

Immunitor signs agreement to initiate steps toward clinical development of oral tuberculosis (TB) vaccine in China

HONG KONG, HONG KONG, November 27, 2018 /EINPresswire.com/ -- Immunitor China Ltd. (Hong Kong) announces signing a service agreement with [Kun Tuo](#) Medical Research and Development (Beijing) Co., Ltd. - China-based subsidiary of global contract research organization (CRO) – IQVIA, formerly [Quintiles](#). The signed agreement aims to provide registration regulatory

consultation before starting clinical trial and ultimately the commercialization of the first-in-class therapeutic vaccine designed to treat tuberculosis. This landmark document is a preliminary step which will lead to filing a clinical trial application with the National Medical Products Administration (NMPA, formerly [CFDA](#)) – the China government regulatory organization, which approves and monitors clinical trials in mainland China and ultimately grants marketing authorization.



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consultation on clinical development of V7 – oral tableted adjunct immunotherapy patented by Immunitor. V7 is an oral, tableted formulation of heat-killed *Mycobacterium vaccae* which has been developed and manufactured by Immunitor company since 2010. V7 has been through two Phase II clinical trials, followed by successful Phase III trial financed by Grand Challenges Canada grant. One daily pill of V7 can shorten TB treatment duration to as little as one month and enhance at the same time the efficacy and safety of standard TB drugs.

“The potential upside of reaching this agreement to move toward clinical trial is enormous since one-tenth of all TB patients is in mainland China”, said Dr. Aldar Bourinbaiar – Director of Immunitor China Ltd. – a company set up to address the unmet medical needs of the Asian market. “Our TB vaccine, V7, has been clinically validated starting eight years ago. In 2007, the WHO expert committee recommended *M. vaccae* for immunotherapy of TB suggesting that an oral version would be more desirable due to obvious advantages of such a formula. The injectable version of *M. vaccae* has been sold in China since 2001 as immunotherapy for TB by Anhui Longcom Biologic Pharmacy Co., Ltd. “Given familiarity with this product in China market, this will facilitate our effort of gaining approval for oral version of *M. vaccae*”, added Dr. Bourinbaiar.

Tuberculosis is the main cause of death from an infectious agent. This year at the UN high-level meeting on TB held on 26 September 2018, the WHO estimated that in 2017, 10 million people became sick with TB, with 558,000 cases of drug resistant TB, including MDR-TB. China has about 900,000 new TB cases every year and ranks second after India. Current TB drugs are not very effective, particularly against multidrug-resistant TB (MDR-TB) and TB with HIV, requiring 24-36 months of treatment rather than usual 6-9, and far more expensive - costing about 100-times more than those drugs required to treat simpler, drug-sensitive forms of TB. Affordable and faster-acting intervention such as V7 satisfies the unmet medical needs, especially that MDR-TB and TB/HIV are equally susceptible to one-month of V7 treatment.

Immunitor China Ltd. is a commercial stage biopharmaceutical company registered in Hong Kong with a wholly-owned subsidiary in Beijing. Immunitor's strength and leading position resides in its proprietary oral vaccines platform validated by multiple clinical trials conducted over the past 15 years. Immunitor markets several immunotherapy products addressing major health problems, i.e., in infectious diseases area: HIV, HBV, HCV, influenza, malaria, fungal and microbial infections including tuberculosis; in area of autoimmune and metabolic diseases: renal failure, thyroiditis, Alzheimer disease, hypertension, atherosclerosis, obesity and diabetes; and recently in oncology space. Immunitor anticipates that in the future approval to proceed with clinical trial to be sought by Kun Tuo from NMPA will clear path toward marketing the first oral TB immunotherapy in China as well as globally.

Aldar Bourinbaiar

Immunitor

+1 301-476-0930

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