

Washington roundup

Roberts casts deciding vote to uphold Affordable Care Act

By MARK McCARTY

Medical Device Daily Washington Editor

Chief Justice John Roberts surprised almost the entire nation in voting to uphold the Affordable Care Act after months of speculation that Justice Anthony Kennedy would provide the deciding vote, and the Affordable Care Act is nearly intact going forward. The decision reinforces the most sweeping piece of healthcare legislation since the inception of Medicare in 1965, and sets up a controversial vote in the House of Representatives on legislation to repeal the ACA. The effect on device makers is expected to be mixed, however, even though the device tax is still set to take effect.

In a June 28 statement, Glenn Novarro of **RBC Capital Markets** (New York) said the outcome offers "mixed
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Cornell team develops GEDI to fight prostate cancer

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

A team of researchers at **Weill Cornell Medical College** (New York) and **Cornell's College of Engineering** (Ithaca, New York) has built a device that may hold the key to helping clinicians match prostate cancer patients with the right drug for their specific cancer cells. The device is described as a sticky silicon chip dubbed GEDI (Geometrically Enhanced Differential Immunocapture) and, yes, it is pronounced like the Star Wars Jedi forces of good.

Brian Kirby, associate professor of mechanical and aerospace engineering, told *Medical Device Daily* that the device is designed to identify and collect cancer cells from a patient's bloodstream. The geometry of the device is like a little maze for the cells and is designed to trick the cancer cells, which are usually larger and more rigid than normal
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Veracyte gets favorable results in Afirma classifier test study

By OMAR FORD

Medical Device Daily Staff Writer

Veracyte (South San Francisco) reported results from a large, prospective, multicenter study, which demonstrated the potential for its Afirma Gene Expression Classifier, a gene expression test, to reduce the large number of unnecessary surgeries in thyroid cancer diagnosis by more than half.

The results are being shared during a late-breaking data presentation at The **Endocrine Society's** (Chevy Chase, Maryland) ENDO 2012: The 94th Annual Meeting & Expo in Houston, and coincide with online publication by the *New England Journal of Medicine*. The study is scheduled to appear in the journal's August 23 print issue.

The two-year study involved 265 indeterminate thyroid
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Financings roundup

Benvenue secures \$25M through series D round

A *Medical Device Daily* Staff Report

Benvenue Medical (Santa Clara, California), a maker of minimally invasive solutions for spine repair, has completed a \$25 million Series D round of financing. The spine company intends to use the proceeds to sustain global commercialization of its three minimally invasive products to treat degenerative disc disease (DDD) with spinal fusion and vertebral compression fractures (VCFs), as well as for additional initiatives to bring its fusion and VCF products to the U.S. market.

The Series D financing was completed with existing investors DeNovo Ventures, Domain Associates, Technology Partners and Versant Ventures. "Our investors share our excitement about our rapid growth and positive
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GEDI

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cells, into colliding with the sticky surfaces of the device in order to trap and capture only the cancer cells while allowing the other cells to flow through, he explained.

The researchers' work is described in a paper in the April issue of the journal *PLoS ONE* and was announced during a recent press conference at Weill by Kirby; David Nanus, MD, the Mark W. Pasmantier Professor of Hematology and Oncology in Medicine; and Evi Giannakakou, associate professor of pharmacology. The team also includes 12 other researchers from both campuses.

"There's this whole concept of targeted therapy," Nanus said during the press conference. "It used to be we would just give everything to everybody and see if it worked. Now we try to say, 'well this is going to work in you, and this is going to work in him,' . . . but how do we achieve that? How do we match the drug to the patient?"

So the good news, Nanus said, is that as a clinician he now has a lot of different drugs to choose from when treating his prostate cancer patients. "For me, I've been in this field for a long time, never had so many drugs I could treat a patient with. The challenge is, well, which patient gets which drug when? That's what we're trying to answer."

The hope is that a device like the GEDI will be able to help answer those questions.

According to the researchers, the device captures an unprecedentedly high concentration of rare cancer cells from metastatic prostate cancer patients for a quick, noninvasive analysis to determine the efficacy of the patients' current chemotherapy. The ability to collect a relatively pure sample of circulating tumor cells (CTCs) may also enable research to better understand the biology of metastasis and develop new treatments, the researchers noted.

Metastatic cancer is cancer that has spread from the place where it first started – in this case, the prostate – to another place in the body, most commonly the lungs, bones and liver. Metastasis accounts for the majority of cancer-related deaths.

Kirby told *MDD* that the motivation behind the development was the fact that there are so many different drugs that can be used to treat prostate cancer, but patients respond to each drug differently and these drugs are associated with strong negative side effects. Kirby and his colleagues want to help clinicians like Nanus pinpoint which drug will work without putting the patient through a trial and error process and subjecting them to toxic side effects without any benefit.

On the GEDI chip, blood flows through an array of posts just a few millionths of a meter in diameter, coated with antibodies that stick to cancer cells. Each row of posts is offset from the one before by a distance that causes the larger cancer cells to collide with them – and stick on – more often, while other cells in the blood flow smoothly past.

Metastasis is believed to be caused by cells that detach from the primary prostate tumor, circulate in the bloodstream and seed new tumors. Extensive clinical research shows that a reliable CTC count is a strong predictor of overall survival in metastatic prostate cancer patients. However, since the incidence of CTCs can be very small – one CTC per 100 million blood cells – pure CTC capture is difficult.

There are other cell-capture devices currently in use that are designed to bind to an antigen found on the surface of nearly all malignant prostate cancer cells. The problem is that these antibodies also bind to other cells in the bloodstream and can collect a highly impure sample.

On the GEDI chip, a milliliter (mL, one-thousandth of a liter) of blood is pumped through a nanoscale channel filled with tiny posts just a few microns (millionths of a meter) in diameter, coated with antibodies. Successive rows of posts are offset in a carefully calculated way so that only cells larger than 15 microns will collide with the posts and stick to them, while most smaller cells flow smoothly around them. That's what makes this device unique, Kirby said.

"It's actually harder than you might think to get a cell that is flowing in blood to stick to the wall of the device you make," Kirby said. He added that the project has been a learning process for the team. "It turns out that the design that we're using is not what we first thought of when we started."

After the test, the chip is removed from the device and the captured cells are extracted for analysis. In an experiment with a blood sample containing 200 mL of CTCs and 5 billion blood cells, the device captured 170 mL of CTCs and only 91 mL of irrelevant blood cells, according to the researchers.

The GEDI device is scheduled to go into clinical trial this year. Meanwhile, the researchers are actively working on detectors for breast, ovarian and pancreatic cancers.

The research is one of several joint Ithaca-New York City projects associated with the Cornell Center for Microenvironment and Metastasis, a \$13 million National Institutes of Health-funded Physical Sciences-Oncology Center created to use physical techniques and processes to improve understanding and care of metastatic cancer in patients. ■

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