Elsevier Business Intelligence

"The Gray Sheet"®

MEDICAL DEVICES AND DIAGNOSTICS

March 14, 2011 Volume 37 Number 11 Page 15

Nanotechnology Cancer Detection Technology Moves To Clinical Trial

A first-in-man clinical trial to measure very small levels of residual leukemia cells using a unique nanotechnology-based magnetic imaging method has enrolled its first 35 patients.

The technology, in development by Senior Scientific and nanomedicine-focused investment firm Manhattan Scientifics, is still years from reaching the market, but the firms say they are in active partnering discussions with several large drug, device and imaging companies.

The trial, which will enroll 60 patients in all, is expected to be completed within two years. In leukemia, the focus is on monitoring the effect of chemotherapy by detecting residual disease. The technique also has applications in gauging therapy response in a range of other cancers, according to the developers.

"If you're doing chemotherapy, hyperthermia or even surgery, we can use our device to see that you get it all," said Edward Flynn, founder and president of Senior Scientific. "The leukemia case is just one example."

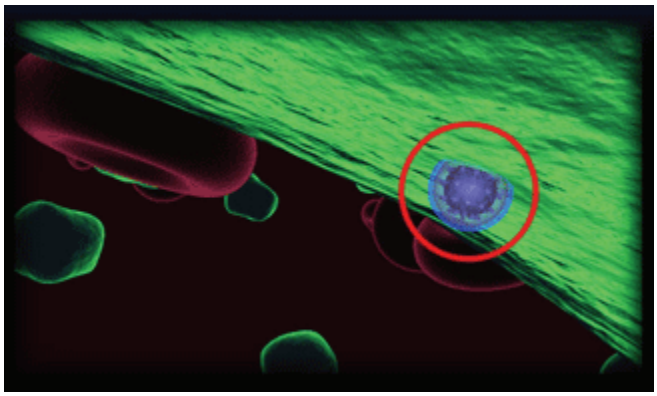
The companies are also assessing the tool for early detection of breast cancer, other malignancies and Alzheimer's disease, he said.

Magnetically Measuring Cancer Cells

The technique being studied in the leukemia trial involves first extracting bone marrow cells from leukemia patients; injecting the cell sample with magnetic nanoparticles linked to antigens that preferentially bind to leukemia cells rather than normal cells; and measuring the concentration of leukemia cells in the sample by employing a patented magnetic biopsy needle and a specialized sensor array for magnetic fields.

Flynn says the technology can detect "minimal residual disease" down to 0.3% of a sample. Achieving that level of sensitivity is the primary endpoint of the study, which is being conducted at the University of New Mexico's Health Sciences Center. Comparatively, current biopsy techniques typically fail to detect leukemia cells that account for less than 5% of a sample, he notes.

Detecting the presence of minimal residual disease provides information on how well chemotherapy is working, and when it might be appropriate to stop treatment or change doses or drugs. More refined monitoring of chemotherapy is particularly important in pediatric leukemia, Flynn says, because the treatments can have significant short- and long-term adverse effects on the young patients.



A magnetically active nanoparticle coated with agents designed to selectively bind to cancer cells. (Image: Manhattan Scientifics/Senior Scientific)

Flynn also specifically pressed the promise of the technology for early detection of breast cancer, noting that magnetic nanoparticle-based detection can localize a breast tumor containing 100,000 cells – or 1/1000th of what a mammogram requires.

The magnetic-based detection also limits the potential for false positives and is not affected by the presence of scar tissue from surgeries and implants, he points out.

In Vivo Approach Is Next Step

Ultimately, Flynn says the goal is to perform the technique by an in vivo approach, where the antigen-linked nanoparticles are injected into the body, providing a means to detect the precise location of cancer cells.

This presents a potential strategy for monitoring tumor evolution. As the tumor grows or shrinks, for instance, the number of nanoparticles bound to the cancer cells also grows or shrinks and could be promptly measured, Flynn suggests.

It also could allow for more targeted chemotherapy, limiting adverse effects of widespread treatment.

"It's a smart-bombing approach," explains Marvin Maslow, founder and chairman emeritus at Manhattan Scientifics.

In February 2010, Manhattan acquired rights to all commercial applications of the technology, which was developed by Flynn.

Flynn, a nuclear physicist by training, founded privately held Senior Scientific in 1996 to develop magnetic-based cancer cell detection. The firm has received $7 million in research grants from the National Institutes of Health since 2002, mostly through the Small Business Innovation Research program.

By Zach Miners