"Luck and happiness in our endeavors may bring each day out the way very best in us!"

Summary & Conclusions
7. SUMMARY & CONCLUSIONS

PRECLINICAL & CLINICAL STUDY SUMMARY

► In vitro and in vivo preclinical studies on novel Supralimus-Core® sirolimus eluting coronary stent, we summarize that Supralimus-core® stent is noncytotoxic, cytocompatible, hemocompatible and not mutagenic. It is not showing any intradermal reaction and does not elicit any skin sensitization. The pyrogen test also indicated that, the rise in temperature is under acceptable level. In biofunctional study, no weight loss or adverse cardiac events observed during the study. In the animal pharmacokinetic study the peak Sirolimus tissue level reached within the first week after stent placement while systemic detection of the drug was negligible.

► Human pharmacokinetic, recoil and first-in-man studies, it summarize that Supralimus-Core® stent has ability to deliver a potentially therapeutic arterial tissue concentration of sirolimus and insignificant levels in the systemic circulation. It has greatest radial strength and promising approach for the prevention of restenosis.

CONCLUSIONS

► Our preclinical study has shown that sirolimus coated Supralimus-Core® stents allow sufficient concentrations of biologically active sirolimus available to inhibit smooth muscle cell proliferation. Further it showed the safety, biocompatibility and potentially efficacy of biodegradable polymer coated Supralimus-Core® stent.

► The preclinical and clinical pharmacokinetic studies confirm the limited exposure to the systemic circulation of the eluted drug with the use of the Supralimus-Core® stent. Therefore, a systemic cause of adverse events is unlikely. The sirolimus drug released from stent is in a controlled and predictable fashion.

► The principal finding from the stent recoil and first-in-man study, Supralimus-Core® sirolimus eluting stents with biodegradable polymer matrix is feasible, safe, effectively reduces in-stent neointimal hyperplasia and has greatest radial strength.
Supralimus-Core® stent is feasible, safe & effectively reduces in-stent neointimal hyperplasia.

Supralimus-Core® stent has greatest radial strength.

Blood & tissue concentration of sirolimus is below toxic level.

Sirolimus drug released from stent is in a controlled & predictable fashion.

Supralimus-Core® stent is proven safe & biocompatible.

Conclusions