Introduction: Solithromycin (SOLI) is a fourth generation oral and intravenous macrolide, the first florfenicol, which is a Phase II clinical development for the treatment of community-acquired pneumonia caused by Haemophilus influenzae and Streptococcus pneumoniae strains that demonstrate elevated resistance. It has demonstrated a high activity in vitro against these strains compared to conventional macrolides. In this study, we investigated the safety and efficacy of SOLI in healthy adult volunteers.

Materials and Methods: This study was a randomized, double-blind, placebo-controlled, 3-phase clinical trial conducted in 52 healthy adult volunteers. The study included 2 phases: phase 1 involved 3 arms (placebo, 10 mg/kg, and 20 mg/kg SOLI), and phase 2 involved 2 arms (placebo and 20 mg/kg SOLI). The primary endpoint was the safety and tolerability of SOLI. The secondary endpoint was the pharmacokinetic profile of SOLI.

Results: The findings revealed that SOLI was well-tolerated and had a favorable safety profile. The pharmacokinetic analysis showed that SOLI had a rapid absorption profile with a peak concentration at 3 hours, followed by a long elimination half-life. The study also highlighted that SOLI was effective against H. influenzae and S. pneumoniae strains, demonstrating high in vitro activity.

Discussion: The results of this study suggest that SOLI is a promising new macrolide for the treatment of community-acquired pneumonia caused by H. influenzae and S. pneumoniae strains. Further studies are needed to evaluate its long-term safety and efficacy in clinical practice.

Conclusions: This study provides valuable insights into the safety and efficacy of SOLI in healthy adult volunteers, highlighting its potential for future clinical trials.