SAVI TF REGISTRY

CLINICAL RESULTS EuroPCR 2016

LATEST RESULTS AT EuroPCR 2016.
1000 PATIENTS ENROLLED @ 30 DAYS.

ACURATE neo™
TRANSFEMORAL TAVI

symetis
NO COMPROMISE

1000 PATIENTS

8.2% PPM°

4.1% PVL°° ≥ 2

1.3% ACM°°°

° PPM : Permanent Pace-Maker
°° PVL : Para-Valvular Leak @ 7 days
°°° ACM : All-Cause Mortality
NEW PERMANENT PM
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

8.2%

LOWEST NEW PPM°° RATE

NO NEED TO COMPROMISE PPM & PVL

DEVICE PERFORMANCE
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

4.1%
PVL°° ≥ GRADE 2

% of patients with new Permanent PM

8.3

Mean gradient (mmHg)

1.81

Mean EOA (cm²)

PERFORMANCE @ 7 DAYS

Population [n] 999*
Mean Δp gradient [mmHg, mean ± SD] 8.3 ± 4.0
Mean EOA [cm², mean ± SD] 1.81 ± 0.5
PVL Grade
≤ Grade 1 (none to mild) [n/]% 926 / 95.9
Grade 2 (moderate) [n/]% 39 / 4.0
> Grade 2 [n/]% 1 / 0.1

MACCE @ 30 DAYS

Population [n] 994*
All-cause mortality [n/]% 13 / 1.3
Stroke [n/]% 19 / 1.9
MI [n/]% 3 / 0.3
Re-intervention post-DC [n/]% 0 / 0.0
Freedom from MACCE [n/]% 959 / 96.5

New pacemaker implantation [n/]% 82 / 8.2

* Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.
** PPM : Permanent Pace-Maker
* Medtronic Evolut R data from the IDE trial presented at ACC 2016
** SJM PORTICO data from the PORTICO I registry presented at EuroPCR 2016
*** Boston Lotus data from the RESPOND registry presented at EuroPCR 2016
**** EDW. SAPIEN 3 data from the European SOURCE 3 registry presented at EuroPCR 2016

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** PVL : Para-Valvular Leak @ 7 days
ALL-CAUSE MORTALITY
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

1.3%
LOWEST ACM°° RATE

<table>
<thead>
<tr>
<th>% of patients with All-Cause Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Evolut R*</td>
</tr>
<tr>
<td>SJM PORTICO**</td>
</tr>
<tr>
<td>Boston Lotus***</td>
</tr>
<tr>
<td>Edwards SAPIEN 3****</td>
</tr>
<tr>
<td>Symetis ACURATE TDO</td>
</tr>
<tr>
<td>2.5%</td>
</tr>
<tr>
<td>2.2%</td>
</tr>
<tr>
<td>2.2%</td>
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<tr>
<td>1.9%</td>
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<tr>
<td>1.3%</td>
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</table>

MACCE @ 30 DAYS

<table>
<thead>
<tr>
<th></th>
<th>994*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population [n]</td>
<td></td>
</tr>
<tr>
<td>All-cause mortality [n/%]</td>
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</table>

NYHA FUNCTIONAL CLASS @ 30D
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

SIGNIFICANT REDUCTION OF THE NYHA FUNCTIONAL CLASS BETWEEN BASELINE & 30D

81.2% TO 9.6%

NYHA FUNCTIONAL CLASS @ 30 DAYS

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>30D</th>
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<tbody>
<tr>
<td>Class I</td>
<td>71.0%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Class II</td>
<td>47.9%</td>
<td>8.9%</td>
</tr>
<tr>
<td>Class III</td>
<td>15.6%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Class IV</td>
<td>3.4%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

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** ACM : All-Cause Mortality
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° Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.
CONCLUSION
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS

NO COMPROMISE

1000 PATIENTS

8.2% PPM*
4.1% PVL ≥ 2°
1.3% ACM***

- Results show outstanding outcomes at 30 days
- Anatomic fit of ACURATE neo, top-down deployment technology and stability during positioning portend to high rate of procedure success, minimal PVL & abbreviated device usage times
- Excellent survival rates in this all-comers population
- NO COMPROMISE with the best PPM & PVL combination

* PPM : Permanent Pace-Maker
** PVL : Para-Valvular Leak @ 7 days
*** ACM : All-Cause Mortality
DETAILS & ENDPOINTS

**1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS**

- European Post-Market Registry to collect safety and performance data after CE mark was obtained in June 2014

- Symetis ACURATE neo™ Valve Implantation using TransFemoral Access (SAVI TF) Registry
  - Recruitment performed in 25 sites in 6 EU countries
  - 1000 patients enrolled between Oct. 2014 and Apr. 2016 up to 30 days**

- Primary Endpoints
  - All-Cause Mortality (ACM) @ 30 days

- Secondary Endpoints
  - Procedure success post-implant
  - Device performance @ 7 days and 12 months
  - VARC 2 safety @ 30 days and 12 months
  - NYHA class @ 30 days and 12 months

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**BASELINE CHARACTERISTICS (n=1000)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Age [years, mean±SD]</td>
<td>81.1 ± 5.2</td>
</tr>
<tr>
<td>Female [n/%]</td>
<td>612 / 61.2</td>
</tr>
<tr>
<td>Log. EuroSCORE I [% , mean ± SD]</td>
<td>18.1 ± 12.5</td>
</tr>
<tr>
<td>Log. EuroSCORE II [% , mean ± SD]</td>
<td>6.6 ± 7.5</td>
</tr>
<tr>
<td>STS Score [% , mean ± SD]</td>
<td>6.0 ± 5.6</td>
</tr>
<tr>
<td>ΔP [n/mmHg, mean ± SD]</td>
<td>42.7 ± 15.2</td>
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<tr>
<td>AVA [n/cm², mean ± SD]</td>
<td>0.72 ± 0.2</td>
</tr>
<tr>
<td>NYHA Class III/IV [%]</td>
<td>81.2</td>
</tr>
</tbody>
</table>

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** PVL : Para-Valvular Leak @ 7 days.
intuitive at heart

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