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COMPANY SEEKS 2017 CLEARANCE FOR T2 BACTERIA TEST

T2 Biosystems hopes to gain market share with sepsis detection technologies

By Omar Ford, Staff Writer

Sepsis is one of the most expensive hospital-treated conditions, costing the U.S. health care system more than $20 billion each year, according to the U.S. Dept of Health & Human Services and CDC Sepsis Fact Sheet.

Additionally, up to 50 percent of survivors suffer from post-sepsis syndrome. The market has seen an increase in companies seeking to develop technologies to adequately test for the potentially life-threatening condition.

Lexington Mass.-based, T2 Biosystems Inc., which was founded back in 2006, is vying for significant market share in the space. John McDonough, president/CEO of the company spoke with *Medical Device Daily* about their progress.

McDonough helped build Cytyc Corp., a company focused on developing women's health products, and led its sale to Bedford, Mass-based Hologic Corp. for $6.2 billion. (*Medical Device Daily*, May 22, 2007.) T2 was co-founded by Bob Langer, a renowned professor at MIT and owner of 1,080 issued patents worldwide which are licensed or sub-licensed to more than 300 companies.

"Sepsis is the most expensive health care treated condition in the U.S.," McDonough told *Medical Device Daily*. "What we've developed at T2 is a new method of doing diagnostic detection. We use magnetic resonance."

T2 Biosystems uses nanotechnology and has an FDA-approved molecular diagnostic panel for sepsis. T2MR is a miniaturized, magnetic resonance-based technology that measures how water molecules react in the presence of magnetic fields.

The technology requires a small blood sample – not blood culturing and delivers faster, more accurate results in just three-to-five hours – versus two to five days with traditional blood culture. In clinical trials, the T2 Candida panel demonstrated 91 percent overall sensitivity and 99.4 percent specificity.

The T2MR Technology and sepsis diagnostic was approved by the FDA in 117 days in September 2014.

"Diagnostics are tremendously overlooked," McDonough said. "When people think of health care they tend to think biotech and pharmaceutical companies. But the truth is, none of those drugs are effective if they don't have a diagnostic to determine which patients would benefit from a drug. In many cases, the real problem in terms of the effectiveness of drugs and the mortality rate of patients is it's all about putting patients on the right drugs fast enough."

T2 Biosystems is working on a second assay for the T2Dx system called T2 Bacteria. This assay will be able to diagnose key sepsis-causing bacteria directly from a patient blood sample in the same time frame as T2 Candida. A clinical trial for the test began in December.

About 1,850 patients are to be enrolled in the study according to listing in clinicaltrials.gov. The primary endpoint of estimated specificity will be determined by comparing the negative blood culture results with the concomitantly collected T2Bacteria panel results from the prospective clinical specimens. The company said clearance for the test could be in the early 2017 time frame.

"The problem with Sepsis is not that we need better drugs – though that would help – but the real problem is we need a diagnostic to detect the infection," he said. "The drugs are actually there you just don't have the diagnostic to [diagnose] the patient fast enough."

T2 is also working on T2 Hemostat. It is designed to be the first test to rapidly provide comprehensive hemostasis measurements directly from whole blood at the point of care. The panel, which will run on the T2plex Instrument, is intended to provide data across the hemostasis spectrum including measurements of clotting time, fibrinogen, fibrinolysis, and platelet activity. The company said FDA trials for T2 Hemostat could occur sometime this summer.

Analysts of the space have spoken favorably of the company, noting that T2's technology could be a true "breakthrough technology."

"We believe T2's technology represents a once-in-a generation breakthrough technology with its ability to identify life-threatening infectious diseases directly from a blood sample in three to five hours," Mark Massaro, an analyst with

Canaccord Genuity, said. "We believe T2 is poised for growth given achievable pacing of catalysts: near-term uptake for candida and bacterial sepsis, mid-term uptake on hemostasis, and LT opportunity around a broad range of applications not yet announced."

Recent movements in the Sepsis space

T2 isn't alone in its bid for sepsis testing. Recently Toronto-based Spectral Medical Inc. said it was in the process of recruiting the last 46 patients into its pivotal Phase III EUPHRATES trial for its Toraymyxin technology. (*Medical Device Daily*, Feb. 1, 2016.) The company pointed out that it was using a device-centered approach to treat sepsis, while in the past pharmaceutical products have been used. Spectral has also developed a diagnostic for sepsis.

During the treatment, blood is pumped out of the patient through a cartridge, which acts as a filter to take the endotoxin out. It then flows right back into the patient. The treatment is about two hours in all and is done twice over the course of a day.

To date about 400 patients have been enrolled in the trial, representing 90 percent of the total estimated sample size of 446 evaluable patients. Spectral said it will have finished the clinical trial enrollment by June.