EXACT Therapeutics announces positive final results in Phase 1 ACTIVATE trial in liver metastases from colorectal cancer

- These results indicate that EXACT Therapeutics' Acoustic Cluster Therapy (ACT®) significantly enhances the local effect of chemotherapy
- In the patients who had a response to chemotherapy, ACT-treated tumours showed a significantly greater reduction in diameter compared to control tumours (-29% vs. -7%, $p<0.05$)
- Final analysis mirrors the excellent safety profile of PS101 seen in the interim read-out and suggests a dose-response relationship
- The data supports the company's plans for its Phase 2 trial (ENACT) in patients with locally advanced or borderline resectable pancreatic cancer

Oslo, Norway, 20 May 2025. EXACT Therapeutics (Euronext Growth: EXTX), a clinical-stage precision medicine company, is pleased to announce the final and positive data set from its Phase 1 ACTIVATE trial. The trial investigated the use of EXACT's proprietary Acoustic Cluster Therapy with chemotherapy in hard-to-treat patients with liver metastases of colorectal origin. These encouraging clinical data provide proof of principle for the clinical application of ACT technology and offer strong support for initiating the ENACT Phase 2 study in pancreatic cancer, a disease with a high unmet medical need.

"I am excited about the data from the ACTIVATE trial, which yet again underscore the attractive therapeutic proposition from our proprietary ACT technology. The strength of the response to treatment, the safety profile and its non-invasive nature points to a unique and highly differentiated therapeutic regimen. We continue our efforts to bring ACT to cancer patients as fast as possible. Building on the momentum of the ACTIVATE study, we are excited to be approaching the first patient dosing in our Phase 2 ENACT trial in locally advanced pancreatic cancer." said Per Walday, CEO of EXACT Therapeutics.

The final results affirm the previously reported positive ACTIVATE outcomes and indicate the significant added efficacy of ACT with chemotherapy compared with chemotherapy alone. Among patients who responded to chemotherapy, tumor shrinkage was significantly greater with ACT and chemotherapy compared to chemotherapy alone in the same individuals (−29% vs. −7%, $p<0.05$).

ACT treatment with EXACT's proprietary agent PS101 had a clear dose-response relationship. Shrinkage of tumour lesions was significantly greater in patients who received 40 µl/kg PS101 compared with 20 µl/kg PS101. In the group of patients who showed a response to chemotherapy in the control lesions, 3 out of 4 patients who received 40 µl/kg PS101 showed tumour shrinkage of more than 30% in diameter. Tumour shrinkage was seen in 6 out of 9 patients who received ACT with chemotherapy. PS101 was safe and well tolerated when given with chemotherapy.

Chief Medical Officer of EXACT Therapeutics, Amir Snapir continued, "Today's update marks the successful completion of the ACTIVATE trial. The results give us great confidence in the treatment potential of the ACT technology for patients with solid tumours."

EXACT Therapeutics is committed to advancing cancer therapies and sharing its research findings with the broader scientific community. The company plans to present the detailed data from the Phase 1 ACTIVATE trial in a future scientific publication and at a forthcoming medical conference.

The company wishes to thank the patients, their families and the investigators for their participation and contribution to the ACTIVATE trial.

About the Phase 1 ACTIVATE trial

ACTIVATE is a multi-center, single arm, open-label Phase 1 trial to assess the safety and tolerability, pharmacokinetics, and preliminary anti-cancer activity of ACT treatment with the chemotherapy regimens FOLFOX or FOLFIRI in patients with liver metastases of colorectal origin. The trial is designed in the way that each patient serves as their own control, with primary assessment of anti-tumour activity consisting of within-patient comparison of radiographic responses between ACT-treated lesions (insonated plus chemotherapy) and control lesions (chemotherapy alone, non-insonated). Assessment was done at week 8 by blinded central review. The trial enrolled 11 hard-to-treat patients, hereof 9 evaluable, at sites in the United Kingdom. Additional information about the ACTIVATE trial is available at clinicaltrials.gov (NCT04021277).

About Acoustic Cluster Therapy
Acoustic Cluster Therapy (ACT®) consists of PS101 administered intravenously and insonated over a target tissue with ultrasound. PS101 is a formulation of microclusters of perfluorobutane microbubbles and perfluoromethylcyclopentane microdroplets. High frequency insonation causes PS101 to form larger ACT bubbles that are temporarily lodged in capillaries, followed by low frequency insonation, which induces oscillation of the lodged ACT bubbles, enhancing the delivery of the concurrently given chemotherapy to the target tissues.

About EXACT Therapeutics
EXACT Therapeutics is a clinical-stage precision medicine company utilizing the power of ultrasound and microbubbles to enable targeted drug delivery in oncology. Acoustic Cluster Therapy (ACT®) follows a unique approach and may be applied to a wide range of therapeutic agents within oncology and across a multitude of other indications, including brain diseases. EXACT Therapeutics' shares are traded on Euronext Growth Oslo (EXTX). Further information may be found here: www.exact-tx.com

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