Background

Selects, among other adhesion-mediated functions, facilitates and augments physiological transports mediated by lectins. The current study is to evaluate the safety and tolerability of GMI-1271 when administered to healthy subjects. GMI-1271 is a soluble form of E-selectin, a highly conserved protein that plays a key role in inflammation and thrombosis.

Methods

**Safety**

Safety assessments were conducted at baseline, 8 and 24 hours after dosing for each subject. Blood samples were collected before and after dosing. Additional safety assessments included physical exams, vital signs, laboratory evaluations, and electrocardiograms (ECGs). Patients were also monitored for adverse events, and the safety profile was evaluated.

**Pharmacokinetics**

Pharmacokinetic analyses were performed on plasma samples collected at specific time points after dosing. The data were analyzed using non-compartmental methods to determine key pharmacokinetic parameters such as peak concentration (Cmax), time to peak concentration (Tmax), area under the curve (AUC), and terminal elimination half-life (t1/2).

**Biomarker Comparisons**

Biomarker data were collected from the study population to assess the effects of GMI-1271 on key biological markers related to inflammation and thrombosis. The biomarkers evaluated included: C-reactive protein (CRP), von Willebrand factor (vWF), platelet count, and fibrinogen.

**Clinical Measures**

Clinical measures were assessed to evaluate the impact of GMI-1271 on bleeding risk. These measures included: International Normalized Ratio (INR),activated partial thromboplastin time (aPTT), and platelet count.

**Summary and Conclusion**

The study demonstrated that GMI-1271 is well-tolerated and has a favorable safety profile in healthy subjects. The pharmacokinetic data showed that GMI-1271 is rapidly absorbed and has a short half-life, making it a potential candidate for oral administration. The study also confirmed the biological activity of GMI-1271, with reductions in key biomarkers related to inflammation and thrombosis. Further studies are needed to evaluate the efficacy and long-term safety of GMI-1271 in clinical settings.

References


For further information, please visit: www.glycomimetics.com