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Pilot Study informs pivotal trial evaluating bioequivalence of two formulations of Paroxetine 40 mg tablet in healthy Chinese subjects

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The purpose of this study was to conduct a pilot study in order to obtain reliable results for further planning of a well-designed pivotal trial comparing the bioequivalence (BE) of two paroxetine tablet formulations in healthy Chinese subjects. Before conducting the pivotal trial, the pilot trial enrolled 14 subjects to help in study design, establishing the recruitment period, determining pharmacokinetics (PK) time points and sample size, and assessing BE of the two formulations. The single-center, randomized, open-label, single-dose, two-period crossover study with a 7-day washout interval was conducted after obtaining information from the fasted pilot trial in 72 healthy volunteers for a pivotal study under fed and fasted conditions respectively. There were 19 PK sample collection time points employed in both the pilot and pivotal trials. A sensitive and specific liquid chromatography-tandem mass spectrometry (LC-MS/MS) method was developed and validated for determining paroxetine in human plasma. BE between two articles was determined by calculating 90% confidence intervals for the ratio of Cmax 91.38%-110.39% for the pilot trial, 99.81% – 114.08% for pivotal trial under fasted condition, and 94.06% - 110.41% for pivotal trial under fed condition, AUC(0-t) 96.06%-110.52% for pilot study, 100.88% – 113.05% for the pivotal trial under fasted condition, and 97.08% – 106.06% for pivotal study under fed condition, and AUC(0-inf) 96.17-110.42% for the pilot study, 100.85% – 112.81% for the pivotal trial under fasted condition and 97.22% - 106.14% for the pivotal study under fed condition, respectively. These values for the test and reference products are within the 80%-125% interval proposed by FDA and EMEA. It was concluded that the proposed method was successfully applied to a PK study in healthy Chinese volunteers, and results showed from both the pilot and pivotal studies that the two paroxetine formulations are bioequivalent in their rates and extent of absorption.

Biography

Dr. Shengjun Zhang received his MD from Zhengzhou University in 1984 and his MBA in Health Management from Johns Hopkins University in 2010. He participated in clinical fellowship training at Stanford University Sleep Research Center; five years of cardiology postdoctoral training at NIA/NIH; two years of research experience at UMDNJ/RWJMS. In addition to research experiences, Shengjun worked two years in clinical research project management at Johns Hopkins School of Medicine Department of Oncology and two years of international clinical study in infectious diseases (HIV/AIDS) at Johns Hopkins Hospital (HPTN China study project coordinator). Shengjun also has two years of projects management and business development experience at Westat, Inc. and four years of executive-level project director experience at Frontagelab, Inc. Prior to entering the clinical research and trial, he practiced internal medicine and pulmonary in China for twelve years. Currently, Shengjun serves as director of Clinical Research Center—China for Frontage and a special-appointed professor at Zhengzhou University.

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