BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# US FDA grants Lion TCR two orphan drug designations of T cell therapy against Hepatocellular Carcinoma

21 August 2017 | News

**Lion TCR are developing two product candidates -- HBV specific TCR redirected T cell therapies against HCC with transient mRNA and a longer lasting DNA transduction technology.**


**Singapore** – US FDA has granted two orphan drug designations (ODD) for T cell therapy products to Singapore-based biotech company, Lion TCR Pte Ltd, for the treatment of hepatocellular carcinoma (HCC). Lion TCR are developing two product candidates -- HBV specific TCR redirected T cell therapies against HCC with transient mRNA and a longer lasting DNA transduction technology.

HCC is the world's third leading cause of death due to cancer and the second for China. Globally, 60% of HCC is a result of chronic hepatitis B infection, for the case of China, it is more than 90%. There are 780,000 new HCC cases reported annually, the general prognosis is poor with overall survival rates of 3-5%.

US FDA Orphan drug designations are granted to drugs and biologics intended for rare diseases that affect fewer than 200,000 people in the U.S., and provides incentives that may include tax credits trials and user fee waivers. For products that treat diseases or conditions which cannot be satisfactorily treated by available alternative drugs, FDA may grant in condition approval for marketing after product's completion of phase II pivotal clinical trial. This designation also entitles Lion TCR to a seven-year period of marketing exclusivity in the U.S. upon issuance of the new drug license.

Lion TCR's founder and CEO, Dr. Li Lietao commented, "Profiting from US FDA's well established regulatory framework and the ODD grant of our HBV specific TCR-T cell products, we aim to develop the clinical program internationally under FDA IND covering multiple sites in US, Europe and Asia. It will significantly accelerate our product development and speed up the commercialization of our products to both US and Asian markets.