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29 August 2007

Dear Reenan,

**Kiwimed Ltd. Response to:
Coronary Artery Stents Review 'Appraisal Consultation Document'**

I would like to draw your attention to wording in the evaluation report section 2.8 as below:

Other than one trial (the ELUTES trial), there is little evidence to support coating the stent directly with an active drug (without a polymer).

Our non Polymer YUKON DES has been in use now for 5 years with clear clinical outcomes that do verify it's equivalence with polymer based DES. The ISAR TEST study (attached) for example, clearly showed our equivalence with the Taxus stent in late lumen loss and restenosis.

Anti platelet therapy

The other cost factor influencing the financial viability of using DES over BMS is that of long term anti-platelet therapy. Although the reasons for the increase of late thrombosis in drug eluting stents is still unclear it is generally accepted that this long term safety issue was not apparent with BMS.

In regard to increase in anti platelet therapy with DES your appraisal took account of this additional 9 months of Clopidogrel cost however generalised that all DES required 12 months anti-platelet therapy.

Due to the unique nature of the Yukon DES we will shortly be in a position to recommend the same anti platelet therapy as prescribed for patients receiving BMS's and should receive recognition for this cost saving in your appraisal.

The Harefield and Royal Brompton Hospital Trust are just completing a study looking at endothelialisation of the stent struts of the Yukon in comparison with the Cypher. The early coverage of stent struts is generally accepted to be a good surrogate indicator for long term safety and will allow for reduced anti-platelet therapy. The outcome data from this study will be published shortly.

Price premium

It is clear that much of the DES and BMS pricing that has been used in the assessment groups model is now out of date and if reviewed in light of price changes over the past year many of the available DES's would fall within the price premium bracket of £300 making them price effective in patients with small vessels and long lesions. The pricing on the Yukon DES has always fallen under this recommended price premium.

Your consideration of the above points would be appreciated

Yours Sincerely



Kiwimed Ltd.