Analyst: FDA OK Unlikely For Heart Valve Repair Device

A medical device industry analyst says Abbott Laboratories is unlikely to win approval anytime soon for its device used to repair heart valve problems, following a tepid endorsement by government experts.

A Food and Drug Administration panel of heart experts voted 5-3 on Wednesday that the benefits of Abbott's MitraClip system outweigh its risks. The panel voted unanimously that the device is safe and 4-5 on the question of whether the device is effective.

The company is developing the MitraClip to repair leaky heart valves.

Wells Fargo analyst Larry Biegelsen said in a note Thursday, "We believe FDA is unlikely to approve the device," until the results of another study are submitted. That study may not be completed until the summer of 2019, according to a government website.

The device is inserted through a catheter placed in the patient's leg. It clips together leaflets of the heart's mitral valve, which is between the left upper and lower chambers, to reduce significant mitral regurgitation. Mitral regurgitation can cause blood to flow backward into the heart's left atrium leading to an irregular heartbeat, heart failure, a stroke or heart attack.

Biegelsen said a delay in approval is unlikely to hurt Abbott's stock, since most Wall Street analysts had low expectations of the product's commercial potential going into the FDA review. Biegelsen holds an "Outperform" rating on the company stock.

Currently mitral regurgitation is treated with blood-thinning drugs for mild regurgitation or surgery for more severe cases. The MitraClip is intended for patients with significant regurgitation who may not be healthy enough to undergo surgery.

Following the meeting Wednesday, Abbott said in a statement, "We are pleased with the outcome of today's panel, and we look forward to continuing discussions with the agency regarding the panel's comments."

Shares of North Chicago, Ill.-based Abbott fell 33 cents to $33.48 in afternoon trading Thursday.

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