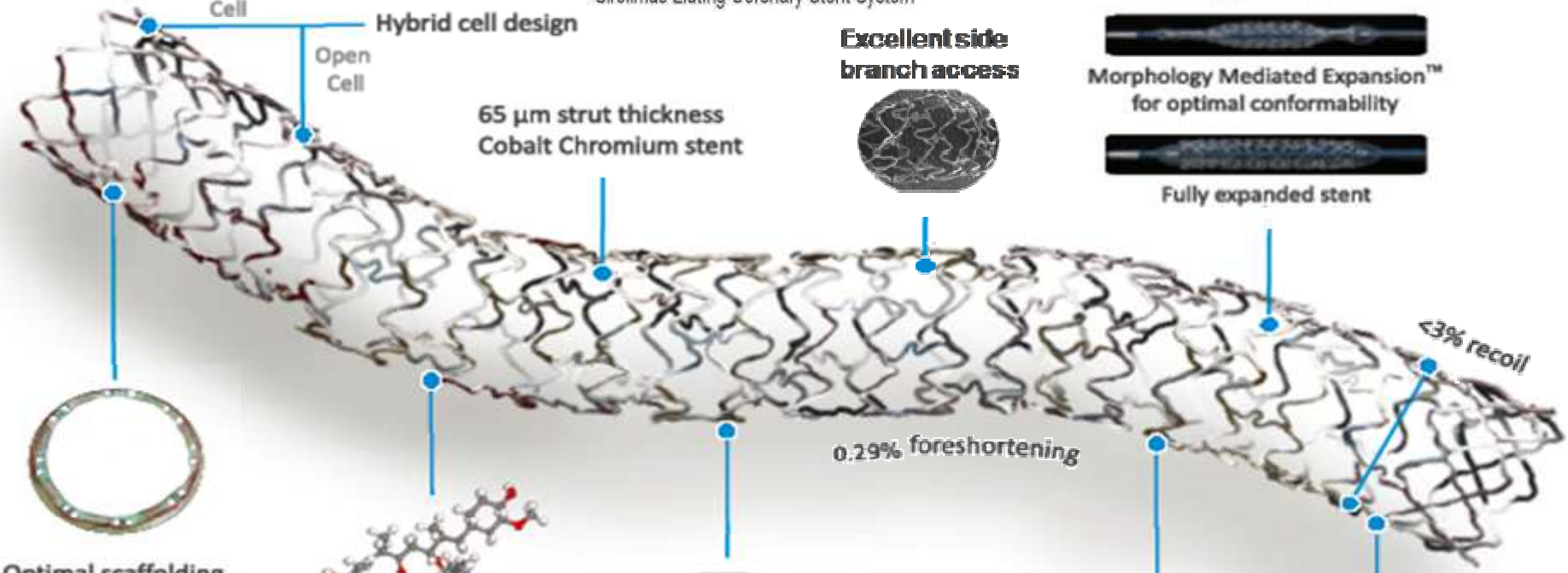
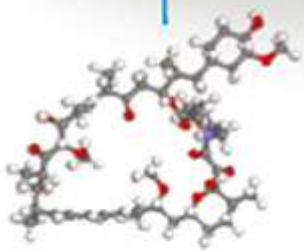
biomime

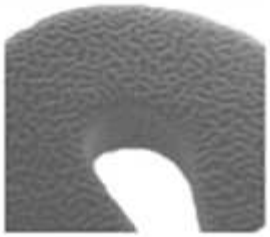
Sirolimus Eluting Coronary Stent System



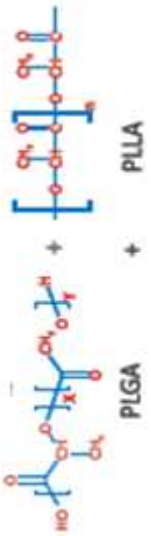
Optimal scaffolding, wall apposition with superior acute gain[1]



Sirolimus 1.25 µg/mm² of stent surface, 30-days elution kinetics



Stable, elastic non - inflammatory BioPoly™- Biodegradabl coating, 2 µm thick.



