

CStone, Numab announce exclusive regional licensing agreement for ND021

03 May 2019 | News | By Prapti Shah

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CStone Pharmaceuticals and Numab Therapeutics have announced that they have entered into an exclusive regional licensing agreement for the development and commercialization of ND021, a potential best-in-class monovalent, tri-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin (HSA).

Pursuant to the terms of the licensing agreement, CStone will fund the research and development of ND021 up to the completion of an initial Phase Ib clinical trial. In exchange, CStone obtains exclusive rights from Numab to develop and commercialize ND021 in Greater China (including Mainland China, Hong Kong, Macau, and Taiwan), South Korea and Singapore. Numab retains all ND021 rights for the rest of the world. Upon completion of CStone's funding period, no further financial obligations will be owed by either party. This collaboration provides CStone with its first access to Numab's novel multi-specific technology platform and Numab the opportunity to bring this innovative drug candidate into this region.

Discovered and engineered using Numab's proprietary γ cap technology and MATCH platform, ND021 is a late-preclinical-stage, monovalent, tri-specific antibody-based molecule (scMATCH3) that simultaneously targets PD-L1, 4-1BB, and HSA. ND021 is designed to bind to 4-1BB and activate T cells only when engaging with PD-L1 on the surface of tumor cells, potentially preventing liver toxicities observed in patients treated with conventional 4-1BB-agonistic antibodies.

Compared to other PD-L1/4-1BB bispecific antibody candidates, ND021's unique monovalent structure and ultra-high-affinity PD-L1-binding is expected to lead to a significantly broader safety window and higher efficacy. Furthermore, half-life extension via the HSA-binding motif in ND021 enables convenient dosing schedules for patients. ND021 is anticipated to be effective against tumors with a wide range of PD-L1 expression-levels and may overcome primary and/or acquired resistance to anti-PD-1/PD-L1 therapies. Therefore, ND021 represents a leading class of next-generation cancer immunotherapies and a new backbone molecule for combinations.

CStone Chairman and CEO, Dr. Frank Jiang, commented: "This collaboration with Numab further strengthens our position as

a leading immuno-oncology player in China and commitment to our IO combination strategy. We look forward to joining global simultaneous development to bring this novel therapy to patients in China and beyond as soon as possible."

Dr. David Urech, CEO of Numab, said: "We are very happy to join forces with CStone to accelerate the progress of ND021 in the clinic. In addition to blocking PD-L1-mediated immune-suppression, ND021 has a novel design that tethers potent T cell co-stimulation to the engagement of PD-L1-positive cancer cells, in order to generate focused anti-cancer immune-responses and a favorable risk/benefit profile. We believe this drug candidate has the potential to become an important treatment option for cancer patients around the world."

ND021 is a next-generation PD-L1/4-1BB/HSA monovalent, tri-specific scMATCH3 that potently blocks PD-L1/PD-1 signaling while eliciting tumor-restricted co-stimulation of 4-1BB+ cells. In preclinical models, ND021 was well tolerated and induced exquisite antitumoral effects. Its unique, rationally designed molecular architecture and binding properties endow ND021 with several advantageous features that may translate into a significant clinical benefit in a broad population of cancer patients.

CStone Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicine to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline with a strategic emphasis on immune-oncology combination therapies. Currently, 4 late-stage candidates are at or near pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model, and substantial funding, CStone's vision is to become globally recognized as a leading Chinese biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.