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Stockholm3 included in American guidelines as a primary test for early detection of prostate cancer

Stockholm3 has been included as a primary test in the revised 2023 American Urological Association (AUA) guidelines for early detection of prostate cancer. The AUA stated that the PSA blood test remains the first-line screening test of choice and, at the same time, that Stockholm3 has a higher predictive accuracy compared to PSA alone, with the advantage of reducing unnecessary biopsies. In addition, Stockholm3 is recommended as a secondary test for men with elevated PSA levels as well as after a negative biopsy.

"This is the first mention of any test in international guidelines for primary prostate cancer testing since PSA was introduced more than 35 years ago, and a major step forward for Stockholm3 in setting a new standard of care for early detection of prostate cancer. Entering the US market is one of our top priorities and we expect that the new AUA guidelines will increase the interest in Stockholm3," says David Rosén, CEO of A3P Biomedical.

In its review, the AUA stated that the PSA blood test remains the first-line screening test of choice based on randomized trials of PSA-based screening showing reductions in metastasis and prostate cancer death. At the same time, the AUA stated that Stockholm3 as a primary prostate cancer test has a higher predictive accuracy compared to PSA alone and the advantage of reducing unnecessary biopsies. The AUA also stated that further validation in diverse populations to confirm findings in Europe will be necessary to move forward into practice.

"The evaluation of Stockholm3 in diverse populations is well underway with the multi-centered, multi-ethnic, North American SEPTA-STHLM3 trial that closes recruitment in June 2023. We expect to be able to present results from this study in 2024, which will provide further clinical evidence and hopefully support a broader use of Stockholm3 in one of the largest global markets", David Rosén concluded.

In the AUA guidelines, Stockholm3 is also recommended as a next test for patients with elevated PSA (conditional recommendation, grade C) as well as a next test after a negative biopsy (conditional recommendation, grade C).

Prostate cancer is the most common form of cancer in American men. In 2023, it is estimated that 288,300 men will be diagnosed and that 34,700 will die from prostate cancer in the United States. Early detection is crucial for improved treatment outcome and decreased mortality in prostate cancer.



For additional information, please contact:

David Rosen, CEO

Telephone: +46 10 1823325 Email: david.rosen@a3p.com

About A3P Biomedical

A3P Biomedical's mission is to improve quality of life of men by radically increasing the precision in prostate cancer diagnostics. The company's lead product is **Stockholm3**, a blood test for early detection of aggressive prostate cancer. Stockholm3 has been developed by scientists at Karolinska Institutet and validated in clinical studies including more than 75,000 men. A3P Biomedical is headquartered in Stockholm, Sweden. For more information, please visit www.a3p.com.

About Stockholm3

Stockholm3 is a blood test that combines protein markers, genetic markers, clinical data, and a proprietary algorithm, to predict the risk of aggressive prostate cancer at an early stage. In clinical practice, Stockholm3 finds 100 percent more aggressive prostate cancers and reduces 50 percent of unnecessary biopsies compared to current practice with PSA (1).

Stockholm3 has been evaluated in clinical studies with more than 75,000 men. Data from the latest pivotal study, a randomized study including 12,750 men, was published in The Lancet Oncology in 2021. The study was also awarded the European Association of Urology (EAU) "Prostate Cancer Research Award 2022". Multiple additional studies have been published in high-impact journals, including a previous study with 58,000 men, published in The Lancet Oncology in 2015 (1).

Based on robust peer-reviewed clinical data, leading Nordic healthcare providers such as Capio S:t Görans Hospital in Sweden and Stavanger University Hospital in Norway have replaced PSA with Stockholm3. Region Värmland has introduced general screening for prostate cancer with the help of Stockholm3 for men in the age category 50-75. Patients benefit from a more precise test (increasing sensitivity and specificity) and healthcare providers can reduce the direct costs by 17 to 28 percent (1).

(1) Publications, results and clinical validation.



About prostate cancer

Prostate cancer is the second most common male cancer, and the fifth leading cause of cancer related death in men worldwide. According to WHO, 1.4 million men were diagnosed with prostate cancer and 375,000 deaths were reported in 2020. Incidence of prostate cancer is expected to increase by 70 percent until 2040, driven by an aging population.

Attachments

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