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CMAB, Kintor announce comprehensive collaboration

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To develop and manufacture the ALK-1 Monoclonal Antibody



China based CMAB Biopharma Inc. (CMAB), a pure-play CDMO business in biologics and Suzhou Kintor Pharmaceuticals, Inc. (Kintor), an innovative biopharmaceutical enterprise, have announced a comprehensive strategic cooperation agreement for the development and manufacturing of Kintor's ALK-1 mAb.

ALK-1 (Activin receptor-like kinase-1) antibody was originally developed by Pfizer who completed two Phase I clinical trials in more than 100 patients with advanced solid tumors in the United States, Italy, South Korea, and Japan.

ALK-1 mAb has been studied in two Phase-I clinical trials in the United States, Italy, South Korea and Japan from 2007 to 2014. In these two clinical studies, ALK-1 mAb demonstrated favorable PK and safety profile and reasonable clinical benefits, which suggest that this novel therapeutic antibody has a potential to be a first-in-class in targeting ALK-1, an angiogenesis target.

Kintor has been granted the exclusive and worldwide rights to develop, manufacture and commercialize this novel anti-angiogenic drug, and has initiated a Phase II clinical trial in combination with *nivolumab* in patients with hepatocellular carcinoma (HCC) in Taiwan.

This is the first time Pfizer has licensed a Chinese company to develop a new antibody drug for oncology indications, which is expected to become the first fully human therapeutic monoclonal antibody that targets ALK-1 in the world.

According to the agreement, CMAB will provide a full range of CMC research and manufacturing services that meet the IND application requirements of China and the United States. This strategic cooperation will support the clinical development of ALK-1 antibody worldwide by Kintor. Importantly, this collaboration is based upon CMAB's sophisticated CMC process development and manufacturing platform, experienced R&D team in IND applications in both China and the United States, and an impeccable product quality system.