Press release 2020-02-19

# WntResearch discloses CEO comments

**WntResearch is disclosing the CEO comments from the year-end report covering the period January to December 2019, which will be published on 20 February, since it contains detailed information.**

The focus during the fourth quarter has almost exclusively been on the clinical trial and on facilitating the provision of information according to plan. Additional applications have been submitted in both Hungary and Spain to increase the number of clinics and thereby accelerate patient recruitment.

An extended application in Spain was approved, and seven new clinics could be added. We currently have 17 Spanish clinics, most of them with patients included.

By early November, an important milestone was achieved as we included the 20th patient – thus reaching the number required to carry out an initial safety assessment of Foxy-5 administration to patients. At the end of December, the assessment was concluded and the findings were presented to the safety committee, which gave its approval to proceed with the clinical trial according to plan. This stamp of approval will facilitate patient recruitment and enhance the treating physicians' trust.

At the moment there are 37 patients included in the trial, which means an increase by 14 patients since late December.

At the end of the quarter, our application to initiate the study was unexpectedly rejected by the Hungarian authorities. We immediately responded and addressed the reasons for refusal; a second application was submitted, and this was approved very swiftly during the current quarter. However, in combination with a slow recruitment rate in Spain, the result of the process was that we failed to meet our estimated patient recruitment. Our initial forecast, on which the estimate to potentially be able to begin data evaluation by summer 2020 was based, relied on a quick initiation of patient recruitment in Hungary for safety margin. Due to the Hungarian authority's decision to initially reject the initiation of the study, it is now entirely conditioned on the already included patients not deviating from our assumptions based on historic assessment of risk and WNT5A expression.

Most encouragingly, we find that the time between operation and relaunch of Foxy-5 treatment has decreased following the protocol amendment that was applied during the last quarter. It is difficult to determine the consequences of a longer post-operation interruption of administration (as observed in the patients first included) with any certainty, and future analyses will show.

The criteria we are using for inclusion in the statistical analysis are the stage of the cancer at the onset of treatment and the level of WNT5A expression in the primary tumor. These are necessary parameters to take into account in order to assess how

many of the patients included in the study that fulfill the criteria to be included in the statistical analysis.

An initial assessment of level of risk and WNT5A expression will be brought forward and carried out concertedly with regard to treated patients during Spring 2020. This assessment will be of significant importance in confirming the Company's assumption that approximately 70 percent of patients have a low WNT5A expression as well as that the risk of relapse has been correctly estimated in the clinical diagnosis, that is, 30-60 percent in the patient group. Provided that this is correct, we will be able to analyze and compare the outcome of ctDNA in plasma for 12 patients each in the control and treatment arm respectively, that have undergone surgery at least 3 months prior to analysis; this will be carried out during the Summer of 2020. It still remains to be seen whether this patient base is sufficient to observe an efficacy trend. The Company hopes to be able to include additional patients in February and early March to improve the patient base of the analysis. If the patient base is deemed to be insufficient, there will be analysis made at a regular basis while the patient base increase and the time from surgery increase.

Preclinical trials have been conducted within psoriasis and Box-5. Previous results have shown elevated levels of WNT5A in the damaged skin of psoriasis patients. Few preclinical models are considered to be useful for determining the efficacy of novel drugs, and Box-5 has been tested with a model which is recommended by many research teams. In an early study, we were able to demonstrate elevated WNT5A levels in this model. In continued experiments, where Box-5 was compared with a control group, it was discovered that the model needed to be optimized. At the same time, it was found that Box-5 did not have a negative effect on the disease. According to a preliminary assessment of the results from new experiments where the treatment schedule had been optimized, Box-5 likely has no effect in this model. In recent days, we have also received results from another study conducted by an external party, which does not demonstrate a treatment response from Box-5 either.

The overall results from these studies leads the Company to consider them not attractive for commercial cooperation. The Company will therefore put the project and further work relating to this indication on hold, and instead focus its entire effort towards the phase 2 study and Foxy-5.

We are continuing our preclinical work on Foxy-5 interactions with so called checkpoint inhibitors. The studies conducted in collaboration with the University of Copenhagen have been analyzed in detail without being able to verify the previously observed tendency to potentiate efficacy. The study, however, unambigously demonstrates that Foxy-5 does not have a negative impact on the efficacy of checkpoint inhibitors. It is known that different tumour types vary greatly in their expression of checkpoint molecules, both with regard to the kind of molecules and to expression levels.

Complementary studies on a number of new tumour cell types will be conducted during the current quarter to shed light on how the Company should handle this project in the future.

To summarize, this quarter did include some disappointment, but it also offered a positive development with regard to the NeoFox study, which is the Company's main priority project. We also received a very encouraging piece of news this quarter: that NeoFox is now approved in Hungary as well. Intensive work is currently underway to activate these clinics and proceed with our study to reach our goal of demonstrating a positive effect from Foxy-5 in patients with colon cancer.

*Peter Morsing, Chief Executive Officer*

**For more information, please contact:**
Peter Morsing, CEO, WntResearch AB
E-mail: pm@wntresearch.coman
Telephone: +46 727 200711

*This information is information that WntResearch AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, on February 19, 2020.*

**About WntResearch**
*WntResearch is developing an entirely new kind of cancer drug, which inhibits the tumour cells' ability to spread through the body and metastasize. The majority of cancer deaths are due to metastases, and there are no therapies available that can prevent that. Foxy-5, the Company's most advanced drug candidate, is a peptide that mimics the body's own WNT5A protein. In preclinical trials, Foxy-5 has demonstrated ability to suppress the mobility and invasive power of cancer cells, and thus to inhibit metastasis. Phase 1 studies on patients with colon, prostate and breast cancer have demonstrated a good safety profile and favourable pharmacokinetics, and early data indicates biological activity. A Phase 2 multicenter study is underway on patients with colon cancer, in order to study the anti-metastasizing efficacy of Foxy-5. WntResearch's share is listed on Spotlight Stock Market. For more information, please visit: www.wntresearch.com*