

AnHeart Therapeutics signs \$40 M deal with Nippon Kayaku for cancer treatment in Japan

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US-based startup AnHeart Therapeutics has entered into an exclusive license agreement with Nippon Kayaku to market and distribute AnHeart's lead investigational therapy, taletrectinib, in Japan. Taletrectinib is a next-generation ROS1 tyrosine kinase inhibitor (TKI) being developed for the treatment of ROS1-positive non-small cell lung cancer (NSCLC).

Under the terms of the agreement, AnHeart will receive an upfront payment of \$40 million and is entitled to potential regulatory and sales milestone payments and royalties based on annual net sales of taletrectinib in Japan.

Nippon Kayaku will be responsible for regulatory approvals and commercialization of taletrectinib for ROS1-positive NSCLC in Japan, and will have rights to further develop taletrectinib for new indications in the region. AnHeart will be responsible for the clinical development of taletrectinib for ROS1-positive NSCLC and for supplying taletrectinib to Nippon Kayaku for future commercialisation purposes in Japan.

AnHeart has reported positive data from two Phase 2 trials in 2023 showing taletrectinib has the potential to be a best-in-class therapy for people with ROS1-positive NSCLC, an underserved group of lung cancer patients in great need of new options. In both trials, interim results showed taletrectinib shrank tumors in more than 90% of patients with ROS1-positive NSCLC who had not previously received a ROS1 TKI (TKI naïve) and more than 50% of patients who had previously received a ROS1 TKI (TKI pre-treated), and responses were durable. Taletrectinib was generally well tolerated with a low incidence of neurological adverse events.