AGA Medical commences trial for stroke-prevention 'plug'

Mass Device

By Brandon Glenn *[1]*

AGA Medical Inc. (NSDQ:AGAM) enrolled the first patient in a clinical trial of a cardiac device aimed at preventing strokes in patients with abnormal heartbeats.

CEO John Barr called the first enrollment in the company's Amplatzer Cardiac Plug trial "a significant milestone" for the company, according to a statement [2] from AGA.

The trial is intended to evaluate the safety and efficacy of the plug in preventing blood clots in the heart that can lead to strokes. The trial will be conducted with patients suffering from atrial fibrillation [3], a condition in which the heart quivers and doesn't pump blood properly. The condidition can cause clots that travel to the brain and result in strokes, according to a statement from the company.

Such patients are typically treated with warfarin [4], a blood-thinning medication that can lead to complications such as bleeding. The trial will compare the Amplatzer plug's abilitiy for stroke-prevention with that of the drug.

The cardiac plug won regulatory approval for sales in Europe in December 2008 and is also sold in South America and parts of Asia, according to the company. The trial, if successful, could pave the way to federal approval that would allow AGA to begin marketing the device in the U.S.

SOURCE [5]

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