Put It on the Board

AACC panel votes Inflammatix technology most disruptive

September 2019—Inflammatix, a molecular diagnostics company, received the American Association for Clinical Chemistry's Disruptive Technology Award at the AACC annual meeting in August. The company, in Burlingame, Calif., won for its rapid HostDx tests.

The award was based on Inflammatix's presentation during the meeting. It was one of three finalists selected to present to a panel of expert judges during a special session.

Dr. Sweeney

"We're developing rapid tests that read the immune system to improve disease diagnosis and are initially focused on developing tests for acute infections and sepsis, which are two of the biggest public health challenges of our time," Tim Sweeney, MD, PhD, Inflammatix cofounder and chief executive officer, told CAP TODAY.

The company's first test, HostDx Sepsis, measures the expression of multiple immune genes to determine rapidly if a patient has a bacterial or viral infection and whether the patient has or is likely to develop sepsis, Dr. Sweeney said. It is intended for use in hospitals, particularly in the ER and ICU, he said, where results will help physicians determine the appropriate treatment and the level of care required. Inflammatix is also developing a HostDx Fever test to help physicians in outpatient settings determine whether patients need antibiotics.

"Our innovation lies in developing tests using advanced bioinformatics to integrate multiple data sets that represent a broad spectrum of disease," Dr. Sweeney said. "This ensures that the results are accurate and generalizable regardless of infection type or severity, and across patient populations and settings." The scientific approach, he said, is based on biomarkers licensed exclusively from Stanford University and has been validated in 38 cohorts of more than 2,400 patients.

He and colleagues expect to bring their test system to market in two to three years. "We've recruited a world-class team of diagnostic industry veterans to help translate our tests through FDA clearance and into widespread clinical use," he said, adding that they believe the same approach can "reimagine diagnosis and treatment selection" for tuberculosis, transplant rejection, and autoimmune and other disorders.

The company is funded by Khosla Ventures, Northpond Ventures, the Stanford-StartX Fund, and Think.Health Ventures.

The other two finalists were PixCell, for its lab-on-cartridge and AI technology, and Singlera Genomics, for its ColonES assay. Singlera's test uses next-generation sequencing-based targeted methylation haplotyping of bisulfite-treated cell-free DNA for early colorectal cancer screening.

FDA approves Rozlytrek, targets *ROS1* and *NTRK*

The Food and Drug Administration approved Rozlytrek (entrectinib) for the treatment of adults with *ROS1*-positive, metastatic non-small cell lung cancer. The FDA also granted accelerated approval to Rozlytrek for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation, are metastatic or where surgical

resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.

These approvals are based on results from the integrated analysis of the pivotal phase two STARTRK-2, phase one STARTRK-1, and phase one ALKA-372-001 trials, and data from the phase one/two STARTRK-NG study. In the integrated analysis, Rozlytrek was studied in several solid tumor types, including breast, cholangiocarcinoma, colorectal, gynecological, neuroendocrine, non-small cell lung, salivary gland, pancreatic, sarcoma, and thyroid cancers. In *ROS1*-positive, metastatic NSCLC, Rozlytrek shrank tumors in 78 percent of people with the disease (N = 51) and the duration of response ranged from 1.8 to 36.8+ months (N = 40 of 51). Rozlytrek also shrank tumors in more than half of people with *NTRK* gene fusion-positive, locally advanced or metastatic solid tumors (N = 54), and objective responses were observed across 10 tumor types. Objective responses to Rozlytrek were seen in people with central nervous system metastases at baseline.

“Rozlytrek is the first FDA-approved treatment that selectively targets both *ROS1* and *NTRK* fusions, and, importantly, has also shown responses in these rare cancer types that have spread to the brain,” Sandra Horning, MD, Genentech chief medical officer and head of global product development, said in an Aug. 15 statement.

Foundation Medicine will submit FoundationOne CDx to the FDA for approval as a companion diagnostic for Rozlytrek. An FDA-approved companion diagnostic for Rozlytrek is not available at this time.

Exact Sciences and Genomic Health to combine

Exact Sciences and Genomic Health have entered into a definitive agreement under which Exact Sciences will combine with Genomic Health for $72 per share in a cash and stock transaction valued at $2.8 billion. The transaction is expected to be completed by the end of this year.

The combined company will offer Cologuard and Oncotype DX, “providing a robust platform for continued growth,” Exact Sciences said in a July 29 statement.

“Together, with our collective resources and broader platform, we will be able to provide our existing tests to more people, while also accelerating the development and launch of future cancer diagnostic tests,” Kevin Conroy, chairman and CEO of Exact Sciences, said in the statement.

Sysmex releases PS-10 Sample Preparation System

Sysmex America has made available its PS-10 Sample Preparation System for use in flow cytometry. Sysmex says the highly automated and flexible PS-10 provides clinical labs a new level of workflow efficiency and confidence in results.

The PS-10 automates sample preparation and eliminates variability among operators. It also offers programmable sample preparation for antibody cocktailing and reduces the amount of manual transfer of samples performed by laboratory staff.