

**Table 6-19 Summary of Clinical Endpoints, RCT (ITT)**

| Measurements   | XIENCE V<br>(N=669) | TAXUS<br>(N=333) | Difference<br>[95% CI] <sup>4</sup> |
|--|---------------------|------------------|-------------------------------------|
| <b>Acute Success</b>   |                     |                  |                                     |
| Clinical Device Success  | 98.3% (750/763)     | 98.7% (374/379)  | -0.38% [-1.86%, 1.09%]              |
| Clinical Procedure Success   | 98.5% (651/661)     | 97.3% (322/331)  | 1.21% [-0.78%, 3.19%]               |
| <b>Per-Subject Analysis<br/>Clinical Endpoints to 284 Days<sup>1</sup></b>     |                     |                  |                                     |
| TVF-free   | 92.4%               | 90.5%            | 1.98% [-1.80%, 5.76%]               |
| TLR-free   | 97.3%               | 95.0%            | 2.24% [-0.44%, 4.92%]               |
| Revascularization <sup>2</sup> -free   | 94.7%               | 93.5%            | 1.21% [-1.98%, 4.41%]               |
| Cardiac Death-free   | 99.4%               | 99.4%            | 0.01% [-1.04%, 1.05%]               |
| MACE-free  | 95.0%               | 91.4%            | 3.62% [ 0.15%, 7.09%]               |
| <b>Per-Subject Analysis<br/>Clinical Endpoints to 393 Days<sup>5</sup></b>     |                     |                  |                                     |
| TVF-free   | 91.5%               | 88.9%            | 2.62% [-1.41%, 6.65%]               |
| TLR-free   | 96.7%               | 94.4%            | 2.26% [-0.61%, 5.12%]               |
| Revascularization <sup>2</sup> -free   | 93.9%               | 92.5%            | 1.39% [-2.02%, 4.79%]               |
| Cardiac Death-free   | 99.2%               | 99.1%            | 0.17% [-1.08%, 1.41%]               |
| MACE-free  | 94.1%               | 89.8%            | 4.27% [0.51%, 8.02%]                |
| <b>Safety Measures-Per Subject<br/>Analysis</b>                                |                     |                  |                                     |
| TVF in-hospital <sup>3</sup>   | 0.9% (6/669)        | 2.4% (8/330)     | -1.53% [-3.33%, 0.28%]              |
| TVF through 37 days  | 1.6% (11/667)       | 3.3% (11/330)    | -1.68% [-3.85%, 0.48%]              |
| TVF through 194 days   | 4.1% (27/663)       | 5.5% (18/326)    | -1.45% [-4.35%, 1.45%]              |
| TVF through 284 days   | 7.6% (50/657)       | 9.7% (31/320)    | -2.08% [-5.90%, 1.75%]              |
| TVF through 393 days   | 8.6% (56/653)       | 11.3% (36/320)   | -2.67% [-6.75%, 1.40%]              |
| MACE in-hospital <sup>3</sup>  | 0.9% (6/669)        | 2.4% (8/330)     | -1.53% [-3.33%, 0.28%]              |
| MACE through 37 days   | 1.3% (9/667)        | 3.0% (10/330)    | -1.68% [-3.73%, 0.37%]              |
| MACE through 194 days  | 2.9% (19/663)       | 5.2% (17/326)    | -2.35% [-5.08%, 0.38%]              |
| MACE through 284 days  | 5.0% (33/657)       | 8.8% (28/320)    | -3.73% [-7.24%, -0.21%]             |
| MACE through 393 days  | 6.0% (39/653)       | 10.3% (33/320)   | -4.34% [-8.14%, -0.54%]             |
| <b>Stent Thrombosis</b>  |                     |                  |                                     |
| Acute (< 1 day)  | 0.1% (1/669)        | 0.0% (0/330)     | 0.15% [Assump. not met]             |
| Subacute (1 to 30 days)  | 0.3% (2/667)        | 0.0% (0/330)     | 0.30% [Assump. not met]             |
| Late (31 to 284 days)  | 0.2% (1/653)        | 0.0% (0/319)     | 0.15% [Assump. not met]             |
| Late (31 to 393 days)  | 0.3% (2/646)        | 0.6% (2/317)     | -0.32% [Assump. not met]            |
| Stent Thrombosis (per ARC)<br>Definite + Probable, uncensored<br>(at 393 days) | 1.1% (7/648)        | 0.6% (2/317)     | 0.45% [Assump. not met]             |