FACEBOOK Questions – TEQ-103

#	Question	Answer	Comments
1	When do you think clinical trials will start?	A precise date for the start of the study cannot be specified at the moment. However, we assume that the study with TEQ103 will start in the second half of 2025. The initiation of the study, as well as other relevant milestones, may be published on social media or found in corresponding publications. Furthermore, we refer to the FDA ClinicalTrials.gov website.	
2	What will be the process in 2024 to get this drug ready for clinical trials?	Currently, the substance TEQ103 is in the preclinical testing phase. This evaluation is expected to be completed in year 2024. Following that, the submission to the relevant authorities will take place, both in the US and the EU. In parallel, the substance will be manufactured. The initiation of the clinical study is planned for the second half of the year 2025.	
3	How does a patient become part of the clinical trial?	Participation in the study follows a standard process in accordance with relevant regulatory guidelines and regulations. The Clinical Study Protocol defines the enrolment criteria for study participants and the patient's treating physician responsible for the conduct of the study at the Clinical Study Site (usually a hospital or an experienced trial site) will decide together with the patient if participation in the study is adequate. We would like to emphasis that Oncoteq does not have any influence on the inclusion of patients. This responsibility lies entirely with the investigator.	
5	In which countries will the trials take place?	The study will most likely be conducted in the US and selected EU countries.	
6	Will there be a way for people in other countries to participate?	Yes - either the study will be conducted in the patient's country or the patient who is able and willing to travel finds an agreement for abroad healthcare coverage with his home health insurance. We would like to point out that Oncoteq will not be able to assume financial coverage	

		and travel expenses for foreign participants.	
7	If a person can't participate due to distance, will there be any compassionate use options? Can someone travel to participate?	Unfortunately, there will be no compassionate use program before the safety and tolerability of TEQ103 is established. Referring 'travel', please see answer to question #6.	
8	When will it reach all patients, including those in Europe?	Projections on the general availability of the drug cannot be made at the moment (and we therefore avoid providing speculative estimates). Experience from comparable studies has shown that it is not uncommon for a standard clinical development phase to require 5-7 years before a drug reaches the market. The study will likely be conducted in the US and selected EU countries. (please see answer to question #5).	
9	Is there anything we can do to contribute to getting a multi-center international clinical trial that covers countries in the Global South? What can we do to push for that?	Unfortunately, advancing the inclusion of countries of the Global South in innovative drug development is a slow process that is largely driven by large pharma companies with strong local presentation and direct access to local resources. The currently prevailing risks for a start-up biotech company like Oncoteq of including these countries outweigh the potential benefits for patients.	
10	In the vaxinia trial they dosed in three different amounts. If you received the smallest dose, which was less effective, you were unable to get the higher dose. Will this be the case, or do you let them move to a higher dose off trial?	For our planned study with TEQ-103, Oncoteq is exploring options to both, minimize exposing study participants to non-therapeutic doses and allowing exposure to higher doses wherever possible.	
11	Will all participants receive the trial drug, or will some get placebo?	In the first study with TEQ103, all patients will receive TEQ103. No patient receives a placebo in this study.	
12	Will they be trialing with all subtypes of MBC that are Er+? Is this treatment also suitable for HER 2 positive, for any metastases?	Patients with ER-positive metastatic breast cancer will be eligible for the first study; co-expression of HER2 might be acceptable but will depend on non-clinical studies currently being carried out and informing the final study design.	

13	If the patient has the ER+ breast cancer, does the cancer have to become resistant to other lines of treatment to be included in trial?	Eligibility for study participants in the first TEQ103 study will require that they have received therapies approved for the stage of the disease or are unable to tolerate such treatments. Resistance to endocrine therapies will not be a requirement to participate in the study.	
14	Which types of metastases are they looking to include in trial (bone/organ)?	Patients with any type of metastases could be included in the study; for some forms of metastasis (e.g., brain metastases) special medical conditions are likely to apply.	
15	How many years since the original MBC diagnosis will they include in trial? Those diagnosed 10+ years ago? 5-10 years? 1-5 years?	Time elapsed since the initial diagnosis will not be a criterion to participate in the study.	
16	Is there a certain age group or across age groups?	Patients who are 18 years or older could be included in the study.	
17	Is it possible to participate in clinical trials and live distantly? Take blood tests locally, take drug where one resides?	In principle, it is possible to participate in clinical studies remotely, however, it will depend on the participants medical condition and their acceptance of the additional burden to frequently return to the study site (hospital). TEQ103 medication will only be administered at the study site, and certain examinations and blood tests will have to be carried out at the study site.	
18	How is it administered: IV, pills, how often, etc?	TEQ103 will be administrated intravenously; the exact frequency of administrations is still subject to evaluations.	
19	When in human trials does a patent have to fail a certain number of lines of treatment to be considered?	Please see response to question #13.	
20	When in human trial can a patient stay on the current line of treatment?	Only patients who stopped other anti-tumor treatments will be eligible for the study.	
21	How long to determine if it is working? If it works on the first cohort, will you then open it for more patients while sell in Phase I? *Are they calling this a cure or a treatment?	The study design must be exactly prespecified in the clinical study protocol. Potential changes to the planned study design will be data driven and are difficult to project at this time. Usually, a number of different dose levels must be explored before tolerability and efficacy can be determined.	

		It is generally accepted that once the disease stage is assessed as being “metastatic” breast cancer is no longer curable with currently available therapies, however, there are exceptions to the rule. Cures are usually possible only in early breast cancer before distant metastases have established.	
22	Will they allow the trialing to take place on newly diagnosed and metastatic thrivers (no accounting for how many lines) given the effusiveness in petri dish studies?	First and convincing signals of efficacy in Phase 1 study participants with metastatic breast cancer may encourage us to propose further studies in newly diagnosed patients.	
23	Will Oncoteq be open to the idea of using patient advocates in the trial design process, and if so, how will those participants be selected?	The study design and resulting study protocol are created by experienced oncologists. However, we are always interested in evaluating opinions and suggestions from patient advocacy groups.	
24	Can they please include a compassionate study group, if possible, women and men who have been waiting for a long time for the drug and are out of other options?	Please see response to question #7.	