

Open label, dose escalation, Phase I / pilot study is designed to provide preliminary evidence of the safety, pharmacokinetics (PK), and pharmacodynamic (PD) activity of pentosan polysulfate sodium (PPS) given orally as a single dose to subjects with sickle cell disease.

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Synopsis:

This open label, dose escalation, Phase I / pilot study is designed to provide preliminary evidence of the safety, pharmacokinetics (PK), and pharmacodynamic (PD) activity of pentosan polysulfate sodium (PPS) given orally as a single dose to subjects with sickle cell disease. Safety measures will include clinical observations and tests of coagulation; measures of pharmacodynamic activity will include P-selection blocking activity in plasma (or serum); and microvascular blood flow will be determined by both computer-assisted intravital microscopy (CAIM) and laser Doppler velocimetry (LDV).