

Treatment of Proximal Deep Vein Thrombosis (DVT): Rivaroxaban Once or Twice Daily Had Similar Efficacy and Safety to Standard Therapy in Phase II Studies

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INTRODUCTION

Rivaroxaban – an oral, direct Factor Xa inhibitor – was evaluated in two dose-ranging studies relative to standard therapy – heparin/LMWH + vitamin K antagonist (INR 2–3) – for the treatment of patients with acute, symptomatic, proximal DVT without pulmonary embolism (PE).

METHODS

In EINSTEIN-DVT (n=543), patients received rivaroxaban 20, 30 or 40 mg once daily (od) or standard therapy, and in ODIXa-DVT (n=613), patients received rivaroxaban 10, 20 or 30 mg twice daily (bid), 40 mg od or standard therapy. The efficacy outcome in EINSTEIN-DVT was symptomatic, recurrent DVT or symptomatic PE (recurrent venous thromboembolism [VTE]),

and asymptomatic deterioration on ultrasonography (US) or perfusion lung scan, at 3 months. In ODIXa-DVT, the efficacy outcome at 3 weeks was thrombus regression on US without recurrent VTE, and at 3 months was recurrent VTE and asymptomatic deterioration on US.

RESULTS

Efficacy outcomes at 3 months are shown in the table. Thrombus regression at 3 weeks occurred in 53.0%, 59.2%, 56.9%, 43.8% and 45.9% of patients receiving rivaroxaban 20, 40, or 60 mg bid, 40 mg od or standard therapy, respectively.

Table: Rivaroxaban (total daily dose)

	20 mg	30 mg	40 mg	60 mg	Standard Therapy
ODIXa-DVT (bid study)					
Efficacy outcome (%)	1.1	--	1.1/3.0*	1.0	1.0
Major bleeding (%)	1.7	--	1.7/1.7*	3.0	0
EINSTEIN-DVT (od study)					
Efficacy outcome (%)	6.1	5.4	6.6	--	9.9
Major bleeding (%)	0.7	1.5	0	--	1.5

*Results are shown as 20 mg bid/40 mg bid.

CONCLUSION

This oral direct Factor Xa inhibitor that can be given as the sole treatment in a fixed dose appears to be a very attractive alternative to standard therapy in patients with DVT. Additional results will be presented.