Pharmacokinetics of WCK 2349 in Patients with Complicated Skin & Soft Tissue Infections (cSSTIs) Caused by Gram Positive Bacteria Including MRSA

Shailly Mehrotra¹, Vijay Ivaturi¹, Joga Gobburu¹, Rakesh Chugh², Ashima Bhatia²

¹ Center for Translational Medicine, School of Pharmacy, University of Maryland, Baltimore, MD, USA
² Department of Clinical Research & Development, Wockhardt

Background & Objective
- The global spread of methicillin resistant Staphylococcus aureus (MRSA) in hospital and, more recently, in community is an unmet medical need [1,2].
- WCK 2349, a novel fluoroquinolone, is being developed by Wockhardt as an oral anti-MRSA agent.
- Objective: To evaluate the pharmacokinetics (PK) of WCK 2349 after multiple oral dosing in selected subjects with cSSTIs caused by Gram positive bacteria including MRSA.

Data & Methodology
- A phase II open label, parallel, randomized, multicenter clinical trial to evaluate safety and efficacy of oral WCK 2349 (1000 mg BID and 1200 mg BID) in the treatment of cSSTIs caused by gram positive bacteria, including MRSA was conducted in 60 subjects.
- The PK data was available from 5 subjects administered 1000 mg BID and 2 subjects administered 1200 mg BID.
- Fourteen venous samples were collected in each subject i.e. 30 minutes prior to dosing and then 0.5, 1, 1.5, 2, 4, 6, 8, 12, 13, 14, 16, 18 and 24 hours after the 8th dose (98 observations).
- WCK 2349 converts to levonadifloxacin as the active drug in vivo.
- Non compartmental analysis was conducted in Phoenix WinNonlin version 6.4 to characterize PK of oral WCK 2349.