

MOST...In Brief

What is the MOST Payment Schedule?

START-UP

Payment 1 in the amount of **\$2,000.00** upon full execution of the FDP Fixed Price Research Clinical Trial Agreement; and, Payment 2 in the amount of **\$1,500.00** upon receipt of CIRB approval for Study Start-Up

SUBJECTS ENROLLED AND ALL REQUIRED FOLLOW-UP VISITS COMPLETED

After enrollment to one of the study arms (Placebo, Eptifibatide, or Argatroban), the Maximum per subject payment is \$3,853.00 + (\$1,618.80) = \$5,471.80 total. Indirect costs (42% StrokeNet F&A) shown in parentheses. All payments are contingent on receipt of eCRFs at the relevant study visit.

Payment will be divided into three increments per subject enrolled. Each payment will be inclusive of the 42% StrokeNet F&A where allowed.

Payment 1: Issued after Baseline - payment inclusive of Baseline activities:

Payment of \$1,737.80 will be made after verification of receipt of required eCRFs for baseline and successful administration of, at minimum, study drug bolus dose.

Payment 2: Issued after Day-30 - payment will be inclusive of protocol adherence after baseline activities, up to and including Day-30 activities:

Payment of \$1,134.00 will be made after verification of receipt of required eCRFs for activities in the interval.

Payment 3: Issued after Day-90 - payment will be inclusive of Day-90 activities:

Payment of **\$2,600.00** will be made after verification of receipt of required eCRFs for Day-90 activities and verification of mRS video recording uploaded to secure server for independent scoring of mRS at 90-Day visit.

What safety data supports the MOST trial?

Six phase 2 clinical trials have been competed to study the safety of argatroban and eptifibatide in combination with alteplase in Acute Ischemic Stroke:

Table – Design and Sample Size of Six Completed Phase 2 Trials						
	ARTSS	ARTSS-2	ARTSS-IA	CLEAR	CLEAR-ER	CLEAR-FDR
PMID	22223235	28507269	30249518	18772447	23887841	26243231
Intervention	0.9mg/kg rt-PA + low dose argatroban	0.9mg/kg rt-PA + low or high dose argatroban	0.9mg/kg rt-PA + high dose argatroban + ET	0.3mg/kg and 0.45mg/kg rt-PA + eptifibatide	0.6mg/kg rt- PA + eptifibatide	0.9mg/kg rt-PA + eptifibatide
Study Size	n=65, single arm	n=90, 3-arms	n=10, single arm	n=94, 69 combination, 25 rt-PA	n=126, 101 combination, 25 rt-PA	n=27, single arm
Randomized	No	Yes	No	Yes	Yes	No
sICH Rate	5.1%	7%*	0%	1%	2%	3.7%
*high dose arm						

If the patient's exam improves or good recanalization is achieved before study drug is administered, should study drug still be given?

Yes – study drug should be administered within 60 minutes of alteplase in subjects eligible prior to alteplase treatment, even if there is clinical improvement or good recanalization before study drug is started because:

- IV rt-PA alone opens ~50% of occluded arteries; 14-34% reocclude leading to worse outcomes
- Based on ET treated patients in published trials, 31% did not achieve good recanalization and 25% had persistent occlusion at 24 hours