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AACR Conference: Molecular Diagnostics in Cancer Therapeutics

Novel Blood Test Detects Prostate Cancer

By Charlene Laino

CHICAGO—A novel blood test that spots a protein that is elevated in patients with prostate cancer shows promise as a method of early detection, according to data presented here at the American Association for Cancer Research conference on Molecular Diagnostics in Cancer Therapeutic Development: Maximizing Opportunities for Individualized Treatment.

The test, which homes in on a protein called human aspartyl (asparaginyl) beta-hydroxylase, or HAAH, appears to be more accurate than current methods for early detection of prostate cancer, said Stephen Keith, MD, President and Chief Operating Officer of Panacea Pharmaceuticals, Inc., in Gaithersburg, MD, which is developing the new test.

"We believe that by adding HAAH to the standard DRE and PSA tests, we can increase the accuracy of early screening for prostate cancer and reduce the number of unnecessary biopsies."

According to Dr. Keith, HAAH has been detected by immunohistochemical staining in more than 99% of tissue samples from more than 20 different cancer types, including liver, breast, ovarian,

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After identifying the presence of HAAH at detectable levels in the sera of cancer patients, researchers at Panacea developed a sandwich ELISA (enzyme-linked immunosorbent assay) for its detection in the blood.

The research involved 16 men with prostate cancer and 23 healthy individuals, all of whom had elevated PSA. HAAH was detected above a threshold level of 11 ng/mL in 100% of the sera of all the men with prostate cancer, but was undetectable in all of the healthy men. Prostate cancer status was confirmed by biopsy.

Reducing Unneeded Biopsies

"We believe that by adding HAAH to the standard DRE and PSA tests, we can increase the accuracy of early screening for prostate cancer and reduce the number of unnecessary biopsies," Dr. Keith said.

While the American Cancer Society recommends that all men over 50—as well as high-risk men over age 40—be screened annually with the digital rectal exam (DRE) and PSA, both tests are fraught with problems, he explained.

While highly sensitive for the detection of prostate cancer, total serum PSA has low specificity, resulting in large numbers of false positives and unnecessary biopsies. A high PSA level may signal cancer, Dr. Keith said, but it can also reflect infection, inflammation, or an enlarged prostate. The digital rectal exam relies on subjective judgment.

Nevertheless, they are the best tests available and "if a man has a high PSA level and an abnormal DRE, he is referred for a biopsy. But up to 70% to 80% of men sent for biopsies are found not to have cancer," Dr. Keith said.

D. James Morre, PhD, Distinguished Professor of Medicinal Chemistry at Purdue University, agreed that the new test could reduce the number of unnecessary biopsies. The test shows "extreme promise as an adjunct to PSA for the detection of prostate cancer," said Dr. Morre, who is researching yet another biomarker for prostate cancer.

Monitoring Response to Therapy

Hossein Ghanbari, PhD, Chief Executive Officer and Chief Scientific Officer at Panacea, said that he is all too familiar with unnecessary biopsies. Due to high PSA levels, he was referred for biopsies three times—and three times was declared cancer-free.

"It's painful, terrible actually," he said. "The last time, they took 24 tissue samples. Then I had to take antibiotics for three or four weeks to avoid infection."

But had the new test been available, Dr. Ghanbari said, this all may have been avoided. "My blood HAAH level is zero," he said.

The same test could also be used to monitor response to therapy, Dr. Keith said. "If treatment is working, HAAH would basically go back down to zero. If it in fact goes up, that would prompt the physician to investigate whether the cancer has returned locally or has spread."

Panacea scientists have just begun a clinical trial in which they will examine HAAH levels in 400 men with prostate cancer and 400 healthy men over age 50.

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Additionally, the company is developing a drug to target HAAH. "If you hit it with a monoclonal antibody, you can basically turn it back to normal," Dr. Keith said. "This in turn, would hopefully help to halt abnormal cell division, movement, and invasion."