NMT Medical dives on Closure I trial failure

Mass Device

A clinical trial of NMT Medical Inc.'s (NSDQ:NMTI) flagship StarFlex device failed to meet its primary endpoint, sending the company's stock down 5 percent in late-day trading.

The Boston-based company said its Closure I trial, examining the use of its cardiac implant in treating stroke and transient ischemic attack, failed to meet its primary endpoint of demonstrable superiority to "current best medical therapy for preventing recurrent strokes and TIAs," according to a press release.

The study did show that the device, which is implanted in the heart via catheter to close small holes between its chambers, "provided a small, but not statistically significant, benefit over current best medical therapy," according to the release [1]. The trial also showed that the device had low rates of complications and thrombosis, with closure rates of 86.5 percent.

The news derails the company's plans to submit a pre-market approval application to the Food & Drug Administration [2], something it had hoped to do late this year. CEO Frank Martin said in prepared remarks that the company is in discussions with the FDA about rescuing the stroke/TIA indication for the StarFlex device and is continuing to evaluate the study data. The full results are expected to be released at the American Heart Assn.'s meeting in November, Martin said.

"The preliminary data did demonstrate that our implant device provided a small benefit over current best medical therapy and maintained an excellent safety profile," he noted. "NMT remains committed to addressing structural heart disease through minimally invasive, catheter-based procedures. We are continuing to develop the next generation of bioabsorbable implants, including our BioTrek device. In addition, we should note that the results of Closure I have no impact on the status of our current FDA and CE Mark approvals for ventricular septal defect (VSD) and atrial level shunt patients."

Word of the trial's failure sent NMT stock tumbling [3] in late-day trading, to below 70 cents from its $2.68 open.

SOURCE [4]

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