

医疗翻译样稿

药学:

Population pharmacokinetic/pharmacodynamic modeling activities assessed the influence of various continuous covariates (age, weight, height, body mass index [BMI], creatinine clearance, and liver chemistries) and categorical covariates (race, gender, differences between patients and healthy subjects) on the parameters of the models, and provided individual exposure variables for subsequent exposure-safety and response analyses.

群体药代动力学/药效学建模活动评估了各种连续协变量（年龄、体重、身高、体重指数 [BMI]、肌酐清除率和肝脏化学）和分类协变量（人种、性别、患者与健康受试者之间的差异）对模型参数的影响，为后续暴露量-安全性和反应分析提供了个体暴露变量。

Population pharmacokinetic modeling was also performed to determine pharmacokinetic differences between Asian and Western subjects. Monte Carlo simulations were performed to determine the probability of target attainment (PTA) over a range of MIC values, with each of the pharmacodynamic target values determined by the Clinical and Laboratory Standards Institute (CLSI) and the European Committee on Antimicrobial Susceptibility Testing (EUCAST). Exposure-response analyses were conducted using pharmacokinetic data from 232 isavuconazole-treated patients in study 9766-CL-0104 to assess whether there was a relationship between any exposure parameter and safety/response, and to support possible breakpoint criteria.

此外，还进行了群体药代动力学建模，以确定亚洲受试者和西方受试者之间的药代动力学差异。执行蒙特卡罗模拟，以确定一系列 MIC 值的目标获得概率 (PTA)，每个药效学目标值由美国临床和实验室标准协会 (CLSI) 和欧洲药敏试验委员会 (EUCAST) 确定。使用研究 9766-CL-0104 中 232 例接受艾沙康唑治疗的患者的药代动力学数据进行暴露-反应分析，以评估任何暴露参数与安全性/反应之间是否存在关系，并支持可能的折点标准。

Further details on the pharmacokinetic studies and key results are provided in the Module 2.7.2.4 Appendix Tables.

关于药代动力学研究和关键结果的更多详情见模块 2.7.2.4 附录表。

医疗器械:

The Integra® Ti6® Internal Fixation System is comprised of five types of screws used for bone fixation of the hand and foot following trauma or osteotomy. Available screws and instrumentation are packaged as a single system and organized around the five types of screws described below:

Integra® Ti6® 内固定系统由五种螺钉组成，用于创伤或截骨术后手脚的骨固定。提供的螺钉和内固定装置采用独立包装，围绕如下描述的五种类型的螺钉进行组装：

The TS-Series (Titanium Solid) is a non-cannulated, threaded bone screw which is offered in 2.0, 2.5, 3.0& 4.0mm diameters with lengths of 6 to 50mm.

TS 系列（钛实心）是一种非空心螺纹接骨螺钉，提供 2.0、2.5、3.0 及 4.0mm 的直径供选，长度为 6 至 50mm 不等。

The TC-Series (Titanium Cannulated) is a cannulated, threaded bone screw which is offered in 2.0, 2.5, 3.0 & 4.0mm diameters with lengths of 2.0 (6-22mm), 2.5 (8-30mm), 3.0 (10-40mm), & 4.0(12-50mm).

TC 系列（钛空心）是一种空心螺纹接骨螺钉，提供 2.0、2.5、3.0 及 4.0mm 的直径供选，长度为 2.0 (6-22mm)、2.5 (8-30mm)、3.0 (10-40mm) 及 4.0 (12-50mm)。

The TH-Series (Titanium Headless) is a cannulated, dual threaded, headless bone screw which is offered in 2.5mm diameter in lengths of 10 to 22mm and 3.0mm diameter in lengths of 14 to 34mm.

TH 系列（钛无头）是一种空心、双螺纹无头接骨螺钉，2.5mm 直径时长度为 10 至 22mm，3.0mm 直径时长度为 14 至 34mm。

The TQ-Series (Titanium QuickSnap) is a snap-off solid core screw which is offered in 2.0mm diameter in lengths of 8 to 16mm and 2.7mm diameter in lengths of 12 to 22mm.

TQ 系列（钛快速折断）是一种可折断实心螺钉，2.0mm 直径时长度为 8 至 16mm，2.7mm 直径时长度为 12 至 22mm。

The DS-Series (Digital Screw) is a cannulated, threaded bone screw which is offered in a 2.0mm diameter with lengths of 24 to 50mm.

DS 系列（数字螺钉）是一种空心螺纹接骨螺钉，直径为 2.0mm，长度为 24 至 50mm 不等。

The system includes instruments (drill bits, drill guides, guide wires, depth gauges, countersinks, bone clamps, forceps, and screwdrivers) to facilitate the placement of the screws.

套件包含一系列装置（钻头、钻导引器、导丝、深度计、埋头锥、骨钳、镊子和螺丝刀），以便于放置螺钉。