ORAL ZOLIFLODACIN FOR TREATMENT OF UNCOMPLICATED GONORRHOEA IN HIGH RISK POPULATIONS: SUBGROUP ANALYSES OF A GLOBAL PHASE 3 RANDOMISED CONTROLLED CLINICAL TRIAL

Authors:
Luckey A[1], Broadhurst H[2], Bettiol E[1], Srinivasan S[1], Hook EW 3rd[3] for the zoliflodacin Phase 3 study group

[1]Global Antibiotic R&D Partnership (GARDP), [2]Plus Project, [3]University of Alabama at Birmingham

Background:
The first-in-class oral bacterial topoisomerase inhibitor zoliflodacin has potent *in vitro* activity against *Neisseria gonorrhoeae* (NG), including multidrug-resistant strains. A global randomised controlled Phase 3 trial, enabled through a public-private partnership, evaluated zoliflodacin efficacy and safety for uncomplicated gonorrhoea treatment in a diverse group of participants. Urogenital microbiological cure rates (95% confidence interval [CI]) were 90.9% (88.1-93.3) vs 96.2% (92.9-98.3) for zoliflodacin vs ceftriaxone-azithromycin, respectively, demonstrating non-inferiority of zoliflodacin to the comparator with a 5.31% difference (95%CI: 1.38-8.65). Cure rates for pharyngeal and rectal infections were comparable between treatment arms.

Methods:
The primary endpoint was microbiological cure, determined by culture from urethral/endocervical sites at Day 6±2 in the microbiological intention-to-treat (micro-ITT) population (i.e. randomised participants with baseline cultures positive for NG and no resistance to both ceftriaxone and azithromycin). Descriptive subgroup analyses were performed using demographics, baseline characteristics and STI risk factors in the micro-ITT and evaluable populations (EP), defined as participants in micro-ITT with an assessable microbiological outcome at Day 6±2.

Results:
Urogenital cure rates in subgroups were consistent with the primary endpoint analysis. Among the subgroup of men who reported sex with men (MSM), cure rates with zoliflodacin vs ceftriaxone-azithromycin were 94.4% (n/N: 153/162; 95%CI: 89.7-97.4) vs 96.3% (79/82; 89.7-99.2) in the micro-ITT and 98.7% (153/155; 95.4-99.8) vs 100% (79/79; 95.4-100) in the EP, respectively. In heterosexual males, cure rates were 88.1% (259/294; 95%CI: 83.8-91.6) vs 97.1% (134/138; 95% CI: 92.7-99.2) in the micro-ITT and 95.6% (259/271; 95%CI: 92.4-97.7) vs 100% (134/134; 95%CI: 97.3-100) in the EP for zoliflodacin vs ceftriaxone-azithromycin, respectively. Subgroup analyses in the EP of urogenital cure rates for PrEP users, persons living with HIV and sex workers were comparable between treatment arms.

Conclusion:
Descriptive analysis of subgroups at high-risk for STIs demonstrated cure rates for zoliflodacin vs ceftriaxone-azithromycin comparable to the primary endpoint analysis.

Disclosure of Interest Statement:

Zoliflodacin is co-developed by the Global Antibiotic Research & Development Partnership (GARDP) in collaboration with Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (Nasdaq: INVA).
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