Circulating translation

By Lauren Martz, Staff Writer

Johnson & Johnson has teamed up with **Massachusetts General Hospital** to develop and commercialize new technologies for capturing and characterizing circulating tumor cells. The partnership is the first under the hospital's translational research centers technology innovation initiative, which promotes industry alliances for early stage research projects. For the pharma, the deal is part of an external innovation strategy that is intended to lower the cost and improve the success rate of clinical development.

Circulating tumor cells (CTCs) break off from solid tumors and circulate in the bloodstream at very low levels. These cells have the potential to be used for noninvasive diagnosis of cancer and provide biological and genetic information about the tumors.

J&J is no stranger to the field, as its Veridex LLC diagnostic unit developed the first FDA-approved CTC product. The company launched its CellSearch System to identify and count CTCs in blood samples in 2004. The *in vitro* diagnostic is approved to predict prognosis for patients with metastatic breast, colorectal and prostate cancers.

According to Nic Dracopoli, VP of oncology biomarkers at J&J's Ortho Biotech unit, the company's existing CTC technology only counts circulating tumor cells in the blood. "The idea for the new technology is to make inferences about the tumor based on the molecular characterization of the CTCs and a better understanding of the molecular pathology underlying each patient's response to therapy and disease progression," he said. "Our current technology is observational. It doesn't let you isolate and characterize the cells easily or comprehensively."

"It is very well recognized that the existing CTC platforms have low efficiency of capture and only have the ability to process small blood volumes. The sensitivity and specificity of the existing systems need much improvement," said Frances Toneguzzo, executive director of Partners HealthCare Research Ventures & Licensing, which is the technology transfer arm for MGH and Brigham and Women's Hospital at **Harvard Medical School**.

MGH and J&J plan to develop a next-generation CTC platform capable of capturing, counting and characterizing tumor cells from whole blood with better specificity and selectivity.

"The goal is to bring to market over the next three to five years a next-generation platform that will change the current abilities of CTC technology," Dracopoli told *SciBX*.

The platform is a microchip involving magnetic bead technology for high-volume sorting and efficiency. MGH has filed patent applications covering the technology. Uma Sundaram, senior business strategy and licensing manager at MGH, said the IP is distinct from earlier CTC microchips developed at the hospital.

"What we are looking for is not just an incremental improvement," said Toneguzzo. "We are interested in orders-of-magnitude improvements over currently available CTC technologies. We aim to be able to process large quantities of blood, to collect the CTCs more efficiently and to collect functional and viable cells for biologic and genetic analysis."

Starting early

The five-year collaboration will join researchers with CTC technology expertise from the MGH BioMicroElectroMechanical Systems (BioMEMS) Resource Center, clinical researchers and molecular biologists from the hospital's Cancer Center and R&D staff from two J&J units—Veridex and the Ortho Biotech Oncology R&D unit.

The partners plan to bring a CTC platform through the remaining preclinical work at MGH before handing the technology off to

Veridex for clinical validation and regulatory submissions within three to five years. Veridex will market the resulting technology.

"The idea is to be working in a product development mode. Pairing product development engineers with academics, with a focus on a core technology, will help us guide the technology in the right direction from an early stage," said Toneguzzo.

"Academics aren't necessarily focused on milestones and deadlines, but bringing in people to work hand-in-hand with the researchers

could help ease the transition," she continued. "We're targeting optimistically three years as the hand-off, and if that comes earlier, then we will be able to take the opportunity to continue to work closely with J&J through the clinical development phases"

"We hope that working together while the work is still in the pre-clinical stages will be more cost and time effective than traditional technology transfer," because companies that in-license products often have to repeat many of the studies run by the academic institutions, added Toneguzzo. "The goal of this type of partnership is for MGH to develop the technology further than we would normally go and to have the company step in earlier than they normally would."

"Johnson & Johnson evaluated a lot of potential opportunities," Dracopoli noted. "MGH has a third-generation technology that is very compatible with our existing platform from Veridex. They also have strong capability in terms of clinical testing and validation of the technology. What we really hope to achieve with this collaboration is a more thorough understanding of why drugs work in patients and why they don't. Academics put a lot of research into understanding patient responses to treatment, and we need to understand why resistance to

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therapy and disease progression occurs in each patient.”

Dracopoli told *SciBX*, “I think our company’s goal is to be doing increasingly more collaboration with academia.”

Last June, J&J’s Ortho-McNeil-Janssen Pharmaceuticals Inc. subsidiary entered a five-year joint cancer research agreement with the **Massachusetts Institute of Technology’s** David H. Koch Institute for Integrative Cancer Research. The deal focuses on cancer diagnostics, the biology of premalignancies, genetic disease models and tumor micro-environment profiles.

Going forward, Toneguzzo said the hospital hopes to form similar

deals with other companies. She said therapeutic areas for such deals include orthopedics, dermatology and additional applications within BioMEMS outside of cancer.

Financial terms of the J&J deal were not disclosed.

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