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Emerging Company Profile

Predictive Bio: Putting cancer in silos

By Urooj Mujtaba
Staff Writer

A non-invasive diagnostic that could determine the presence or absence of cancer would significantly reduce the number of patients who unnecessarily go through colonoscopies, cystoscopies and biopsies only to discover they are disease free. **Predictive Biosciences Inc.** is developing urine-based assays that could enable physicians to diagnose new cancers and monitor cancer survivors with significantly less cost, time and inconvenience than current options.

“Billions of healthcare dollars are used to screen patients who might be at risk for cancer; however, only a small percentage of the patients susceptible to have cancer will actually have it,” CTO Anthony Shuber told BioCentury. As an example, he said about 80% of abnormal mammograms are false positives. Finding that out currently requires needle or surgical biopsy.

Predictive also hopes its assays will allow physicians to focus more aggressive methods on high-risk patients. The company’s initial focus is on survivors of epithelial cancers, including bladder, breast and colorectal cancers, who require ongoing surveillance.

The assays detect urinary biomarkers, including matrix metalloproteinases (MMPs) and ADAMs (a disintegrin and metalloproteinases).

Predictive has exclusive, worldwide licenses to seven issued patents and 10 pending patent applications covering the use of the biomarkers from **Children’s Hospital Boston** and affiliated institutions **Massachusetts General Hospital** and **Beth Israel Deaconess Medical Center**.

“Preclinical studies by our scientific co-founders at Children’s Hospital, as well as other researchers in the field, have demonstrated that there is an increased incidence of MMPs in the urine of epithelial cancer patients, as well as increased presence of MMPs and ADAM12 in patients with breast cancer,” said Shuber.

MMPs mediate cancer progression through the degradation of the extracellular matrix (ECM) and subsequent invasion of cancer cells, leading to metastasis.

A pilot study using urinary levels of MMP-2 and MMP-9 to discriminate disease-free patients from those with bladder cancer resulted in about 86% sensitivity and 84% specificity at a fixed protein level.

Applying Predictive’s Clinical Intervention Determining Diagnostic (CIDD) algorithm allowed the company to identify with almost 100% predictive value one group of patients that had cancer and one group that did not, plus a third “intermediate” group that should receive standard procedures.

“Our algorithm stratifies the three groups, separating the cancer patients from cancer-free patients. The population in the middle would be intermediates, and 100% of them will require cystoscopy,” said Shuber.

Predictive is developing three kinds of assays for use in different patient populations: a triage monitoring assay, an interval monitoring assay and a stratification assay.

The triage assay is intended to delay costly and/or invasive diagnostic procedures. The first one, which is in preclinical development, is for bladder cancer survivors who typically need cystoscopies every three months to check for recurrence. Patients could have a triage test immediately prior to their scheduled cystoscopy and, if the results are negative, could skip the procedure for that period.

According to Shuber, although 75-85% of bladder cancer patients will have

a recurrence over their lifetime, only a small percentage will have a recurrence at the time of a scheduled cystoscopy.

“Our triage assay will prevent a large percentage of those patients from the anguish and expense of a cystoscopy,” Shuber said. “We are not replacing colonoscopies, cystoscopies or other necessary procedures. Instead, we are supplying physi-

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Predictive Biosciences Inc.

Lexington, Mass.

Technology: Clinical algorithms and urinary protein biomarkers

Disease focus: Cancer

Clinical status: Pilot studies

Founded: 2006 by Eugene Chiu, Tony Shuber, Marsha Moses and Bruce Zetter

University collaborators: Not disclosed

Corporate partners: None

Number of employees: 8

Funds raised: \$10 million

Investors: Highland Capital and IDG Ventures Boston

CEO: None

Patents: 7 issued covering cancer biomarkers

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cians with a tool to stratify the population and see who really needs the costly and invasive procedures.”

The interval monitoring assay would be used for high-risk patients between standard three-month follow-ups, when a positive result with high positive predictive value would accelerate diagnostic procedures and/or treatment.

“Physicians might use the triage, interval or both assays depending on the patient they are dealing with and how aggressive their original tumor was,” said Eugene Chiu, VP of business development.

The stratification assay is for de novo diagnosis, allowing a physician to determine whether a new patient with symptoms requires no follow-up, a standard follow-up exam or intensive diagnostic procedures.

The three assays will be performed in CLIA service labs and yield results in 2-5 days. The company also plans to develop a point-of-care test, which can be performed at the doctor’s office or hospital and yield real-time results.

Predictive is performing preclinical studies for the triage test and plans to start a pilot study in mid-2008.

It also is doing pilot clinical studies to determine the predictive value of the current biomarkers for the interval and stratification products for epithelial cancers, including bladder cancer. The goal is a multi-center pivotal trial in the next couple of years.

Predictive, which raised \$10 million in a series A round in late 2006, expects to complete a series B round this year.

COMPANIES AND INSTITUTIONS MENTIONED

Beth Israel Deaconess Medical Center, Boston, Mass.

Children’s Hospital Boston, Boston, Mass.

Massachusetts General Hospital, Boston, Mass.

Predictive Biosciences Inc., Lexington, Mass.

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