Highly flexible and deliverable stent system

Low balloon overhang, short, abrupt balloon shoulders for low balloon - related edge injury

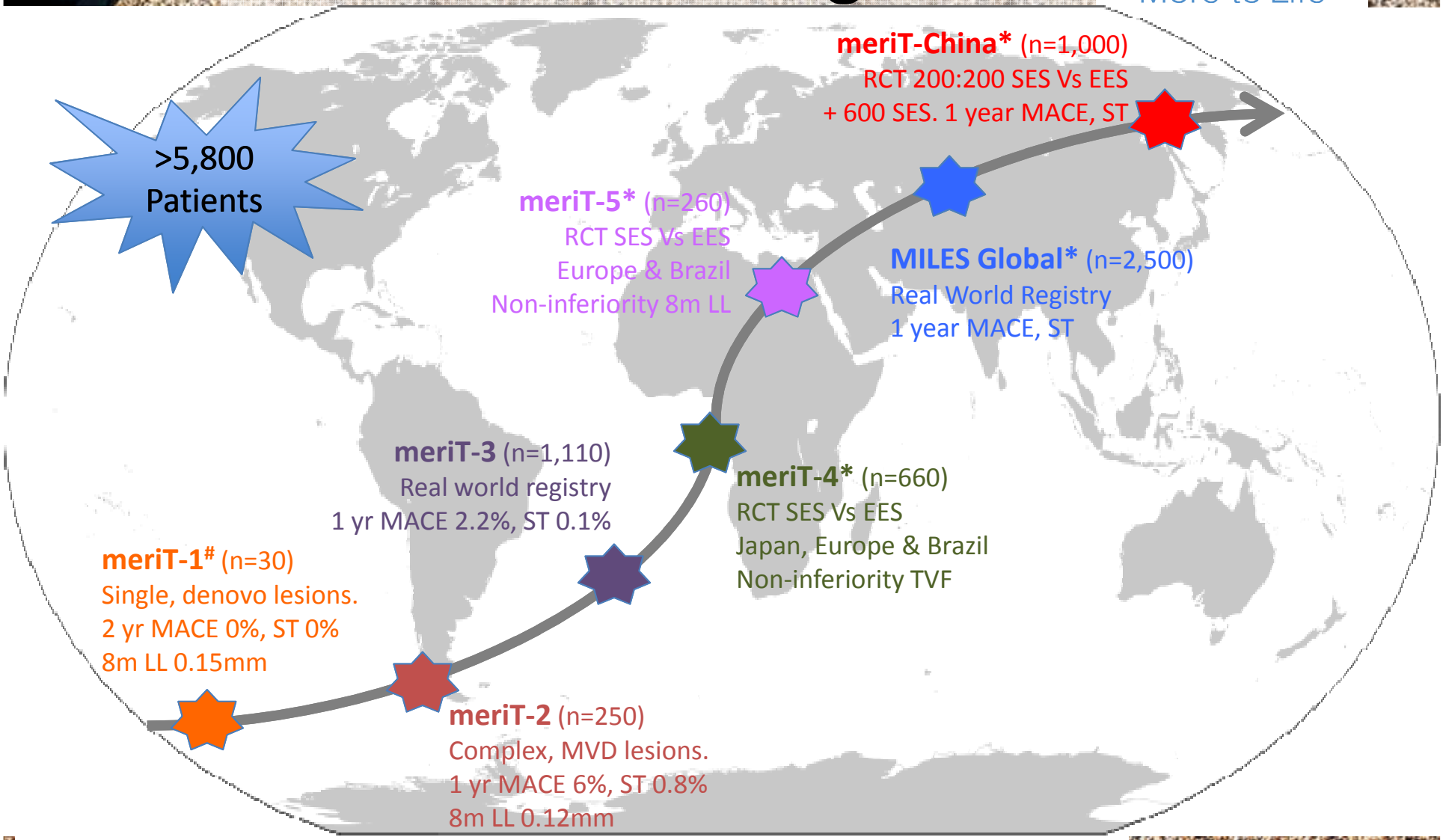
CE & ANVISA approved

New 2.00, 2.25 dia & 44, 48 mm Lengths

Available in 54 sizes-
Diameters (mm): 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Lengths (mm) : 8, 13, 16, 19, 24, 29, 32, 37, 40

BioMime Clinical Trial Program

Meril
More to Life



S. Dani et.al. EuroInterventions 2013; 9:493-500

* To be initiated. Under preparation.

meriT-1, 2, 3 Study Designs

Meril
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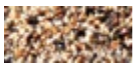
Study Design	meriT-1*	meriT-2#	meriT-3$
Principal Investigator	Dr. Sameer Dani, Ahmedabad, India	Dr. Ashok Seth, New Delhi India	Dr. R. K. Jain, Hyderabad, India
Study design	Prospective, phase IV, single center, non-randomized	Prospective, phase IV, multi-centric, non-randomized	Prospective, phase IV, multi-centric, non-randomized
N	30	250	1,110
Inclusion criteria	Single, discrete, de novo lesions, Mean vessel lumen diameter 2.5, 3.0 and 3.5 mm. Stent lengths 19 to 24mm	Most lesions (+CTO's). Vessel Dia. >2.5 and <3.5mm Lesion lengths upto 37mm treated with max. stent length of 40mm	Real world. All patients eligible for angioplasty and stenting with Sirolimus Eluting Coronary Stent system
Exclusion criteria	CTO's, Bifurcations, SVG's, AMI's, LM disease, LVEF <30 %	SVG's, AMI's, LM disease, LVEF <30%	None. Classical DES Tx exclusion criteria.
Clinical follow-up	30d, 6m, 8m, 1y, 2y	30d, 6m, 8m, 1y, 2y, 3, 5y	30d, 6m, 1y
Angiographic follow-up	All patients 8 months	All patients 8 months	None

