REGULATE-PCI

Purpose: comparison of safety and efficacy of REG1 (pegnivacogin [Factor IX inhibitor] + anivamersen [active control]) to bivalirudin for improved reduction of periprocedural major bleeding and ischemic complications with PCI.

Trial Design: Phase 3, 1:1, interventional, randomized, open label, multi-center, safety and efficacy study. N= 3,232. Arm 1 = Bivalirudin; Arm 2 – Reg1 + anivamersen

Primary Endpoint: Composite of events through day 3 (death, nonfatal myocardial infarction or stroke, revascularization)

Trial Results	Primary Endpoint @ 3 Days	P value	BRAC bleeding @ 3 days	P value
REG1	6.7%	0.72	6.5%	0.002
bivalirudin	6.4%		4.1%	

Conclusions: Because of excessive allergic reactions with REG1, this trial was stopped early. REG1 was associated with more bleeding. By day 3, the rates of the primary endpoint were similar for REG1 and bivalirudin.

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