About The Company

Founded in 2003, Lumen Therapeutics is a biopharmaceutical company focused on the development and commercialization of biopharmaceuticals based on polymers of L-arginine. Lumen is researching a pipeline of novel vascular therapeutics based on this proprietary technology. LT-1951, the firm’s first product, is in development for the prevention of Vein Graft Failure after Coronary Artery Bypass Graft (CABG) surgery.

Lumen Therapeutics is working on extending the use of LT-1951 for Peripheral Arterial Bypass grafts and related products in: drug eluting stents; transplant-care markets for heart, kidney, liver and pancreas; and Arterio-venous grafts required for hemodialysis. Lumen can also apply its core technology to address unmet needs in additional disease states modulated by nitric oxide. Lumen expects to establish development partnerships with leading pharmaceutical companies to facilitate advanced clinical study and marketing of its products.

Scientific Rationale

CABG procedures are an important mainstay for treating Coronary Artery Disease. While CABG surgery is a very effective procedure, grafts fail early after grafting due to thrombosis, or later due to saphenous vein graft disease (SVGD), a narrowing of the vein’s internal diameter (lumen) characterized by neointimal hyperplasia and subsequent formation of atherosclerotic plaque. In the early period after grafting, a significant percentage of grafts fail and by the first year after bypass surgery, up to 50% of vein grafts occlude and most grafts exhibit some degree of SVGD. The consequences of failure can be silent, but can also include heart attacks, chest pain, congestive heart failure, irregular heartbeat, and death.

LT-1951 for CABG is an aqueous solution of a short peptide comprised of a polymer of L-arginine. The drug efficiently penetrates into vascular tissues such as the saphenous vein and supplies the tissue with a sustained reservoir of L-arginine, the substrate for production of nitric oxide. Nitric oxide has the potential to limit both acute thrombosis and neointimal hyperplasia.

A dramatic reduction of neointimal hyperplasia following treatment with LT-1951 has been demonstrated in preclinical vein to artery interposition studies in three animal models. Marked improvement following a single ex vivo application of the drug in interposition grafts demonstrated that the beneficial effect of the drug is not dependent upon continued treatment of the grafted tissue.

Clinical Development

Lumen Therapeutics’s first product, LT-1951, was tested in a blinded, randomized, placebo-controlled, Phase I/II clinical study. The Lumen sponsored PATENT trial (PolyArginine Treated vElN gralT) was performed at Toronto General Hospital (TGH), the Phase I portion of the trial, completed in Q3/2005, indicated that LT-1951 was well tolerated. Subjects suffered no drug-related serious adverse events; all reported adverse events were typical of this patient group. A total of 20 patients were treated and evaluated with cardiovascular imaging at 1 month. The data showed a clear signal that treatment with LT-1951 provided a significant (p<0.01) reduction in the rate of early failure relative to PBS treated vein grafts. The performance of the vehicle used in this study, phosphate buffered saline (PBS), indicates that it will not be suitable for future studies. A new Phase II trial currently is being planned which uses Lactated Ringers as the vehicle.

Product Pipeline

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Selected Advisors

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