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Prescribing decisions should be made based on the approved package insert in the country of prescription.

Sponsor: Sanofi **Drug substance:** Teicoplanin	**Study Identifiers:** U1111-1230-0601; NCT04003818 **Study code:** LPS16229
Title of the study: Prospective, interventional, phase IV study, evaluating the efficacy and safety of teicoplanin (100-200 mg, administered orally twice a day) in patients with Clostridium difficile infection-associated diarrhea and colitis (LPS16229)	
Study centers: Ten centers in China.	
Study period: Date first participant enrolled: 15/May/2020 Date last participant completed: 21/Jan/2021 Study Status: Terminated	
Phase of development: Phase 4	
Objectives: Primary Objective To explore the efficacy of teicoplanin (100-200 mg administered orally twice a day for 7 to 14 days) in patients with Clostridium difficile infection-associated diarrhea and colitis. Secondary Objective To evaluate the safety of teicoplanin in patients with Clostridium difficile infection -associated diarrhea and colitis.	
Methodology: Prospective, single group, open-label, interventional study.	
Number of participants: Planned: 50 Treated: 5 **Evaluated:** Efficacy: 5 Safety: 5	
Diagnosis and criteria for inclusion: Adult inpatients with a diagnosis of mild-moderate or severe Clostridium difficile-associated diarrhea (CDAD) with diarrhea and positive C. difficile toxin test.	

Study treatments **Investigational medicinal product:** Teicoplanin (Targocid®) Formulation: Teicoplanin 200 mg: powder for solution for injection/infusion or oral solution. Water for injection 3 mL Route of administration: Administered orally Dose regimen: 100-200 mg twice a day
Duration of treatment/participation: 7-14 days **Duration of observation:** 3-day screening, 7-14 days treatment, and 8-week follow-up period
Criteria for evaluation: Efficacy: Primary endpoints: ・ Clinical cure rate ・ Recurrence rate ・ Time to resolution of diarrhea Safety: ・ Incidence of nephrotoxicity ・ Incidence of hepatotoxicity ・ Incidence of thrombocytopenia ・ Incidence of hearing and balance/vestibular disorders ・ Additional renal endpoints such as renal failure, dialysis and renal replacement therapy ・ Any untoward adverse events (AEs)/reactions

Statistical methods:

Analysis population: Enrolled population was defined as any screened subjects who met the inclusion criteria but did not meet the exclusion criteria; Full analysis population (FAS) was defined as subjects who have finished the treatment period and have had the 3rd visit on EOT+2 days; Safety population was defined as subjects who were assigned to study intervention and took at least 1 dose of study intervention. Subjects were analyzed according to the intervention they actually received.

Primary analyses:

Descriptive analyses:

• Percentage of subjects with clinical cure

• Percentage of subjects with recurrence

• Time to resolution of diarrhea

Analyses of secondary endpoints:

· Incidence of nephrotoxicity

· Incidence of hepatotoxicity

· Incidence of thrombocytopenia

· Incidence of hearing and balance/vestibular disorders

· Additional renal endpoints such as renal failure, dialysis and renal replacement therapy

· Any untoward adverse events/reactions

The incidence rates above were summarized.

Interim analysis: Not applicable

Summary:

The study was prematurely terminated on March 10, 2021 due to the impact of the COVID-19 and the huge difficulties during patient enrollment. All participating sites were promptly notified to stop enrollment.

Population characteristics: A total of 27 subjects were screened, 5 subjects (18.5%) were successfully screened and enrolled into the study. All 5 enrolled subjects (100.0%) were included into the FAS population and safety population. Four subjects (80.0%) completed the study. One subject (20.0%) prematurely discontinued from the study with the reason of "Other: V7 interview data were not collected as the poor compliance of the subject, and subsequent collection cannot be continued". All enrolled subjects (n = 5, 100.0%) were Asian and were male. The mean age of subjects was 75.4±14.88 years. The mean duration of CDI was 1.8±0.84 days.

Efficacy results: Among all 5 subjects in the FAS population, 2 subjects responded to Teicoplanin, and the clinical cure rate was 40% (95% CI: 5.27%-85.34%). No subject experienced relapsed diarrhea, and the recurrence rate was 0%. The mean time to resolution of diarrhea was 5.6±4.56 days.

Safety results: In the safety population, 4 subjects reported at least one TEAE, including the one who experienced thrombocytopenia. No SAE, no drug related TEAE, and no AESI was reported. No subject discontinued of study drug due to TEAE. There were no deaths reported during the study.

Conclusions: Due to the limited data, there is no solid evidence to support the conclusion that teicoplanin is efficient and safe in the treatment of CDI, further studies are required.

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