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REGULATORY

FDA wins kudos from industry in combo product good manufacturing practice final

By Mark McCarty, Regulatory Editor

The FDA final guidance for combination product good manufacturing practices (GMPs) grew by 10 pages compared to the draft guidance, but the final product was hailed as "a good guidance document" by Bradley Merrill Thompson of Epstein Becker & Green, the law firm that has represented the Combination Products Coalition on combo product regulatory matters before the FDA.

The January 2015 draft guidance for combo product GMPs followed a similar document published in 2004, which the agency eventually withdrew. This was followed in 2013 by the final rule for combo product GMPs, an effort the agency undertook due to the concerns expressed regarding the 2004 draft guidance.

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FDA says scientific data trumps speed in drug, device development

By Mari Serebrov, Regulatory Editor

Pushing back against pressure to shorten the path to the U.S. market for new drugs and medical devices, the FDA has released an analysis of nearly two dozen case studies in which phase III trials didn't bear out the promises of phase II testing.

The case studies – running the gamut from biologics and small-molecule drugs to devices and vaccines – are just the tip of the iceberg, the agency said as it dug in

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EARLY PROSTATE CANCER DETECTION

Canadian and European investors bankroll high resolution, micro-ultrasound technology

By David Godkin, Staff Writer

Just about any med-tech company will tell you raising investment capital in Canada is a long, hard climb. That's why Toronto-based Exact Imaging Inc. is pluming its feathers a bit these days after several investment companies sprang for the

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2017 A CRITICAL YEAR FOR FIRM

Colvera's simple detection method allows CG to stand out in liquid biopsy market

By Omar Ford, Staff Writer

Clinical Genomics Inc. is hoping to make cancer detection less complicated and clear cut. The company said Colvera, its blood-based test for colorectal cancer (CRC) recurrence monitoring, could accomplish this task. During the 35th annual J.P. Morgan Healthcare conference, Clinical Genomics' president and CEO, Lawrence LaPointe spoke with *Medical Device Daily* about the test and how the private company stands out from other competitors in the liquid biopsy space.

LaPointe quickly moved away from the notion that the Bridgewater, N.J.-based Clinical Genomics was just another liquid biopsy specialist. He clearly defined the company as a firm that has developed a test looking for changes in circulating tumor DNA (ctDNA).

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C$21.5 million (US$ 16.25 million) needed to commercialize a high resolution, micro-ultrasound system that could change the way physicians diagnose and biopsy the prostate for signs of cancer.

"It took almost a year to pull together from start to finish and so it's been a grind. But we're very pleased to have got it done," Exact Imaging President and CEO Randy AuCoin told *Medical Device Daily*. "Our understanding is that it is one of the largest venture-backed, private med device deals last year in Canada."

Peter van der Velden is Managing General Partner at Toronto-based Lumira Capital Corp., which co-led the investment deal after following Exact Imaging's development of its Exactvu micro-ultrasound system from its inception four years ago. "We watched them evolve the technology; we watched them respond to the market feedback and the input from the clinical program, and we just felt like the guys really got it right," he told *Medical Device Daily*.

Getting it right meant creating a micro-ultrasound system that provides image resolutions far beyond what other companies' technologies have achieved for visualizing suspicious tissues, said AuCoin: Exactvu images tissues in real-time, followed by immediate biopsy of suspicious tissue, all from the relative comfort of the urologist's office, he said. FDA and European regulators were satisfied enough with Exactvu to approve its use within months of each other late last year.

SMALL IS BEAUTIFUL

Exactvu evolved out of ultrasound technology developed at AuCoin's previous, Toronto-based company Visualsonics Inc. for the study of human disease using mouse models. Where clinical ultrasound operates between frequencies of 1 and 15 MHz, the mouse ultrasound ran between 20 and 55 MHz, Aucoin said. With Visualsonics' assistance, AuCoin's team modified it for use in human urology.

"What makes it novel is that this higher frequency gives it much, much higher resolution," said AuCoin. "Where conventional urology ultrasound achieves between 220 and 250 microns of resolution, we got it down to 70 microns, with a 300 percent improvement in resolution."

That result has profound implications for interrogating suspicious tissue and performing targeted prostate biopsies, said Gregg Eure, research chairman for Virginia Beach's Urology of Virginia Research Department and Exactvu's non-invested, principle investigator. Historically, low resolution ultrasound enabled urologists to perform incomplete "blind" biopsies, but has given way more recently to fusion MRI-Ultrasound, providing a more detailed look inside the prostate gland but requiring a separate biopsy procedure. (See *Medical Device Daily*, Sept. 26, 2016).

"What Exactvu does in one step is put the imaging technology back into the urologist's hands to see that suspicious area in real time and biopsy it," Eure told *Medical Device Daily*. "In that sense, it's a game changer."

WHAT ARE WE MISSING?

Since its FDA approval in December, Eure has used an updated, pre-market release of the technology on 20 of his own patients. In one case, a patient who had been diagnosed with a low grade, low stage cancer, was given a routine surveillance biopsy using the Exactvu ultrasound.

"We found a suspicious area we had not biopsied before, and it showed a very high-grade, aggressive cancer," said Eure. "Nothing else had suggested it was there. Now that patient will be able to get early treatment, which he otherwise would not have."

Great news for the patient and pretty good news for Luxembourg's Vesalius Biocapital Partners, Belgium's Pmv NV, Toronto-based Igan Partners and its sister fund Rowanwood Ventures, which joined Lumira Capital in backing the system's commercialization. Most of the C$21.5 million invested, said AuCoin, will be used to hire sales, marketing and service staff. He puts the system's price tag at between US$119,000 and US$149,000. //

Colvera

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Colvera indicates the presence or absence of two altered genes associated with CRC. The blood-based test measures methylation – a genetic change associated with cancer development – in ctDNA.

Unlike DNA mutations, which are frequent in cancer but may vary widely between patients and may undergo mutation shifts during the course of disease, methylation is a more stable feature in tumors that is readily measured. The company noted that the test is not intended to stratify the risk of recurrence in colorectal cancer patients, but rather to identify the presence of disease at the time of testing.

"We have a relatively simple story of how ctDNA can be applied in a clinically useful way," LaPointe told *Medical Device Daily*. "The test has a yes-no result."

Colvera was launched late last year and Clinical Genomics has established a CLIA-registered laboratory to run the test. (See *Medical Device Daily*, Dec. 21, 2016.) LaPointe said Colvera is now live and the product is being actively sold. Clinical Genomics is working with longtime collaborator Madison, N.J.-based Quest Diagnostics Inc. to increase the test's market reach.

"We have a large collaborator in Quest, and they've been very helpful," LaPointe said.

The two companies have a rich history. Clinical Genomics was formed after colorectal cancer screening test firm Enterix Inc. was acquired by Quest Diagnostics Inc. for $43 million in 2006. (See *Medical Device Daily*, Sept. 9, 2006.) Members from Enterix then formed Clinical Genomics. In 2013, Quest Diagnostics then sold Enterix to Clinical Genomics for an undisclosed amount.

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