to decrease the size of the prostate gland by about 25%. When you biopsy a smaller gland, you are more likely to sample an area of cancer—or high-grade cancer—with your biopsy needle, compared to doing the same biopsy in a larger gland.

Second, as we showed in another analysis of the PCPT, finasteride improves the sensitivity of the PSA test for the detection of overall and high-grade prostate cancer. Because the decision to perform prostate biopsies *during* the study was based on PSA levels, this may have contributed to increased detection of prostate cancer, in general, and high-grade prostate cancer, in particular, among men receiving finasteride.

Due to the effects of this drug on gland size and PSA performance, it seems quite likely that the PCPT not only *overestimated* the harm of finasteride in terms of the observed increase in high-grade cancer, but may have *underestimated* the benefit of finasteride in terms of the amount of reduction in prostate cancer risk.

Moving forward, is there a role for finasteride in the context of prostate cancer prevention?

Although finasteride is not FDA-approved for prostate cancer prevention it is approved for the treatment of urinary symptoms due to benign prostatic hyperplasia (BPH). And while BPH does not appear to be a risk factor for prostate cancer, finasteride is a reasonable choice for the treatment of BPH in that it may decrease a man's risk of developing prostate cancer while improving urinary symptoms due to BPH.

It is important to note that finasteride can have side effects, including sexual side effects. In the PCPT, we saw a small, but statistically significant increase in these side effects. There have also been reports of an increased incidence of depression associated with finasteride. So, the potential risks, as well as the benefits, of finasteride should be part of the conversation about its use.

Source URL: https://www.cancer.gov/news-events/cancer-currents-blog/2019/prostate-cancer-prevention-finasteride-parnes?cid=eb_govdel

New Class of Life-Extending Drugs for Men with Metastatic Hormone-Sensitive Prostate Cancer

June 12, 2019

At the 2019 American Society of Clinical Oncology (ACSO) Annual Meeting, results presented by two PCF-funded investigators from pivotal phase 3 clinical trials will likely lead to approval of **a new class of life-extending treatment options** for men with **metastatic hormone-sensitive prostate cancer (mHSPC)**.

mHSPC refers to men whose prostate cancer has spread to areas of the body outside of the prostate itself, and who are responsive to testosterone-lowering agents. This may refer to men who have had prior surgery or radiation and recurred, or men who were initially diagnosed with disease that was already metastatic (outside the prostate). Patients who are "hormone-sensitive" (aka, "castration-sensitive") may have previously received androgen deprivation therapy (ADT) for a certain amount of time, but their cancer has not yet developed resistance to ADT.

Until 2015, the standard-of-care treatment for men with mHSPC was ADT alone. ADT is a class of treatments that block the production or activity of testosterone, which fuels the growth of prostate cancer cells.

In 2015, the phase III CHAARTED trial demonstrated that if men with a high volume of mHSPC were given *docetaxel chemotherapy in addition to ADT*, they would live an average of 17 months longer than with ADT alone. In 2017, results from the phase III LATITUDE and STAMPEDE trials demonstrated that if men with high volume or high risk mHSPC received *abiraterone* in addition to ADT, they would also live longer: about 17 months longer on average in LATITUDE. Patients who have a lower burden of metastatic disease do better on ADT alone, and only the addition of abiraterone had been shown to improve their survival. Docetaxel is a chemotherapy, whereas abiraterone is a hormonal therapy which decreases testosterone-like hormones outside of the testicles.

Now, results from new trials will likely add two more drugs to the treatment arsenal for mHSPC. Both of these drugs are potent direct inhibitors of the androgen receptor (AR).

Apalutamide

At ASCO 2019, results were presented from the randomized, double-blinded phase III TITAN trial by PCF-funded investigator Dr. Kim Chi, MD, of the Vancouver Prostate Centre. The TITAN trial tested **the addition of apalutamide (Erleada) versus placebo, to ADT** in 1,052 men with mHSPC. Patients on this trial had could have previously received ADT for no more than 6 months for mHSPC or no more than 3 years if used as adjuvant

therapy for localized prostate cancer, and were not on ADT at the time of disease progression and trial enrollment. Patients could also have previously received docetaxel chemotherapy for no more than 6 cycles, and could not have progressed on that treatment.

