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China approves NGS-based genomic alteration tumour test by OrigiMed & Bayer

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First companion diagnostic specifically developed for larotrectinib in China

OrigiMed has announced that the Human *NTRK*1/2/3 Genomic Alteration Testing Kit has been granted the Special Review Procedure for Innovative Medical Devices by the Center for Medical Device Evaluation of NMPA. This testing kit is developed by OrigiMed in cooperation with Bayer.

The Human *NTRK*1/2/3 Genomic Alteration Testing Kit is developed to detect *NTRK* 1, 2 and 3 gene fusions in solid tumors. It is the first companion diagnostic specifically developed for larotrectinib in China and will help identify *NTRK* gene fusion-positive patients for whom treatment with larotrectinib may be appropriate.

Larotrectinib, a highly selective TRK inhibitor exclusively designed to treat tumors that have an *NTRK* gene fusion, is approved in more than 40 countries including the U.S., countries of the EU, and Japan for adult and pediatric patients with solid tumors that harbor an *NTRK* gene fusion. Additional filings in other markets, including China, are underway or planned.

The Human NTRK 1/2/3 Genomic Alteration Testing Kit is based on DNA- and RNA-based next-generation sequencing (NGS) and applies the innovative OriFusion independently patented by OrigiMed as its core technology. Fusion candidates are identified by hybrid-capture based technology. Besides the known fusion, it also can effectively detect novel fusions with high sensitivity and specificity.