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Boston Scientific stock gets boost on FDA device approval

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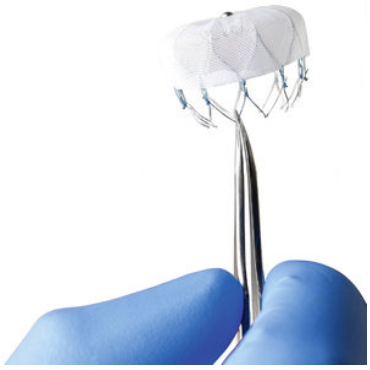

The Watchman The device will help eliminate blood clots in stroke-prone patients who can't use blood-thinning drugs.

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Boston Scientific Corp.'s stock climbed nearly 4 percent Monday after the Food and Drug Administration approved a heavily studied heart device intended to cut the risk of stroke in patients with quivering hearts.

The FDA voted to allow commercial sales of the Watchman left atrial appendage closure device late Friday, following an unusually long approval process that started in 2009. The Minnesota-designed device is approved for patients whose atrial fibrillation causes a high risk of having a stroke and who are seeking an alternative to blood-thinning warfarin drugs like Coumadin.

"We are very pleased with the label," said Boston Scientific's chief medical officer in rhythm management, Dr. Kenneth Stein, referring to the device label approved by the FDA that lists which groups of patients are candidates for Watchman therapy.

There had been concern that the Watchman, after such a probing approval process, would be OK'd for a very limited patient population. But Stein said Monday that wasn't the case: "This is precisely the group of patients who we think ought to be considered for the device."

Some patients can use the device as a "first-line" treatment to reduce the risk of stroke if they have a valid reason to avoid blood-thinning drugs. Patients have to be able to tolerate some level of blood-thinning medication, however, because warfarins are recommended for at least six weeks after the procedure is done. The device label will include a somewhat unusual section describing considerations for selecting the right patients, Stein said.

Atrial fibrillation is an irregular heartbeat that feels like a quivering heart and affects about 2.7 million Americans, according to the American Heart Association. The condition is a risk factor for stroke because an irregular heartbeat can cause blood to pool in an area of the heart called the left atrial appendage, where it can form clots. If a clot breaks away, clogs a vessel and blocks oxygen-rich blood flowing to the brain, a stroke results.

Between 15 and 20 percent of stroke patients have atrial fibrillation, which is why doctors often prescribe blood-thinning warfarin drugs to prevent clots from forming in the heart and throughout the body. But Boston Scientific and other companies working on left atrial appendage closure plugs say their devices are needed because as many 40 percent of patients eligible to take warfarins don't do so.

"If there are patients who are on the drugs who are doing well, we are not pushing for device use on those patients," Stein said. "But for those patients who either have had problems on the drugs, or who predictably will have problems if they're put on the drugs in the long term, that's the population where they stand to benefit from this device."

The device was initially conceived 20 years ago by a group of Minneapolis physicians who formed a company called Atritech to develop it. In 2011, Boston Scientific paid $100 million to buy Atritech, and promised up to $275 million in additional payments based on hitting regulatory and revenue milestones through 2015. Boston Scientific declined on Monday to reveal the full acquisition price including the various goals.

Boston Scientific has stated publicly that the potential global market for left atrial appendage closure devices, including those still under development by other companies, could reach $500 million by 2019. Stock analysts have estimated the market could be double that amount.

For its device, Boston Scientific is planning a gradual release of the Watchman, initially selling it only to health care providers that took part in clinical trials and then rolling it out at hospitals where doctors have a chance to take part in rigorous training programs.

The gradual rollout is taking place in the wake of many questions about the device at the Food and Drug Administration.

Panels of doctors advising the FDA recommended approving the device in 2009, 2013, and 2014. But final approval only came this year, in part because the FDA wanted longer-term studies on patients. The company is also doing a large post-approval study of the device.

Dr. William Katsiyiannis, an Abbott Northwestern Hospital physician who took part in clinical research on the Watchman at the Minneapolis Heart Institute Foundation, said some of the delay in approval at the FDA happened because of medical complications early in testing.

"Early in the studies, it was a new technique and a new approach. We were working in a space, the left atrial appendage, which I believe operators had to get used to. So there were more complications initially when implanting it. As the studies continued, that safety concern diminished quite a bit," Katsiyiannis said.

Boston Scientific stock closed at $17.24 on Monday, climbing 3.8 percent on the day. That growth follows news last month that the company settled outstanding contract litigation with Johnson & Johnson, which boosted Boston Scientific's stock 12.4 percent.

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