

Press release 2019-12-17

Wnt Research announces that results from ongoing phase 2 study may be delayed

WntResearch has today submitted a renewed application to the Hungarian authority, following a positive assessment of the clarifications provided to the ethics committee by the Company. The message that a new application must be submitted, in combination with a lower-than-expected recruitment rate in Spain, will induce delays in the reading of study results.

The Hungarian ethics committee has raised questions regarding the study protocol for the ongoing phase 2 study, and has requested WntResearch to submit a new application. A new application has been submitted to the authority today. The clarifications requested by the ethics committee have received a positive assessment, and the Company's clarifications in the new application provides adequate response to the questions raised.

Since WntResearch has been requested to present a new application in Hungary, the study initiation in Hungary will suffer a two-month delay. All the agreements with Hungarian clinics will be finalized in the near future, and initiation of the clinics will commence as soon as approval is obtained.

The recruitment rate in Spain is lower than expected; presently, 23 patients are included. Important measures have been taken to accelerate recruitment in Spain, but they have not yet had a full effect. The result is that the number of included patients for interim evaluation will not be reached by the end of the second quarter 2020. Out of the seven new clinics that have been approved, six have been activated. In total, eleven clinics are now actively identifying patients for the study. It takes approximately three months between activation of a clinic and inclusion of its first patient.

Last week, WntResearch arranged a meeting in Spain with most of the leaders of the contracted clinics. A review of the activities on the clinics showed the patients' availability for treatment during the Christmas break to be one of the reasons that measures have not yet had a full effect; this is required for treatment to begin during the period October to December, since the Foxy-5 treatment lasts three months. Dr Ramon Salazar, the study's principal investigator, impressed the value of being able to add Foxy-5 as a treatment option for cancer patients on the clinical monitors. He further emphasized that any delay in the execution of the study is regrettable, since this also delays the opportunity to introduce a new treatment with potential to improve the prospects for a large number of patients.

"We are concerned about the last month's development, and we are working assiduously with the authorities and with our contract research organizations to move forward with the study. Our assessments of patient management, logistics and treatment have provided information which is continuously implemented in our efforts.



We are optimistic about an approval to initiate the study in Hungary, so that we can achieve the acceleration we are pursuing,” says Peter Morsing, CEO of WntResearch.

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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 December 17, 2019.

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 was recently initiated 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