Veryan | In The Media

June 2014

Imperial Innovations Set to Increase Investment in Veryan Medical

The technology transfer, incubation and venture investment company Imperial Innovations, Veryan's largest investor with a 44.3% shareholding, is proposing to increase its investment in the company, in order to help fund future growth.

The following is an extract from a report by Edison Investment Research dated 5th June 2014, on the proposed investment, which very positively highlights Veryan's future financial potential. See Edison's website for further details: http://www.edisoninvestmentresearch.com/research/company/Imperial-Innovations.

EDISON

Veryan delivers

Veryan was formed in 2003 as a technology spin out from Imperial College, London. The company's BioMimics 3D technology is based on research by Professor Colin Caro into the link between blood flow mechanics and vascular disease. Innovations first invested in Veryan in 2004 and as at 31 January 2014, the company held a 44.3% stake, with a carrying value of £16.97m (on £9.83m invested by Innovations). Veryan's other shareholders include National Endowment for Science and Arts (NESTA), Oxford Capital Partners, Seroba Kernel and Seven Mile Capital Partners.

Curved better than straight

Veryan's peripheral stents have a three-dimensional helical shape, which more closely mimics the natural geometry of the human vascular system and promotes natural swirling blood flow to elevate wall shear stress in the stented segment. The helical curvature also helps the stented vessel mimic the natural biomechanical performance of the femoropopliteal artery during knee flexion, thereby reducing the risk of stent fracture and vessel kinking, which are common problems with traditional straight stents.

Long-term benefit confirmed

Veryan initiated the 'Mimics' study in 2010 at eight clinical centres in Germany. The trial enrolled 76 patients with peripheral arterial disease (PAD) undergoing femoropopliteal artery intervention, randomised 2:1 to receive Veryan's BioMimics 3D stent (n=50) or a straight Nitinol comparator (n=26); 24 of these patients were treated with C.R. Bard's LifeStent, the market-leading stent in this setting. LifeStent has a helical strut design for flexibility, although it does not have 3D helical geometry.

Based on positive safety data at six and 12 months (the initial primary endpoint), BioMimics 3D stent was awarded CE mark approval in Europe in November 2012, although it is yet to be launched.

A year ago, Veryan reported encouraging 12-month data from the study, with a Kaplan Meier (KM) estimate

of freedom from clinically driven target lesion revascularisation (CDTLR) for subjects receiving the BioMimics 3D stent at 91.2% (or 9% revascularisation rate). The KM estimate of 12-month primary patency was 80.4% for BioMimics 3D subjects vs 72.0% for the control group. No stent fractures were reported in either treatment group.

The 24-month results now released confirm this positive trend and suggest a tangible advantage for the 3D helical stent over current market-leading stents. There was no increase in the CDTLR rate in the BioMimics arm between 12 and 24 months (9% at both time points), compared to an increase of 16% (8% at 12 months and 24% at 24 months) in the control arm. Further, the primary patency after two years was 72% for BioMimics 3D subjects vs 55.0% for the control group, a statistically significant difference (p=0.0497). The data indicate a correlation between primary patency and stent curvature, with BioMimics 3D stented segments showing significantly greater curvature (p=0.02) compared with the control. No stent fractures were reported in either treatment group.

Assessing best next steps

The final Mimics study data provide the launch pad for commercialisation in Europe (launch planned in H214) and the basis to seek a pre-market approval (PMA) in the US. We assume that a larger pivotal study would be required in the US to gain PMA authorisation. For reference, a pivotal study (RESILIENT) with the Bard LifeStent enrolled 206 patients, with six- and 12-month endpoints and a three-year follow-up. At 12 months, patency was 87.3% vs 45.2% on angioplasty alone. The stent fracture rate was 3.1% with no adverse events associated with fracture (fracture rates typically rise with time). Another pivotal study (DURABILITY) with the Covidien EverFlex stent enrolled 207 patients with a one-year patency endpoint (67.7% achieved) and an observed fracture rate of 0.4%.

Veryan and Innovations could seek to commercialise BioMimics 3D stent in Europe and advance US development through regional or global partnerships. A further funding round is also being considered, estimated by Innovations at £10-12m (in total) to cover three years of US development and to initiate European commercialisation. A trade sale would be another viable option, although the fresh funds now being sought by Innovations would certainly enable Veryan to advance its technology to the next level, which could deliver greater value in the long run.

The market opportunity

The global peripheral stent market is >$1bn annually, growing rapidly at 5-10% per year. Within the peripheral vascular stent market, femoropopliteal stents are about 40% of the market, although many stents are used off-label so precise differentiation is not feasible. Veryan estimates that 80% of patients undergoing intervention in the femoral artery will be stented. Patency rates are up to 87% for stented arteries after 12 months, against 40% for non-stented arteries (based on LifeStent clinical data).

The market leaders are Cordis (19% share with SMART range), Gore Medical (17% with TIGRIS) and Covidien (17% with EverFlex). Bard, Boston and Abbott each have approximately 11-12%. Drug eluting stents might prevent restenosis by their localised toxic effects (as in coronary stents), but the FDA is cautious about long, drug-eluting peripheral stents.

The Bard LifeStent is increasingly seen as the technical leader, hence the favourable comparison in the Mimics study should provide a compelling commercialisation case for the BioMimics 3D stent. Although the adoption of medical devices is notoriously hard to predict, and positive clinical studies are no guarantee of commercial success, Veryan's modest total valuation (~£38m) does seem low relative to the market opportunity for its 3D stent.