

3 European studies back use of Matritech's BladderChek

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Matritech's (Newton, Massachusetts) top executive believes results of three independent clinical studies presented in Europe this week only provide more evidence that its urine test for bladder cancer should be considered standard of care.

Two groups of researchers presented data demonstrating the utility of the NMP22 BladderChek Test for monitoring and diagnosis of bladder cancer. Another presentation reported that the high negative predictive value of the NMP22 protein could make it useful as a screening tool. The presentations were made at the annual congress of the **European Association of Urology** (Arnhem, the Netherlands) in Vienna, Austria.

"[The studies have] confirmed or validated what we've been saying all along, that this is the most accurate fluid-based tumor marker of any tumor marker that's available," Chairman and Chief Executive Officer Stephen Chubb told *Medical Device Daily*. "[It is] more accurate for bladder cancer than PSA [prostate specific antigen] is for prostate cancer and approved for screening."

The FDA gave an additional approval to the test in March of last year, allowing it to be marketed as an aid in the initial diagnosis of cancer. That came in addition to its use by urologists to help them determine if bladder cancer was recurring, a use for which it was approved in July 2002.

The test works in a physician's office by placing four drops of urine on the BladderChek cassette. NMP22, a nuclear matrix protein (or one that is in the cell nucleus) is elevated in bladder cancer cells 20-fold to 80-fold and is found in the urine, the company said. If the test detects the presence of the elevated protein, a purple line will appear. The entire test takes about 30 minutes to complete, and results can be provided to a patient before he or she leaves the physician's office.

The test is not recommended to be a stand-alone tool to detect bladder cancer. Instead, Chubb said, it is meant to be used with cystoscope, the traditional method of detection.

"We recommend use of NMP-22 in conjunction with the scope, because that yields accuracy close to 100%, well up into the 90s," he said.

Chubb told *MDD* he was "delighted" with the results of the "third-party independent validation." Matritech now has 40 published reports that support the utility of the BladderChek test, based on studies completed by the likes of the **Cleveland Clinic** (Cleveland, Ohio) and the **University of Miami** (Coral Gables, Florida).

In the first study among those presented at the congress, a researcher at the **University of Bonn** (Bonn, Germany) reported the results of using the NMP22 Bladder-Chek Test for initial diagnosis of patients who presented with blood in the urine, or hematuria. That study involved 212 hematuria patients, of whom 113 also had cytology performed. The BladderChek Test detected 82% of the bladder cancer compared to only 57% found by cytology. The company said the conclusion to be drawn from that is that "NMP22 is more accurate than cytology at identifying patients with bladder tumors."

Both tests ruled out 97% of the patients who did not have cancer.

"The results of [the] study confirm the superior ability of the NMP22 BladderChek Test to identify bladder tumors compared to cytology," said David Corbet, president and chief operating officer of Matritech, in a statement. "In addition to detecting cancers missed by cytology, the test delivers a much faster result."

A second study presented at the congress indicated that the NMP22 test is "clinically useful for monitoring patients who have undergone a common treatment for bladder cancer called BCG," the company said. BCG, which stands for *bacillus Calmette-Guerin*, involves inducing an infection in the bladder to stimulate the lining to slough off cancerous cells from the bladder wall in superficial bladder cancer.

That study, conducted at the **University of Barcelona** (Barcelona, Spain), involved 23 patients in their first evaluation following treatment with BCG. The test showed no interference from the treatment, and it correctly identified 93% of the patients who were free of cancer.

"Recurrence of bladder cancer is estimated to be about 70%, so it's important that [these patients] are monitored closely," Chubb said.

A third study reporting that NMP22 would be suitable as a screening marker for bladder cancer was conducted at the **University of Giessen** (Giessen, Germany). The study involved 517 patients with a variety of urological cancers and other urinary tract disorders and 39 volunteers as controls. In the study, NMP22 was accurately negative in 92% of both the control group and patients with urological cancers other than those of the bladder. It detected 75% of bladder tumors.

Although the NMP22 test was approved by the FDA for initial diagnosis and point-of-care in 2003, in the fourth quarter Matritech revamped its marketing agreement with **Cytogen** (Princeton, New Jersey), which covered the test. Under the restructured agreement, Matritech had the exclusive right to market to urologists in the U.S., while Cytogen was to focus on oncologists (*MDD*, Nov. 4, 2003).

Chubb told *MDD* that Matritech realized as it worked through the first year following approval that the company would be better served by having its own direct sales force, a strategy that has resulted in "excellent success" for the company in the German market.

"Now, we'll be announcing first quarter results for the entire company, including the United States, in early May, and we're eager to show the financial community and our investors the benefits of having gone direct, so we're pleased with the results that we're seeing with this direct sales force here in the states," Chubb said. ■