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WntResearch announces updated information about the phase 2 study

Patient recruitment in Spain and initiation of new clinics in Hungary in the Company’s ongoing NeoFox study with Foxy 5 has proceeded according to plan and accelerated. However, two Spanish clinics have announced that they temporarily halted recruitment for the study during the month of March due to the Corona virus. In addition, ongoing assessments show that the current patient base is not considered large enough to conduct an analysis of the primary endpoint in summer, as previously indicated.

In Spain, more than 40 patients have now begun their treatment in the study, and, as planned, the second safety analysis will be performed by mid-second quarter 2020 when these patients have undergone surgery. By now, all activated centers in Spain have included or screened one or several patients. However, 8 Spanish hospitals have informed that all external visits are limited, which for two clinics includes recruitment stops for clinical studies. We cannot at present assess what effect this will have but prepares that the recruitment stop can be extended.

Start-up in Hungary is well underway, and the first two clinics have been initiated with activation to commence within a week. This means that patients can be recruited. Three additional clinics are planned to be initiated this week, and five clinics are ready to be initiated in the next week. A preliminary assessment of patients in both the active group and the control group of the study has been performed. All of the assessed patients have now undergone surgery. In the material that has been analyzed pathologically, the Company sees a higher proportion of patients with lower risk of metastasis than was projected based on the clinical assessment made with CT at inclusion. This entails that information from additional patients will be required to conduct an analysis that can provide meaningful results. A first ctDNA analysis of patients can thus not be carried out already in summer, as previously disclosed, but is instead expected to be carried out in the second half of the year when more patients have been assessed in the study, increasing the patient base. Measurements will then be performed with higher precision since a larger number of patients will have undergone surgery at that time, and since more of the 3-month patient follow-ups will have reached 6, 9 and in some cases 12 months. The company’s expectation for this first analysis is that, based on the early stage of the clinical study and that all patients have not yet been included, it should be too early to be able to demonstrate efficacy, but that a trend should be demonstrated that in such case would increase the likelihood that a statistically significant effect can be demonstrated later in the study.

"Our continuous effort to optimize patient recruitment in Spain is now bearing fruit, as the significantly improved recruitment rate demonstrates. However, the pandemic we are now experiencing with the Corona virus is a factor of uncertainty. We are continuing our work to ensure that patients with the adequate risk profile are included. Meanwhile, we are experiencing a very positive start in Hungary where the
first patients are expected to be recruited within the next few weeks," says Peter Morsing, CEO of WntResearch.

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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