### #685

#### Time to Onset and Duration of Adverse Events in Patients with Acute Bacterial Skin and Skin Structure Infections Treated with Oritavancin – The SOLO Studies

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**Abstract**

**Background:** Oritavancin (ORI) is a lipoglycopeptide antibiotic that is designed to have prolonged tissue and serum concentration due to its bioaccumulation in macrophages. It is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by Gram-positive pathogens such as Staphylococcus aureus and Streptococcus pyogenes, including methicillin-resistant Staphylococcus aureus (MRSA). Oritavancin is dosed as a single intravenous infusion, which allows for single-dose treatment. The objective of the analysis is to evaluate the time to onset and duration of adverse events (AEs) in patients with ABSSSI treated with oritavancin.

**Methods:** The SOLO studies were global, multicenter, randomized, double-blind trials with evaluable single doses in ORI (1200 mg IV every 24h) or vancomycin (VAN, 1 g IV qd, every 12 hours for 7 to 10 days) in adults with ABSSSI. A safety assessment included all patients randomized or treated with ORI or VAN. All serious adverse events (SAEs) and all AEs leading to study drug discontinuation were recorded. Each bacterial species was evaluated as an AE in proportion to the number of patients randomized to a study arm with this species.

**Results:** Overall, 1987 patients were enrolled in the SOLO studies; 1959 patients were in the safety and efficacy analysis. **Overall incidences of AEs (31%) and serious AEs (6%) were similar between ORI (55.3%, 5.8% and 3.7%) and VAN (56.9%, 6.7% and 4.3%).** Treatment-related AEs were low in both the oritavancin (14%) and vancomycin (10%) groups.

- **Time to onset and duration of all AEs** were similar between treatment groups (Table 1).

**Conclusions:** Oritavancin has a safety profile that is consistent with previous findings and when monitored for up to 60 days following a single dose, it is associated with a lower incidence of selected AEs in patients with ABSSSI compared with vancomycin. The findings support the continued development and evaluation of oritavancin for the treatment of ABSSSI.

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**References**