Optimizing Biomarker Use in Discovery and Development

Biomarker BREAKTHROUGHS

Cambridge Healthtech Institute

Wednesday, September 5, 2007 | www.biomarkerbreakthroughs.com

Forging a New Model for Cancer Monitoring: The Predictive Biosciences Plan

By Malorye Allison

COULD NEW types of cancer tests change the diagnostics market? Many entrepreneurs disdain diagnostics because they are seen as too low margin to ever command a significant reward, unless you are already one of the leading companies in this field. Now a growing number of start ups are entering the field with two goals in mind: introducing new products and changing the way the market works.

Predictive Biosciences is one of these companies. Launched in 2006 with $10 million in financing, the company aims to pioneer tests to greatly augment standard procedures, such as mammograms, cystoscopies, colonoscopies, and biopsies.

The company's first entry point to the market will be detecting cancer recurrence. "We will first produce assays that will let physicians avoid uncomfortable follow-up procedures in patients who don't need them, or follow up more quickly in patients who do need it," says Eugene Chiu, the company's vice president of business development and cofounder. The company's biomarker-based tests, along with its proprietary "informed cancer management" process, involve a total change in the paradigm for cancer monitoring.

The first products will all be based on matrix metalloproteinases (MMPs), a disintegrin and metalloproteinase (ADAM). MMPs are zinc-dependent endopeptidases. Over about fifteen years, Predictive Biosciences cofounder Marsha Moses has carried out studies of these molecules' involvement in tumor growth and metastasis. It appears MMPs help in the break down of the extracellular matrix (ECM), which helps metastasis occur. ADAMs show similar activity.

"The mechanism is fundamentally linked with how tumors grow, how cancer expands, and how it becomes metastatic," says Chiu. In particular, MMP-2, MMP-9, and ADAM12 are elevated in the urine of patients with bladder cancer.

What makes these particularly attractive markers is that they occur in urine, are linked to a range of solid tumors, and are well studied. In fact, assays already exist to test for them. The work ahead for Chiu and his colleagues is to turn these assays into commercial tests and help oncologists use these to improve standard procedures.

MMPs, Chiu points out, are different in important ways from Nuclear Matrix Proteins (NMPs), which are used in a urine-based bladder cancer test already marketed by competitor Matritech. MMPs are secreted proteins while NMPS are found inside the nucleus. Chiu says the fact that MMPs are found in the urine of patients with a wide range of tumors, including breast, bladder, ovarian, and colon, will make it easier to develop a family of products around them.

"You can envision testing any patient for recurrence. Since you already know where the primary tumor was, having this non-invasive follow-up test will be tremendously convenient, time-saving, and cost-effective," he says. The tests will be marketed to oncologists, urologists, and others with information on how to use them in conjunction with existing diagnostics.

According to Chiu, Predictive Biosciences hopes to have a CLIA-approved lab offering their first test, for bladder cancer recurrence, as a service within the next two years. They also hope to begin trials of these markers as screening tools soon.

Diagnostics, Chiu says, is becoming more active. "The level of excitement and awareness of the role that diagnostics has in clinical care is growing," he says. "Challenges do remain with respect to reimbursement, but if you speak to pharmaceutical companies these days, diagnostics is one of the top areas of interest for them."