Take Home Messages

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Disclosure

Speaker name: Eugenio Stabile

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
LEGDEB and REFLOW data encouraging for LEGFLOW® - the new kid on the block

Preliminary results suggest that the LEGFLOW® drug-coated balloon (DCB) is a valid and effective alternative for the treatment of femoropopliteal lesions, according to 12-month data from the LEGDEB trial and six-month data from the REFLOW trial, presented for the first time yesterday.

Speaking to a packed hall at the CARDIONOVUM-sponsored lunchtime symposium, Eric Ducasse (Bordeaux, France), Marc Bosiers (Dendermonde, Belgium), Enrico Maria Marone (Pavia, Italy) and Koen Deloose (Dendermonde) shared their expertise on "Drug-coated balloons for peripheral interventions: a 360° experience."

Co-chaired the symposium were Peter Goverde (Antwerp, Belgium) and Dirk Scheinert (Leipzig, Germany). During their opening address, they drew attention to the fact that earlier in the day Dr Eugenio Stabile (Naples, Italy) presented, for the first time, the one-year LEGDEB results of the real world registry. These results showed that in a real-world population with
Growing Clinical Evidence
SAFEPAX: Over 2500 patients enrolled in clinical studies

- RAPID RCT: J End Ther 2017
- RESTORE OBS: Am J Cardiol 2015
- RESTORE SVD & ISR RCT: JACC 2018
- APERTO REG: J Vasc Acc 2018
- LEGDEB: JEVT 2019
- REFLOW: LINC 2019

# of patients in Clinical Trials
## SAFEPAX: Over 2500 patients in clinical studies

<table>
<thead>
<tr>
<th>Name of Study</th>
<th>RCT Control</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEGFLOW SFA China</td>
<td>POBA</td>
<td>29% enrolment</td>
</tr>
<tr>
<td>MAGNIFICENT (SFA)</td>
<td>POBA</td>
<td>Enrollment completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-up in progress</td>
</tr>
<tr>
<td>LEGFLOW CLI Japan</td>
<td>POBA</td>
<td>90% enrolment</td>
</tr>
<tr>
<td>LEGFLOW BTK China</td>
<td>POBA</td>
<td>28% enrolment</td>
</tr>
<tr>
<td>LEGDEB2 (iliofemoral &amp; BTK)</td>
<td>Observational</td>
<td>First patient in by 2019</td>
</tr>
<tr>
<td>APERTO China</td>
<td>POBA</td>
<td>Enrollment completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-up completed</td>
</tr>
</tbody>
</table>
Legflow Results: Freedom from TLR at 6 and 12 Months

Legdeb, Rapid and Reflow Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
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</thead>
<tbody>
<tr>
<td>REFL ow</td>
<td>120</td>
</tr>
<tr>
<td>RAPID</td>
<td>160</td>
</tr>
<tr>
<td>LEGDEB</td>
<td>139</td>
</tr>
</tbody>
</table>

1 Ad interim Analysis - LINC 2019
2 J Endovasc Ther. 2017 Aug 1
3 J Endovasc Ther 2019
Comparison of 2 Different Drug-Coated Balloons in In-Stent Restenosis
The RESTORE ISR China Randomized Trial

Yundai Chen, MD,d,e,1 Lei Gao, MD,a,b,1 Qiu Qin, MD,a b Shaoxiang Chen, MD,c Jun Zhang, MD,b,4 Hui Chen, MD,b,4 Lefeng Wang, MD,5 Zeming Jin, MD,5 Yang Zheng, MD,5 Zheng Zhang, MD,5 Hui Li, MD,b,6 Xue Li, MD,b,6 Guosheng Fu, MD,1 Lian Chen, MD,a,b Zhijun San, MD,a,6 Yu Wang, MD,a,b Qinhua Jin, MD,a,6 Feng Gao, MD,a,6 Jun Guo, MD,a,6 Yanyan Zhao, BS,a,6 Changdong Guan, MSc,a,6 Wei Li, PhD,a,6 Bo Xu, MD,MS,a,6 for the RESTORE ISR China Investigators

Radiol med (2017) 122:60–76
DOI 10.1007/s11547-016-0580-z

VASCULAR AND INTERVENTIONAL RADIOLOGY

Usefulness of paclitaxel-releasing high-pressure balloon associated with cutting balloon angioplasty for treatment of outflow stenoses of failing hemodialysis arteriovenous shunts

Anna Maria Ierardi1,2,6, Department of Nephrology, University of Naples, Naples, Italy, Marco Franchini1,2, Division of Nephrology, Ospedale Cattinara, Trieste, Italy, Federico Fontana1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy, Gabriele Piffaretti1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy, Etonaa Duka1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy, Massimo Tonolini1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy, Vittorio Miele1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy, Matteo Tozzi1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy, Giampaolo Carrafiello1,2, Department of Nephrology, Ospedale Cattinara, Trieste, Italy

Drug-Coated Balloon Versus Drug-Eating Stent for Small-Vessel Disease
The RESTORE SVD China Randomized Trial

Yida Tang, MD,a,b,1 Shuhui Qiao, MD,a,1 Xi Su, MD,a,1 Yundai Chen, MD,a,b,1 Zeming Jin, MD,a,1 Hui Chen, MD,b,1 Bo Xu, MD,a,b,1 Xiangpeng Kong, MD,a,1 Wenyue Yang, MD,a,1 Yong Liu, MD,a,b,1 Xue Li, MD,b,6 Hui Li, MD,b,6 Yanyan Zhao, BS,a,6 Yang Wang, MSc,a,6 Wei Li, PhD,a,6 Jian Tian, MD,a,6 Changdong Guan, MSc,a,6 Bo Xu, MD,MS,a,6 Runlin Gao, MD,a,6 for the RESTORE SVD China Investigators

Correspondence
Interim analysis at 6 months from the LEG-flow Drug Eluting Balloon for the treatment of aortic stenoses (LEDA) registry
Eugenio Stabile1,2, Marco Magliolo1,2, Dragos Zbelev1,2, Vasilis Christodoulou1,2, Kim Taeysman1,2, Peter Goedheer1,2, Maria Angela Lodi1,2, Gianluca Guglielmi1,2, Bruno Tramarin1,2, Giovanni Esposito1,2
1 Department of Cardiology, University of Milan, Milan, Italy, 2 Department of Interventional Cardiology, San Paolo Hospital, Milan, Italy
>40000 LEGFLOW used in 44 Countries since 2012

4 RCTs with +288 pts enrolled with LEGFLOW

2.1% occurrence of deaths @ 1 year follow up

0 (ZERO) deaths related to LEGFLOW in 4 RCTs ongoing Trials
Take Home Messages

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