9th World Congress on

BIOAVAILABILITY AND BIOEQUIVALENCE

April 16-18, 2018 Dubai, UAE

Bioequivalence and pharmacokinetic profiles of abiraterone acetate 250-mg tablets in healthy Chinese subjects under fasted and fed condition: A four-way replicate crossover study by a RSABE approach

Min Wu and Yanhua Ding The First Hospital of Jilin University, China

Prostate cancer is the second and third leading cause of cancer-related deaths in men and tumor growth is usually dependent on circulating androgens. Abiraterone acetate is a prodrug of Abiraterone, a selective irreversible inhibitor of cytochrome P17A-hydroxylase/C17, 20-lyase that plays a key role in the production of androgens. Abiraterone is categorized into biopharmaceutics classification system (BCS) class-4 (low solubility, low permeability) based on the importance of solubility and permeability on drug absorption, which adds the difficulty of obtaining the bioequivalence (BE) results. The aim of this study was to evaluate the BE of two Abiraterone formulations (250 mg tablets) by the reference-scaled average bioequivalence (RSABE) approach and to investigate the pharmacokinetic (PK) properties of Abiraterone in healthy Chinese subjects. This single-dose, open, randomized, four-way replicate study was conducted in healthy Chinese male volunteers under fasted (n=40) and fed (n=40) conditions. Blood samples were collected over a 72 hours period. Abiraterone concentrations were assayed using a liquid chromatography tandem mass spectrometry (LC-MS/MS) method. Abiraterone plasma C_{max}, AUC_{0-t} and AUC_{0-w} were used to assess bioequivalence. Results showed that the 90% CIs for ratios of lnC_{max}, lnAUC_{0-t} and lnAUC_{0-t} for fasted study were 90.14-114.11, 93.96-115.07 and 93.72-113.331, respectively. For fed study, these data were 81.83-102.51, 91.51-104.89 and 91.46-104.58, respectively. All the 90% CIs were within the RSABE acceptance limits of the Chinese Food and Drug Administration (CFDA). Food intake increased the systemic exposure and C_{max} to Abiraterone by 3-fold and 7-fold, respectively. The sWR of C_{max} and AUC_{0-t} for fasted study were 0.445 and 0.389. For fed study, these data were 0.444 and 0.281. The test and reference formulations of Abiraterone met the regulatory criteria for bioequivalence of the CFDA. Abiraterone was safe and well tolerated at 250 mg dose tested under fasted and fed condition.

Biography

Min Wu has completed her Masters in Pharmaceutical Chemistry (2013) at Jilin University School of Pharmaceutical Sciences, China. She is working as QA in Department of Phase I Clinical Trials Unit from 2014 to till date.

wumin1987mary@126.com

```
Journal of Bioequivalence & Bioavailability
```