TSH Biopharm Submits New Drug Application to Taiwan FDA Seeking Approval of RNTA06 for the Treatment of Angina

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TSH Biopharm’ s (8432) new entity new drug, RNTA06 has completed first Asian people clinical study and today announced its New Drug Application (NDA) were accepted by the Taiwan Food and Drug Administration (TFDA).

The submission dossier of RNTA06 has fully complied with TFDA registration requirement including the Asian people clinical data of Pharmacokinetics/ Pharmacodynamics、efficacy、safety and administration to connect international clinical data. The result shows the primary endpoint of its clinical study revealed the same trend as international study. It estimates there are 550 thousand Angina patients in Taiwan and there are around 30% of the patients cannot be treated well using current medicine.

Data also shows the prevalence rate in women is 1.6-1.8 times in men and it increases year by year among below 45-age women. RNTA06 is used to treat chronic angina disease by its new mechanism (late sodium channel inhibitor and it would not has such side effect like: heart rate、blood pressure、headache etc. RNTA06 can be combined with treated medicine or replace it. That means patients and doctors have more weapon to cope with Angina. According to IMS data, the potential market of Angina is about 2.4 billion NTD in Taiwan.

TSH Biopharm is dedicating to medicines development and innovation in chronic diseases field, especially focusing on cardiovascular diseases and keeps accumulating medicine treatment data in Asian population by conducting clinical trials. RNTA06 not only successfully record its treatment experience in Taiwan patients but also meet US & European manufacturing standard and hope RNTA06 could be launched in other Asian countries in the very near future.