MEDTECH INSIGHT
CITELINE COMMERCIAL

15 Apr 2021 | **News**

Start-Up Spotlight: Pre Diagnostics Picks Up Momentum In Early Neurodegenerative Disease Detection

by Ashley Yeo

Norway's Pre Diagnostics uses the intracellular approach to neurodegenerative disease diagnosis. It believes its technology will open up a world of precision medicine for Alzheimer's disease patients.

Pre Diagnostics is forging ahead with plans to secure a CE mark for its PreADx immunoassay for early detection of Alzheimer's disease. Its target for self-certification of the test under the EU IVD Directive is by the end of the second quarter.

In January, the test completed a clinical evaluation from a Norwegian multicenter trial, achieving an ROC AUC of 0.81 in distinguishing healthy controls from Alzheimer's patients. This result, using an older version of the assay, was "what we needed," said chief commercial officer Charlotte Berg-Svendsen.

It is in line with the generally recognized threshold for diagnostic accuracy. "We were very happy to have the proof-of-concept milestone," said Berg-Svendsen. The company now plans to further optimize the test ahead of CE marking. "We expect the area of the curve to increase as we refine the assay," she said.

Measuring Inside Monocytes

The non-invasive "dynamic" test detects beta-amyloid peptides, which indicate underlying disease pathology for Alzheimer's disease in blood cells. The patented concept could be used in drug development as well as for diagnosis before irreversible brain damage occurs, says the company.

Pre Diagnostics' pipeline technology uniquely uses the intracellular approach. "The company

measures, not in plasma or serum, but inside monocytes, the innate immune cells," said Berg-Svendsen.

> *"We focus intracellularly, and we measure enzymatic degradation." – Charlotte Berg-Svendsen*

The premise is that the immune system evokes certain unique systemic responses to neurodegenerative disease inside the cells. "We focus intracellularly, and we measure enzymatic degradation," said Berg-Svendsen, adding that this approach provides more disease-relevant information.

Alzheimer's disease accounts for some 70% of dementia cases globally, which numbered 46.8 million in 2015 and are set to rise to 74.7 million by 2030, according to information from Pre Diagnostics.

Increasing Activity Around Alzheimer's Disease Diagnosis And Treatment

There has been a recent uptick in activity around the early detection and treatment of Alzheimer's disease patients. On the therapy side, *Biogen*'s aducanumab is due for a US FDA decision on approval or rejection by 7 June. And *Eli Lilly* has reported data from a phase 2 clinical trial.

A blood test has been the holy grail, but there is no single silver bullet for diagnosis and there will be many biomarkers coming, said Berg-Svendsen, who joined Pre Diagnostics in 2015, teaming up with cofounders Håkon Sæterøy and Erik Christensen, who now serve as CEO and chief operating officer, respectively.

Pre Diagnostics is focusing on diagnosing and then monitoring patients in clinical studies. This will help build documentation on the test, X34 assay, to detect cut point 34 on beta amyloid.

"The test is 'dynamic' as it measures the ongoing clearance of amyloid plaque that has accumulated in the brain. The changes can be monitored at six-monthly intervals."

CE Marking

CE marking will be the most significant event for the company to date. It was founded in 2013,

based on scientific findings in 2009 by Tormod Fladby and colleagues at the Akershus University Hospital. Fladby, head of the department of neurology at AUH, remains the company's main scientific advisor.

Berg-Svendsen noted realistically that customers won't come running to Pre Diagnostics' door simply based on receipt of the CE mark. That is why validating the product, from a commercial perspective, is such an important step, said added.

The CE mark is just the entry point. Then it's all about demonstrating the benefits and validation by KOLs, she said. "We need to be thinking about what will drive our biomarker into the doctor's office," said Berg-Svendsen.

Pre Diagnostics will support a CE mark with data from 100 blood samples and will continue collecting data thereafter. Data to support the product's claims is also being generated in a trial run with *BASF AG*. This trial uses Pre Diagnostics' biomarker to assess the effects of Omega 3 treatment.

"Putting products on the market is extremely difficult," said Berg-Svendsen, and PreDX has a further hurdle in being entirely new and not yet taken into use. "Our approach is unique," she said. To date, the test has been used for research use only and in clinical trials.

Broader Approach Beyond Alzheimer's disease

When Berg-Svendsen joined the board, Pre Diagnostics was branding itself as "the new Alzheimer's company." (Also see "*Norway's Pre Diagnostics Has Alzheimer's Test In Its Sights*" - In Vivo, 26 Apr, 2016.)

Six years on, the company has broadened its approach to the using the innate immune system for detection of neurodegenerative diseases. "We see the potential of this concept as going way beyond just one

Pre Diagnostics AS

Address: PO Box 1413 Vika, N-0115 Oslo, Norway (visiting: Gaustadalléen 21, N-0349 Oslo, Norway)

Contact info: Charlotte Berg-Svendsen (charlotte@pre-diagnostics.com)

Founded: 2013

Founders: Erik Christensen and Håkon Sæterøy

Number of employees: 5

Investors: INVEN2 (15.5%), Canio (9.9%), Erik Christensen (9.2%), Investor Corporate (9.1%), Bioventix (7.5%), Hathon Holding (7%), Håkon Sæterøy (6.7%)

Board of directors: Håkon Sæterøy, CEO; Erik Christensen, CMO; Charlotte Berg-Berg-Svendsen, CCO.

disease."

The company has chosen Parkinson's disease for its second platform, and selected the biomarker to be developed. It also has potential to go further on the treatment side, having in-licensed some patents, all centered on modulating the innate immune system. These projects are in preclinical development.

Main scientific advisor: Professor Tormod Fladby, Akershus University Hospital

Financing (2014-21): Grants of €4m; equity raised €2.7m

Funding Plans

The company will seek a series A investment of €5m ($5.95m) to €10m—"a significant investment"—later this year. It has funding for another year, but it's also about momentum, said Berg-Svendsen, alluding to the new opportunities, including those on the treatment side.

Until now, it has been able to use EU Horizon 2020 funding to get to the CE marking stage by H1 2021.

The new capital will also be used to fund its own lab and to prepare for commercialization. That stage can be a challenge for start-ups, which are often overwhelmingly focused on the regulatory needs. But appropriate attention must be put to business build-up, Berg-Svendsen notes, adding that Pre Diagnostics plans to have some commercial income by the end of 2021.

Go-To-Market Strategy

Pre Diagnostics has a three-pronged market strategy. It sees biomarkers as its first market, entailing use of a direct sales model for RuO products to pharma/biotech and academic institutions, via its own lab or in collaboration with regional labs. It is already in dialog with certain companies. At present, it collaborates with US lab *Quanterix Corporation*, using its Simoa digital health technology, to develop the assays.

Second is the IVD market. Out-licensing of the IP is the company's preferred strategy, but "a distribution model for Europe is also a real alternative for us," said Berg-Svendsen. Pre Diagnostics would not approach the US market without a partner, she added.

Thirdly would be developing the over-the-counter market, targeting individuals wanting to buy a blood test for cognition purposes.

Precision Med Potential

PreDx is a tool that will make drug development more systematic and should be of interest to pharmas, the company believes. “We think the intracellular technology will take us into precision medicine,” said Berg-Svendsen. It is also Fladby’s view that integrating Alzheimer’s disease diagnostics with innate immunity may be helpful for precision medicine strategies.