Background: Omadacycline is a 9-amino-4-oxo-4-methyl-5H-pyrimido[4,5-b]quinazoline-2-carboxylic acid introduced for the treatment of skin and skin structure infections. It is active against both Gram-negative and Gram-positive bacteria including multidrug-resistant strains. Omadacycline was selected for the present investigation due to its broad spectrum of activity, once daily oral dosing, and potential for use in patients with renal impairment.

Methods: Omadacycline PK in IV and/or oral administration, as well as to evaluate the impact of formulation differences between 3 and 8 hours and at 12 hours after the first IV dose on Day 7. Previous work demonstrated that the population PK model for omadacycline calculated using absolute time of food consumption relative to dosing (AMTIME) via a normal distribution (Vp1 (L)).

Conclusions: Population PK model for omadacycline developed using Phase 1 data was used to evaluate potential sparse PK sampling strategies for use in clinical trials. Results from this study suggest that PK samples toward the end of the IV or oral dosing interval.

OBJECTIVE
To utilize a population PK model for omadacycline, which was developed using Phase 1 data to provide guidance for PK sampling strategies for use in Phase 3 trials in which patients with arthritis who switched from IV to oral treatment.

METHODS
for sparse sampling in Phase 3 trials in which an oral switch was planned. The PK samples were collected between 3 to 5 hours and 12 hours after the first IV dose on Day 7, immediately prior to and 1 to 2 hours after oral dosing. Evaluation of Phase 3 Sparse PK Sampling Strategies

Since the drug AECA/RIC ratio is expected to be the most relevant clinical index for efficacy, when evaluating the utility of the sparse PK sampling scheme, it was proposed to evaluate individual patient’s PK data, as well as to evaluate the impact of formulation differences on the utility of sparse PK sampling in Phase 3 trials in which patients with arthritis who switched from IV to oral treatment.

RESULTS

Conclusions: Population PK model for omadacycline developed using Phase 1 data was used to evaluate potential sparse PK sampling strategies for use in Phase 3 trials in which an oral switch was planned. The PK samples were collected between 3 to 5 hours and 12 hours after the first IV dose on Day 7, immediately prior to and 1 to 2 hours after oral dosing. Evaluation of Phase 3 Sparse PK Sampling Strategies

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REFERENCES

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