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Heranova: Detecting endometriosis in the blood like it's cancer

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Heranova thinks the similarities between endometriosis and cancer will make the notoriously difficult-to-diagnose disease amenable to non-invasive detection via liquid biopsy of nucleic acids from uterine lining cells undergoing excessive growth, which opens to door to use cases beyond yes/no diagnoses.

"Endometriosis behaves like a cancer," Farideh Bischoff, CMO and head of diagnostics at Burlington, Mass-based Heranova Lifesciences Inc., told BioCentury. "The mechanisms by which this disease progresses and develops results in the shedding of material in the blood."

The concept is similar to the one behind the now-mainstream use of circulating tumor DNA (ctDNA) for cancer profiling and monitoring, and of non-invasive prenatal tests (NIPTs) to screen for fetal chromosomal abnormalities in a pregnant person's blood, both of which Bischoff had previously worked on.

Similarly to NIPTs, Heranova's blood test provides an alternative to invasive biopsies. Tissue histology is considered the gold standard for diagnosing endometriosis, despite its own limitations. The invasiveness of the approach and its susceptibility to insufficient sample collection are among the reasons why diagnosis is often delayed by seven years or more relative to symptoms.

"Histology as gold standard is ridiculous. The evaluation of the biopsy is missing disease in many cases," said Heranova SAB member Ronald Feinberg, who was formerly CMO and IVF director at RADfertility & CCRM-Delaware. He noted that disease lesions are heterogeneously distributed across tissue and often take hold outside the pelvic region, where doctors are most likely to look.

On Thursday, Heranova announced laboratory-developed test (LDT) validation for its HerResolve assay, which became available to physicians last August via an early access program. The company is launching the test at selected clinical centers in the U.S., with future expansion planned in collaboration with commercial partners.

The test detects a panel of five undisclosed microRNAs. Bischoff said that while the associations between these markers and endometriosis had previously been reported, Heranova is the first to turn those findings into a clinically deployable test.

"We came up with a short list of circulating microRNAs that were coming up in the literature as putative biomarkers. No

one had gone to the effort of assessing the pre-analytic workup and the processing," she said. "Just like prenatal testing, it requires standardization in how you collect the sample, how you process the sample, and how you analyze it."

The microRNAs were "selected based on their pathophysiological roles," for example, in uncontrolled growth and apoptosis, said Bischoff. "We don't know what the cause of endometriosis is, that's the challenge, so what we're looking at is secondary biomarkers that are playing a role in the further development and progression of disease."

The company is performing validation studies in two different CLIA environments, in the U.S. and in China, where Heranova acquired labs that were formerly part of the reproductive medicine testing company Igenomics Co. Ltd. Bischoff said the Chinese lab was central to Heranova's early development work, as costs were lower and patient samples were more readily available than in the U.S. It is now helping the company account for heterogeneity across populations.

Heranova reports that its test has 92% diagnostic accuracy, and a sensitivity of 90%. The company plans to pursue FDA clearance by year-end; the first indication it's aiming for is diagnosis of women with suspected endometriosis based on pelvic pain who are considering surgery, and are therefore likely to ultimately have histological tissue available for comparison.

"We can then move the bar to milder conditions, and to asymptomatic detection of disease. But first we have to demonstrate the obvious — the utility and efficacy of this test being equivalent to what is considered the gold standard," Bischoff said.

The potential to quantitatively measure endometriosis markers in the blood could also pave the way for patient stratification and longitudinal disease monitoring, including responses to interventions. "The first version of the test is a yes or a no. But our goal is to have a test that can give you the stage and severity of disease. It will depend on validation from patients providing multiple blood samples," Bischoff said.

Feinberg said the test could help guide treatment decisions for in vitro fertilization (IVF) patients, as endometriosis can interfere with embryo implantation and growth, and is a likely contributor to "unexplained infertility" in asymptomatic patients. "It would be fantastic if we could predict ahead of time that they might have an implantation disorder, and maybe treat that medically," he said.

In the fertility setting, Cicero Diagnostics Inc. markets the LDT ReceptivaDx, which diagnoses endometriosis based on expression of the inflammation-associated transcription factor BCL-6 in biopsied endometrial tissue. The company reports a 93% sensitivity and 96% specificity in the detection of endometriosis.

COMPANY PROFILE

Heranova Lifesciences Inc.

Burlington, Mass.

Technology: MicroRNA-based blood test for endometriosis, undisclosed therapies for endometriosis pain, and diagnostics for female fertility patients

Origin of technology: In-house and via external partnerships

Disease focus: Genitourinary

Clinical status: Market (Diagnostic)

Founded: 2022 by Jonathan Zhao, Steve Landau, Penny Wan, Chun Zhang, Farideh Bischoff and Marcel van Duin

Academic collaborators: Harvard Medical School, Johns Hopkins University

Corporate partners: Not disclosed

Number of employees: >50

Funds raised: $13.5 million

Investors: Emerging Technology Partners, Pivotal bioVenture Partners China, Sinovation Ventures, Triwise Capital

CEO: Jonathan Zhao

Issued Patents: Not disclosed

Feinberg thinks the test could also enable "huge opportunity on the prevention side" in young patients starting to show symptoms. "In many patients, it could be predicted in their teenage years."

The actionability of these test results is of course dependent on the availability of safe and effective therapeutics, something Heranova is also working on. Feinberg said the therapeutic targets of marketed therapies, such as the pituitary glad-targeting hormone GnRH, "are very crude right now."

"We're chopping off the source of estrogen, but that can't address the pathophysiology of disease," he said. Their associated risk of bone loss also limits their duration of use.

Bischoff said Heranova's therapeutics arm is exploring an undisclosed protein that regulates pain in the disease.

So far, pain reduction or related metrics such as quality of life assessments are the most well-established regulatory endpoints for endometriosis. The lack of reliable strategies for measuring changes in lesion size has limited the use of endpoints related to underlying disease, a bottleneck that a blood test like Heranova's could ultimately overcome.

In addition to its endometriosis portfolio, the company is developing tests for fertility patients including an endometrial

receptivity test to identify optimal embryo transfer time windows, uterine and vaginal microbiome assays to test for dysbiosis, and an algorithmic assessment of ovarian reserve.

The company has raised $13.5 million in seed funding, and Bischoff said it is raising additional funds to support commercialization of the test. While Heranova's initial investors are based in China, the company is focusing on U.S. and European investors for its next round, she said.

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