

## PRESS RELEASE

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Large potential for Nanologica's product for the treatment of gastroparesis

**After regulatory investigations and an extended market analysis, Nanologica advances the project NIC-001 towards clinical phase IIa. The market analysis shows good market potential for the product.**

Nanologica has, after careful considerations, decided to focus the clinical development program for the treatment of gastroparesis to the North American market. The decision was based on an extended market analysis of the American market carried out by Informa Pharma Consulting on behalf of Nanologica. In-depth interviews with key opinion leaders as well as payers within the American health insurance system, state that specialists in gastroparesis show great interest in the product and that the possibility of having the product subsidized is good.

Focusing on the North American market also led to a continued regulatory investigation. These investigations, along with cost evaluations, conclude that it is more favorable to conduct the clinical study in Australia, than in Sweden as previously planned. The clinical trial is a cross-over study on gastroparesis patients with the aim of studying the safety of NIC-001 and comparing its pharmacokinetic profile to the formulation of metoclopramide available on the market today. The applications to gain approval to start the study is expected to be handed in during the first half of 2020.

*"We decided to conduct a deeper regulatory investigation as well as an extended market analysis to gain greater knowledge about the American market. The market analysis shows that not only doctors treating patients, but above-all the payers are very positive to what we are trying to achieve with NIC-001. The medical need is so large that even small improvements will mean a high probability for good reimbursement. In practice, this means a lowered risk and greater possibilities for Nanologica to help patients, at the same time as the potential for profitability is large. We now look forward to entering clinical phase",* says Andreas Bhagwani, CEO of Nanologica.

Gastroparesis, delayed emptying of the stomach, is a condition affecting many patients with diabetes. The symptoms consist for example of pain, nausea and vomiting. In the US approximately 2.3 million patients seek medical help for gastroparesis. About 2 million of these are women, whereof approximately half do not respond to available treatment options. The market is assessed to be growing as the number of diabetes patients are growing continually; the National Diabetes Statistics Report from 2017 reports that there are over 30 million people in the US suffering from diabetes.

The market analysis contains estimations of different scenarios based on the results the clinical phase IIa study with the drug candidate NIC-001 could show. In the best-case scenario, where the study results differentiate NIC-001 from existing metoclopramide-based products in a positive way, NIC-001 is believed to gain a prominent place among the treatment options and have a good possibility of being subsidized. In the worst-case scenario, the product would only be used after generic formulations of metoclopramide have shown to be ineffective for the patient. According to the analysis, the project would still be well worth carrying out and the chance for the project to be profitable is good.

A positive outcome of the study is believed to create good preconditions for Nanologica to enter into a license and development agreement with a larger pharmaceutical company to continue the development of the project.

**For further information, please contact:**

Andreas Bhagwani, CEO Nanologica

Ph: +46 70 316 17 02 or e-mail: [andreas.bhagwani@nanologica.com](mailto:andreas.bhagwani@nanologica.com)

**About Nanologica AB (publ)**

Nanologica was founded in 2004 and is a nanotechnology company developing nanoporous silica particles for applications within life science. Nanologica is world-leading in controlling the shape, size and type of porosity of silica particles. This knowledge is applied within drug delivery and chromatography (a separation technique used in drug development and drug production). The company's mission is to contribute to better and cheaper treatments for patients worldwide through the technology platform NLAB Silica™. Nanologica's stock (NICA) is listed on Spotlight Stock Market. For further information, please visit [www.nanologica.com](http://www.nanologica.com).

**About NIC-001**

NIC-001 is a reformulation of metoclopramide for the treatment of gastroparesis. Metoclopramide is a substance used to treat impaired motility of the gut, as well as nausea and vomiting, and is the only drug approved by the FDA for the treatment of gastroparesis. The efficacy of existing metoclopramide-based drugs varies however widely, and the drugs are ineffective for many patients. The purpose of NIC-001 is to address these issues by utilizing Nanologica's technology platform to deliver the active substance through a new administration route, for the indication. The expected advantage of NIC-001 is a faster and more consistent symptom relief, and increased comfort for patients.