

HILOPROBE

COLONODE - NOVEL DIAGNOSTICS TO IMPROVE AND GUIDE TREATMENT OF COLORECTAL CANCER

Market needs and potential

Colorectal cancer (CRC) is the third most common cancer in the world with 1.9 million new cases in 2020. The potential market for ColoNode is ~23 billion SEK, considering that approximately 70% (patients undergoing surgery) of all CRC cases will directly be aided by a diagnostic and predictive analysis using ColoNode.

Surgery, the curative treatment, cures only half the number of patients due to distant metastases. It is therefore of utmost importance to identify patients at risk of recurrence. Detection of tumor cells in lymph nodes in the resected specimen is the most important risk indicator for recurrent disease. A considerable number of lymph nodes harboring tumor cells are missed by today's routine clinical method, i.e. histopathological microscopic investigation, which leads to undertreatment. The reasons are that the method is insensitive, subjective and examines less than 1% of the lymph node volume. In addition, the routine method cannot discriminate between aggressive and less aggressive tumor cells, which may lead to overtreatment. Therefore, many patients are not receiving the best treatment today, which causes unnecessary suffering and high healthcare costs.

Business idea

HiloProbe has developed an innovative diagnostic and prognostic product, ColoNode, for determining the presence of tumor cells and the degree of their aggressiveness in lymph nodes. ColoNode provides the clinician a new tool for designing treatment and surveillance after surgery, which have the potential to save lives by finding all patients at risk for recurrent disease and offer them postoperative treatment. In addition, postoperative treatment is avoided to patients cured by surgery alone. Thus, ColoNode prolongs survival time and yield a higher quality of life for the patients and contribute to a more cost-effective healthcare.



Achievements

The ColoNode biomarker combination and kit has been validated in two clinical studies and recently. ColoNode has been proven to be superior to the routine method by finding more patients with tumor cell spread to the lymph nodes and the ability to categorize patients regarding risk of recurrent disease. Methods for sample preparation from formalin-fixed lymph nodes have been developed.

An in-house manufacturing process for ColoNode has been established.

ColoNode is CE-labelled according to European In Vitro Diagnostic Directive 98/79 / EC (IVDD). A comprehensive health economic analysis supporting the pricing strategy has been performed.

Market analysis, customer need analysis, Key Opinion Leaders (KOLs) and distributors has confirmed a great need for and interest in ColoNode.

The product is patented in Sweden, the US, Japan and South Korea. In addition, a US, Australian and broad PCT applications are pending. The ColoNode trademark is registered in Sweden, Europe, and the US.

A small and efficient organization with staff and a network of consultants has been established.

ColoNode Advantages

Focuses on spread of tumor cells to the lymph nodes in the resected specimen - the most important prognostic factor in predicting the risk of tumor recurrence in CRC. Is more important than blood and primary tumor analysis.

Gives an objective, reliable, sensitive, and specific assessment of tumor spread.

Evaluates the aggressiveness of spread tumor cells - giving clinicians the first ever tool to evaluate the key risk factor for recurrent CRC. Is fast and adaptable for automation.

Competition

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

There are also screening methods for earlier detection of CRC on the market, that finds tumors at an earlier stage. These will most likely increase the market for ColoNode. Overall, this suggests that ColoNode has a unique market niche.

Current activities

The main goal is to initiate sales of ColoNode on the European market. Ongoing activities are based on knowledge from discussions with collaborating hospitals, customer prospects, KOLs, distributors, and CRC care treatment program groups.

Sales and marketing: The Nordic markets are addressed by direct sales and the remaining Europe through distributors. Negotiations are ongoing with potential distributors. In addition, we are participating in conferences and other meetings presenting published research results and market the product.

Prospective clinical study (ColoNode-study): Eight hospitals are participating in the study. The results for the colon cancer patients with 3-year survival data has now been finished and summarized in a manuscript, when published to be used as basis for sales and marketing. Sample preparation and ColoNode analysis of lymph node samples from the rectal cancer patients is ongoing.

Retrospective clinical study: Collaboration with Sahlgrenska University Hospital in Gothenburg Sweden has been initiated to perform a retrospective study on stage II patients with recurrent disease.

Offer to investors

Expected proceeds	10-15MSEK
Use of proceeds	Establish ColoNode on the European market
Subscription period	~ December 2023

Use of proceeds

The main goal is to establish sales of ColoNode on the Europe market.

- Establish sales of ColoNode by addressing the Nordic market through direct sales and the remaining Europe through strategic distributor partners.
- Set up a procedure and offer ColoNode-analysis as a service.
- Finish the rectal cancer part of the ColoNode-study with 3-year survival data.
- Finish the clinical collaboration study with Sahlgrenska University Hospital. Perform collaboration studies with KOLs.
- Expand the network of KOLs.
- Further develop the sample preparation method of RNA from formalin-fixed lymph nodes to facilitate automatized analysis.
- Validate ColoNode on more qRT-PCR instruments.

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Therapeutic area

In Vitro Diagnostics, Colorectal Cancer

IPR

Approved Patent in Sweden, US, Japan and South Korea, Pending PCT application
Registered trademark in Sweden, EU and US

Management / Board

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

Scientific Advisors/Consultants

Marie-Louise Hammarström, Senior Professor, Umeå University

Background

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

Company vision

The product ColoNode will become the new routine method worldwide for determination of the lymph node status in CRC.

Company mission

To help health care professionals make better treatment decisions for CRC patients.