Confidential

CC-CHOC Pediatric Point Person Project (P4)
Protocol Information Form

Follow this link to indicate your interest in Protocol **#21 Thrombotic Disorder**
https://redcap.ctsacentral.org/surveys/?s=7Gifps

Submitted October 9, 2012

Participant ID #21 Thrombotic Disorder

Sponsor Industry

Study Title Single-Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Study Drug in Pediatric Subjects at Risk for a Venous or Arterial Thrombotic Disorder

Short Study Synopsis The clinical trial will be studying an investigational medicine (a direct factor Xa inhibitor) on the prevention of venous thromboembolism in children (neonates through adolescents). The study can be conducted in any patient population that is at risk for venous or arterial thrombotic disorder.

Target Population Pediatric Subjects at Risk for a Venous or Arterial Thrombotic Disorder

Study Objectives

PRIMARY OBJECTIVE

- to assess the pharmacokinetics of a single dose of Study Drug in pediatric subjects

SECONDARY OBJECTIVES

- to assess the single dose safety and tolerability of Study Drug in pediatric subjects
- to assess the single dose pharmacodynamic activity of Study Drug in pediatric subjects

EXPLORATORY OBJECTIVES

- to assess the palatability of Study Drug oral solution in the pediatric population
- to assess the push pull method for blood draws from the central venous catheter

Key Inclusion/Exclusion Criteria

INCLUSION CRITERIA

- Pediatric Subjects at Risk for a Venous or Arterial Thrombotic Disorder
- Ages neonates to < 18 years old
- Subjects with any type of functioning central venous catheter

EXCLUSION CRITERIA

- GI disease or GI surgery that could impact the absorption of the drug
- Active bleeding or high risk of bleeding
- Neonates or infants <37 weeks post conceptual age

or adolescents ≥18 years of age at the time of enrollment.

Total Number of Patients to be Enrolled 40

Enrollment Period 2.5 years

Miscellaneous Details/Requirements None

Has This Study Been Approved by the FDA? Yes

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Any question? Email ctsa_childhealth@ctsaC4.org