

# Executive Summary

## BACKGROUND

- The Translumina Yukon Drug Eluting Stent system (herein referred to as the YUKON DES) represents an alternative treatment to the drug eluting stents that are currently on the market.
- Both the Translumina coating system and the YUOKON DES are both fully CE marked and approved for usage in the European Union.
- To date, over 1000 patients have been treated using this approach as part of clinical trials, with low levels of adverse events.
- A further 5 clinical trials are either underway or in development, including a number of UK centres.
- The system allows the YUKON DES to be coated with an appropriate drug immediately prior to undertaking a percutaneous coronary intervention (PCI).
- The system allows the user to choose the drug coating as well as the dosage so that treatment can be tailored to the user's needs. This approach also overcomes the need for a polymer to secure the drug coating to the stent, as is the case with the pre-prepared DES currently on the market.
- Emerging evidence suggests that there may be benefits to tailoring the dose on DES to a patient's clinical characteristics.
- Additionally, concerns have been raised about adverse events associated with the pre-prepared DES on the market, which appear to be related to the polymer coating.

## CLINICAL SUMMARY

- The manufacturer recommends that the YUKON DES is coated with Rapamycin (Sirolimus), the same coating as the CYPHER stent.
- The YUKON DES has been subject to safety studies as well as case series to evaluate safety and efficacy in practice.
- Results of a dose finding study show that target lesion revascularisation was reduced from 21.5% in the BMS cohort, to 16.4%, 12.6% and 8.8% in the Rapamycin 0.5%, 1% and 2% dose cohorts respectively.
- This represents a 59% reduction in TLR in the Rapamycin 2% cohort.
- A comparative study of the YUKON DES with the TAXUS DES was undertaken to determine non-inferiority of the YUKON DES.
- The results of this study showed that the YUKON DES leads to small reductions in both restenosis and TLR (although the study was powered to detect non-inferiority so the results are not statistically significant).
- In all studies to date, the rate of adverse events with the YUKON DES has been low and comparable to other drug eluting stents.

## **ECONOMICS**

- The cost of the YUKON DES is approximately half the price of the list price of the pre-prepared DES.
- A simple economic model, based on the initial assessment of coronary stents, undertaken by the Liverpool Reviews and Implementation Group (LRIG) was developed. Costs were updated where data allowed or inflated by an accepted inflation index where recent data was unavailable. Efficacy data derived from clinical trials was used to determine the rate of restenosis.
- Results of the economic analysis suggest that DES dominate BMS over the course of 5 years – that is, they are less expensive and more effective.
- This occurs due to the decrease in restenosis and interventions related to it.
- As the YUKON DES is assumed to be clinically equivalent to the Cypher stent, but at significantly lower cost, the YUKON DES leads to greater cost savings over 5 years than other drug eluting stents.

## **SUMMARY**

**The Translumina YUKON DES system is a safe treatment for coronary artery disease that has shown reductions in restenosis of a similar rate to other drug eluting coronary stents already on the market. The average selling price of a YUKON DES is believed to be approximately 50% of other DES currently on the market. The ability to tailor treatment to the clinical needs of an individual patient, along with the absence of a polymer are additional benefits of the Translumina system. On this basis, it should be considered as a suitable alternative to other drug eluting stents.**