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China clears Taletrectinib IND, issues clinical trial authorizations

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Chinese Center for Drug Evaluation (CDE) Cleared Taletrectinib IND and Issued Clinical Trial Authorizations for Two Phase 2 Clinical Trials in China

AnHeart Therapeutics, a clinical stage oncology company focused on underserved patients in global markets, has announced that its new drug candidate taletrectinib has received IND clearance and Clinical Trial Authorization (CTA) for its two Phase 2 clinical trials from CDE, the Chinese drug evaluation agency.

This is a major milestone for AnHeart. We have an experienced team who has successfully completed technology transfer

and navigated through the local regulatory process to simultaneously gain clearance of our two Phase 2 taletrectinib trials, one of which is utilizing a relatively new basket design. We expect to initiate both trials in the next few months, in line with our current global clinical development strategy," said Dr. Junyuan (Jerry) Wang, Chief Executive Officer.

The first Phase 2 trial will enroll first-and second-line Non-Small Cell Lung Cancer (NSCLC) patients with ROS1 mutations and is designed as an open-label, single-arm, multi-center study.

The second trial will enroll patients with locally advanced or metastatic solid tumors with NTRK mutations, and is designed as an open-label, multi-center basket trial.

AnHeart also plans to initiate one Phase 2 taletrectinib trial in Japan and another trial for rest of world (including USA). Trials in China and Japan will support the global development program for taletrectinib.