* S. Dani et.al. EuroInterventions 2013; 9:493-500. # Presented by Dr. Ashok Seth at EuroPCR 2013. $ Presented during IndiaLIVE 2013



meriT-1, 2, 3 Study Designs & Key Demographics

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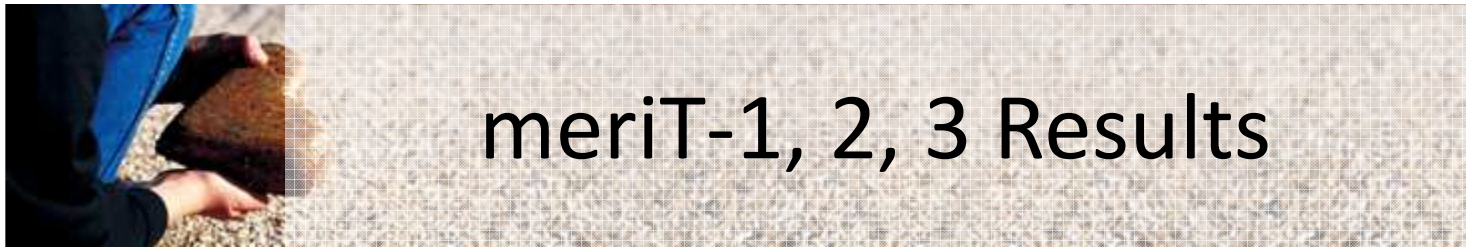
Study Design	meriT-1	meriT-2	meriT-3
Primary End points	30-days MACE and late loss at 8 months angio follow-up	30-days MACE and late loss at 8 months angio follow-up	30-day and 6m MACE
Secondary End points	MACE, ST upto 12months. Late loss at 8m angio follow-up	MACE, ST upto 12months. Late loss at 8m angio follow-up	1 year MACE, ST
Study status	2 years completed.	8months completed.	1 year completed.

Key Demographics	meriT-1 N=30	meriT-2 N=250	meriT-3 N=1,110
Mean age, years	50.5 ± 8	56.72 ± 10.55	56.3± 10.3
Gender, males	25 (83%)	208 (83%)	883 (79.5%)
Diabetics	9 (30%)	91 (36%)	454 (40.9%)
Hypertensives	17 (57%)	123 (49%)	589 (53.1%)
Smokers	7 (23%)	66 (28%)	178 (16.0%)
Hyperlipidimia	3 (10%)	26 (11%)	64 (5.8%)
Previous MI	13 (43%)	80 (32%)	156 (14.1%)

* S. Dani et.al. EuroInterventions 2013; 9:493-500. # Presented by Dr. Ashok Seth at EuroPCR 2013. $ Presented during IndiaLIVE 2013



meriT-1, 2, 3 Results

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Results	meriT-1 2-years f/up N = 28	meriT-2 1-year f/up N=249	meriT-3 1-year f/up N=1,110
MACE	0 (0%)	15 (6.0%)	24 (2.20%)
Cardiac deaths	0 (0%)	2 (0.80%)	10 (0.90%)
Non-fatal MI	0 (0%)	0 (0.00%	2 (0.20%)
Clinical TLR	0 (0%)	13 (5.2%)	7 (0.63%)
Stent Thrombosis			
Acute (<24hrs)	0 (0%)	1 (0.4%)	1 (0.1%)
Sub-acute (2-30d)	0 (0%)	1 (0.4%)	0 (0%)
Late (>30days)	0 (0%)	0 (0.0%)	0 (0%)
Late Loss (8m QCA)	N = 26	N = 218, 309 lesions	
In-segment	0.17	0.11	
In-stent	0.15	0.13	Only Clinical Follow-up
Binary Restenosis	0 (0%)	19 (6.2%)	

Independent Core Lab – CRC – Cardiovascular Research Center, Brazil
Dr. Ricardo Costa, Dr. Alexandre Abizaid

Median Late Loss Values due to non-normality of data

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