



## **HEARTio's Flagship Product ECGio Granted Breakthrough Designation From The United States Food and Drug Administration**

**PITTSBURGH – November 11, 2020** – HEARTio, a digital diagnostic startup utilizing artificial intelligence to help emergency providers identify heart abnormalities more quickly, more accurately, and at a fraction of the cost, announced today that its flagship product, ECGio, was recently determined to be a breakthrough device by the United States Food and Drug Administration (the “FDA”). HEARTio is developing the ECGio platform to assist medical professionals in identifying and localizing obstructive coronary artery disease, stratifying patient risk, and predicting the need for revascularization.

The breakthrough designation is only given by the FDA to devices that demonstrate a more effective treatment or diagnosis of a life-threatening or irreversibly debilitating human disease. According to the FDA, “The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization.”

Adam Butchy, Co-founder and Chief Strategy Officer of HEARTio stated, “This is a significant milestone that enables more frequent and efficient interactions between HEARTio and the FDA during the premarket review phase for ECGio, priority review for future FDA submissions, and reimbursement through Medicare for 4 years post-approval. We are excited to work collaboratively with the FDA to advance the ECGio platform and bring it one step closer to helping patients with coronary artery disease.”

### **About HEARTio**

HEART INPUT OUTPUT, INC. (“HEARTio”) is a digital diagnostic startup utilizing artificial intelligence to help emergency providers identify heart abnormalities more quickly, more accurately, and at a fraction of the cost. HEARTio is committed to saving lives, reducing healthcare costs, and improving the Emergency Department experience for all. Additional information about HEARTio can be found at [www.heartio.ai](http://www.heartio.ai).

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