

HILOPROBE

A NEW DIMENSION OF LYMPH NODE EVALUATION IN COLORECTAL CANCER



Market need and potential

Colorectal cancer is the third most common cancer type worldwide with 1.4 million new cases yearly. The primary treatment - surgery - only cures half of the patients.

The most important indicator for recurrent disease after surgery, is cancer cells in adjacent lymph nodes. Unfortunately, a considerable number of patients are missed by today's routine clinical method; histopathological microscopic investigation of lymph nodes. The reason is that the method is insensitive (<1% lymph node volume is analyzed), subjective, and cannot discriminate between aggressive and non-aggressive cancer cells.

A more precise method would provide better sensitivity and specificity, which means that there is a potential to save lives by finding all patients with a risk for recurrent disease and give them postoperative treatment. In addition, it would also mean you can avoid treating patients already cured by surgery. In both cases, benefits are numerous for both the patients and the healthcare system.

Business idea

HiloProbe is developing a new type of biomarker test - ColoNode® - with very high sensitivity and specificity, that accurately identifies patients at risk for recurrent disease after surgery.

The ColoNode® test works by providing a quick analysis of a unique, carefully selected set of biomarker mRNAs. The test objectively detects cancer cells in lymph nodes with high specificity and sensitivity and has been shown to be superior to the routine method by finding more patients with cancer cell spread to the lymph nodes. In addition, it discriminates between aggressive and non-aggressive cancer cells.

With the ColoNode® test, clinicians are given access to a new powerful tool for lymph node classification to identify which patients that need postoperative chemotherapy, and for categorizing the patients according to risk of recurrent disease.

Competition

ColoNode® is a unique product with few competitors on the market. The routine method is the primary competitor. To our

knowledge, there is one other biomarker test, the OSNA-assay (Sysmex). This test relies on a single biomarker for detection of cancer cells in lymph nodes. Compared to the OSNA-assay, ColoNode® gives a more accurate estimate of cancer cell load, ColoNode shows cancer cell aggressiveness yielding stronger prognostic value, and it is already adapted to clinical practice by using RNA extracted from fixed entire lymph nodes.

There are also screening methods for earlier detections of colorectal cancer that finds more patients in an early stage on the market. These will most likely increase the market for ColoNode®. Overall, this suggests that ColoNode® has a potential unique market niche.

ColoNode® Advantages

- Focuses on spread of cancer cells to the lymph nodes - the deciding survival factor over blood and tumor analysis.
- Gives an objective, reliable, sensitive and specific assessment of cancer cell spread.
- Evaluates the aggressiveness of the spread cancer cells - giving clinicians the first ever tool to evaluate the key risk factor for recurrent colorectal cancer.
- Is fast and readily adaptable for automation. The test requires less work hours and can therefore relieve the diagnostic pressure on specialized pathologists.
- Can offer better patient survival, higher quality of life, more cost-effective healthcare and opens the door to personalized treatment for colorectal cancer patients.

Current status

The ColoNode® biomarker combination has been validated on ~200 colorectal cancer patients. Market survey confirmed great interest and need of ColoNode®.

Currently, HiloProbe has finalized the "Research use only" kit and is preparing for launch in Q2 and CE-labelling in early 2021. A prospective clinical multicentre study is ongoing in collaboration with Umeå University and several Swedish hospitals.

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Therapeutic area

In vitro diagnostics

IPR

Approved Swedish Patent (2016)
Filed PCT application (2017)
Registered trademark in Sweden, EU and US (2016)

Partnership

HiloProbe seek funding, collaboration and competence within sales, distribution, clinical CRO and medical/scientific advisors.

Management / Board

Lina Olsson, CEO
Ernst Westman, Chairman of the Board
Sten Hammarström, Board member
Thomas Busch, Board member
Gudrun Lindmark, Board member
Mattias Pettersson, Board member

Scientific Advisors/Consultants

Marie-Louise Hammarström, Professor Senior, Umeå University
Helen Fält and Andreas Lindberg, Business Advisors, Umeå Biotech Incubator
Niklas Hofverberg Regulatory Consultant, HofverbergMedical

Background

ColoNode is based on high quality research from Umeå University, Norrland University Hospital and Helsingborg Hospital.

The company vision

ColoNode® will become the new routine method worldwide for determination of lymph node status for classification and prognosis of colorectal cancer.