

3SBio to develop antibody for acute leukemia

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Singapore: Chinese biotechnology firm, 3SBio, has signed an exclusive license with Korean firm, DiNonA for the development, manufacturing and marketing of Leukotuximab. It is an anti JL-1 antibody for acute leukemia (AL), including acute myelocytic leukemia (AML) and acute lymphoblastic leukemia (ALL), in the territory of Greater China (including Mainland China, Taiwan, Hong Kong and Macau) and the Middle East (excluding Cyprus, Egypt, Israel and Turkey).

In addition to an upfront payment, milestone payments will be made after completion of technology transfer, approval of Investigational New Drug (IND) application by the China Food and Drug Administration (CFDA), completions of Phase I to Phase III clinical trials and marketing approval in China. 3SBio will also pay DiNonA a sales-based royalty. Additional terms of the license are not being disclosed.

Researchers from DiNonA have developed Leukotuximab, an anti-leukemic agent for JL-1+ acute leukemia. This antibody is targeting JL-1 Ag, an epitope of human CD43 extracellular domain. JL-1 is expressed on tumor cells of T, B, and myeloid lineages in more than 80 percent of acute leukemia patients, but not on mature peripheral blood cells or other normal tissues. Since the expression of JL-1 is highly associated with hematopoietic malignancies and is selectively expressed on the surface of human leukemic cells, anti-JL-1 mAb can be an excellent targeted reagent for treatment of the leukemia.

Leukotuximab showed significant improvement in survival in leukemia animal models. Also, no evidence of toxicity was observed in study animals. An open label and dose-escalating Phase I clinical trial in Korea started at June 2014 and is expected to finish in late 2015.

"We are pleased to collaborate with DiNonA and look forward to moving Leukotuximab into clinical trials in China," Dr Jing Lou, CEO, 3SBio commented, "3SBio continues to seek opportunities to support novel biologics, especially mAb candidates for blood cancer and other unmet medical needs, particularly in 3SBio's core therapeutic areas of oncology, nephrology and hematology."

"Leukotuximab is a drug candidate with great potential to treat acute leukemia," Dr Hyung-Geun Song, CEO of DiNonA commented, "3SBio is an established industry leader in the innovative biological field in China, which makes them an ideal

partner for long-term collaboration. We are looking forward to working with 3SBio to maximize this opportunity and benefit tens of thousands of Chinese patients suffering for acute leukemia and other severe diseases."