Dr. Kim Chi

Compared with a placebo, **the addition of apalutamide to ADT significantly reduced the risk of death by 33%**, and reduced the risk of radiographic disease progression (tumors growing on scans) or death (whichever came first) by 52%. Apalutamide also significantly delayed the average time to PSA progression, use of chemotherapy, and pain progression. Apalutamide was shown to prolong survival of patients with both low and high volume metastatic disease. The treatment combination was considered tolerable, and quality of life in patients receiving apalutamide was similar to those receiving placebo in addition to ADT. Adverse effects that were higher in patients receiving apalutamide vs placebo included rash (27% vs. 8.5% of patients), hypothyroidism (6.5% vs. 1.1% of patients), and fractures (6.3% vs. 4.6% of patients).

Enzalutamide

Results from a second randomized phase III trial, ENZAMET, an academic study led by a new cooperative group called ANZUP in collaboration with Canadian Cancer Trials Group, Cancer Trials Ireland and Dana-Farber Cancer Institute, were also presented at ASCO by PCF-funded investigator Dr. Christopher Sweeney, MBBS (Harvard: Dana Farber Cancer Institute). ENZAMET tested **the addition of enzalutamide (Xtandi) versus a standard-of-care non-steroidal anti-androgen therapy (bicalutamide, nilutamide, or flutamide) to ADT** in 1,125 men with mHSPC.

Patients on this trial could have previously received ADT for up to 24 months in the adjuvant setting if the treatment had been completed at least 12 months prior to enrollment on the trial, or could have begun ADT up to 12 weeks before randomization, and could have received up to two cycles of docetaxel. Because the standard-of-care treatment for mHSPC changed just after this trial began (due to the CHAARTED trial), patients were given the option to initiate early treatment with docetaxel in addition to the treatment they were receiving on the trial.

Dr. Christopher Sweeney

Compared with a nonsteroidal anti-androgen, **the addition of enzalutamide to ADT significantly reduced the risk of death by 33%**, and reduced the time to PSA rise, clinical progression or death (whichever came first) by 61%. Enzalutamide prolonged survival in patients with both low and high volume metastatic disease. The addition of enzalutamide was deemed tolerable, however patients were more likely to experience fatigue, hypertension, falls, cardiac disorders and cognitive dysfunction than patients receiving a nonsteroidal anti-androgen. Enzalutamide patients also had about a 1% incidence of seizures. However, no survival benefit for enzalutamide over a nonsteroidal anti-androgen was seen in patients who additionally received docetaxel, and these patients experienced a modest increase in docetaxel-related side effects.

Dr. Michael Morris, the Prostate Cancer Section Head and Clinical Director of the GU Oncology Service at Memorial Sloan Kettering Cancer Center noted that "Following the results of TITAN and ENZAMET, men with metastatic disease who are either untreated or still responsive to testosterone-lowering agents have an unprecedented number of treatment options that improve their cancer outcomes. These results bring the number of such drugs to four – one chemotherapy, and three different therapies from two different classes of drugs that target the androgen receptor signaling pathway.

Determining which drug is best for a given man will need additional research regarding the side effects of each drug, versus its benefits, a patient's baseline health status, and his disease distribution and biology."

PCF funded the original synthesis of both enzalutamide and apalutamide at UCLA, by Drs. Michael Jung, PhD and Charles Sawyers, MD. Early development of these drugs was also supported by funding from PCF.

Results from the TITAN and ENZAMET trials were also published in the prestigious medical journal, *The New England Journal of Medicine.*

The 2019 ASCO Annual Meeting was held in Chicago, IL, from May 31 to June 4, 2019

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