

Exact Therapeutics receives regulatory approval to reopen the ACTIVATE clinical trial

OSLO, 2 February 2023: EXACT THERAPEUTICS AS (“EXACT-Tx”, Euronext Growth: EXTX), a clinical stage precision health company utilising Acoustic Cluster Therapy (ACT[®]) across multiple therapeutic areas, today announces that the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) has approved reopening of the clinical phase I ACTIVATE trial.

As communicated in a press release of 8 March 2022, EXACT-Tx received a request from the MHRA for an additional submission and approval of medical device documentation associated to the protocol amendment filed with the ACTIVATE phase I clinical trial. EXACT-Tx responded to the request and has now received MHRA’s approval on both the medical device documentation and the amended protocol. The approvals were made without objections.

For EXACT-Tx, this mean that the ACTIVATE phase I trial will be reopened and additional patients will be recruited for the trial.

So far, there have been seven patients enrolled in the study with five patients’ data being evaluable for the study endpoints. Several valuable and encouraging insights have been gained from this first cohort of treated patients.

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About EXACT-Tx

EXACT-Tx is a clinical-stage Norwegian precision health company developing a technology platform for targeted therapeutic enhancement – Acoustic Cluster Therapy (ACT[®]). ACT[®] follows a unique approach to ultrasound-mediated, targeted drug enhancement – with the potential to significantly amplify the clinical utility of a wide range of therapeutic agents across a multitude of indications including within oncology (chemotherapy, immunotherapy), infectious diseases, and brain diseases. www.exact-tx.com

About ACT[®]

- ACT[®] is a proprietary formulation consisting of microbubbles and microdroplets that are activated through the application of ultrasound with the consequent increase in targeted delivery of a co-administered therapeutic agent.
- ACT[®] is supported by a strong and broad preclinical package demonstrating therapeutic enhancement in multiple oncology models (pancreatic, breast, colon, prostate) as well as blood-brain barrier penetration.
- Initial focus of the Company is oncology, however the ACT[®] platform has potential across therapeutic areas (infectious diseases, CNS, immunotherapy) and product classes.

Forward looking statements

This announcement and any materials distributed in connection with this announcement may contain certain forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect the Company's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of material factors could cause actual results and developments to differ materially from those expressed or implied by this forward-looking statement.