

A commentary on the interim Foxy-5 phase 1 study report

The recent publication of an interim report of Foxy-5 clinical Phase 1 study has raised a lot of questions. This has prompted us to write a clarification on how WntResearch values the results obtained so far:

1. The phase 1 study reveals that Foxy-5 is a non-toxic drug and can as such be combined with conventional chemotherapeutic drugs. This is positive and will give WntResearch the freedom to combine Foxy-5 with any other drug in future clinical trials. Since Foxy-5 by itself does not kill cancer cells, the combination treatment will be a requirement for a maximum effect of Foxy-5.
2. The blood measurements of Foxy-5 in treated patients showed that Foxy-5 can be measured throughout a treatment cycle. This is important and positive data since it means that Foxy-5 will be constantly present in a patient and thereby make it possible for Foxy-5 to hit the cancer cells continuously.
3. When designing the study we did not expect to see any signs of tumor shrinkage in Foxy-5 treated patients since Foxy-5 does not induce cell death. Foxy-5 instead inhibits movements of cancer cells and thereby the metastatic process (spreading of cancer which is the main cause of cancer related deaths). As Foxy-5 has shown to be a non-toxic compound, we will be able to hit the cancer cells from different directions by combining Foxy-5 with chemotherapy. This is what we intend to do in the phase 2 study.

However, we got the first indications from the phase 1 study that Foxy-5 might actually prevent tumors from continuing to grow since two patients obtained a long-lasting stabilization of their tumors without having new metastatic lesions. We are very excited by these results and are currently looking into this in more detail. That Foxy-5 can stabilize tumor growth might not be surprising since tumor growth involves movements of cancer cells.

4. The two patients who obtained stable disease also showed stable CTC counts. We are excited over these results, as they are confirmatory to each other. At the same time we want to make clear that we are in need of more information on CTC measurements as markers of the Foxy-5 effect. Hence, in our upcoming phase 1b study we will in addition to CTC measurements explore and validate several other biomarkers for their suitability as markers for patient responses to Foxy-5. We have now employed Professor Klaus Pantel from Germany in the planning of the CTC measurements for the phase 1b study. Professor Pantel is a recognized world expert in CTC's. For more information about how to interpret the CTC results please see the recently updated FAQ on our homepage (www.wntresearch.com).

Conclusion

All in all, our interpretation of the data from the Foxy-5 phase 1 study so far is very positive to us. We cannot see any negative data coming out of the results, and we see several positive indications that Foxy-5 is a promising anti-metastatic compound:

- We have proven Foxy-5 to be a safe drug that is present in the blood even between treatments.
- It will be possible to combine Foxy-5 treatment with chemotherapy.
- We have seen the first suggestions for a tumor stabilizing effect of Foxy-5 and this effect is accompanied by stabilization of CTC's in the blood.

The WntResearch management team is now looking forward to perform the phase 1b study. This study will partly be designed to confirm the positive anti-tumor effects seen in the phase 1 study, and partly as a study where we will obtain additional information to be used in the later phase 2 study.

WntResearch management team, November 10, 2015