1. IVDU vs non-IVDU

- Study endpoints were
- Any systemic or topical antibacterial agent with a spectrum that is active against the potential infecting pathogen(s)
- Omadacycline (OMC), the first aminomethylcycline antibiotic to reach late-stage clinical development, is a
- The incidence and severity of ABSSSI have increased in recent years

- Skin and soft tissue infections are the most common cause for hospital admissions among intravenous drug

- An MRI is a major risk factor for culture-negative cellulitis. It could prevent both OMC and LZD from being studied due to any effect on the efficacy or safety of LZD relative to OMC patients from OASIS-1

2. METHODS

- OMAC was randomized (1:1:1:1:1), double-blind, placebo-controlled, double-dummy cycle (OMC and LZD) for the treatment of adults with ABSSSI
- Patients randomized to the OMC-treated group received OMC 100 mg intravenously (IV) every 12 hours (QD) for 2 days followed by 800 mg OMC orally (PO) every 12 hours (BID) for a total of 14 days.
- Patients randomized to the LZD-treated group received IV LZD 600 mg every 12 hours (QD) for a total of 14 days and PO LZD 600 mg every 12 hours (BID) for a total of 14 days.
- OMC or LZD were administered for a total of 14 days or until resolution of signs and symptoms of the infection such that further antibacterial therapy is not indicated.

3. RESULTS

- Baseline characteristics were similar across treatment arms with the exception of the following:
- The lower clinical success observed in the mITT population was due to the greater number of indeterminate results in the IVDU/HCV+ subgroup than the non-IVDU and non-IVDU/HCV– subgroups in the mITT and CE populations

4. CONCLUSIONS

- Overall TEAEs and drug-related TEAEs were comparable among the OMC- and LZD-treated arms in IVDU and non-IVDU/HCV– subgroups than the non-IVDU and non-IVDU/HCV– subgroups in the mITT and CE populations
- In non-IVDU/HCV–, OMC-treated patients had more frequent infusion site extravasation than LZD-treated patients
- Across all infection types, subgroups, and treatments, Gram-positive aerobes were the predominant class of pathogens in OMC- and LZD-treated patients

5. REFERENCES


- www.americantherapeutics.com
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