Blog Post – Yesterday's FDA Breakthrough Device Designation News

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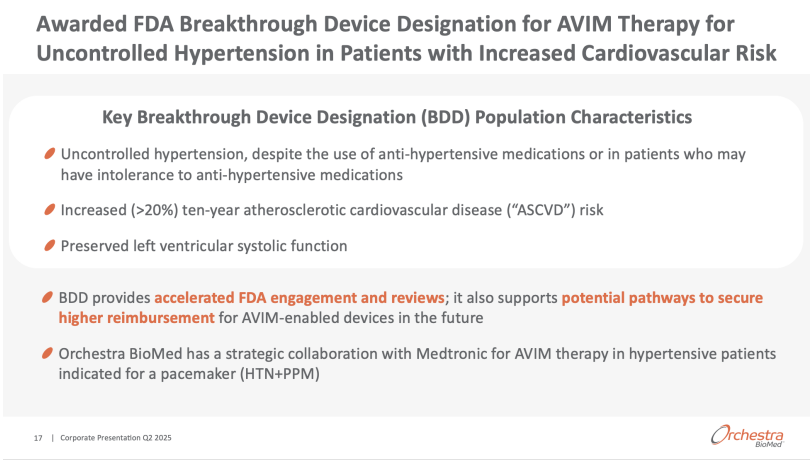
OBIO | YESTERDAY'S FDA BREAKTHROUGH DEVICE DESIGNATION NEWS

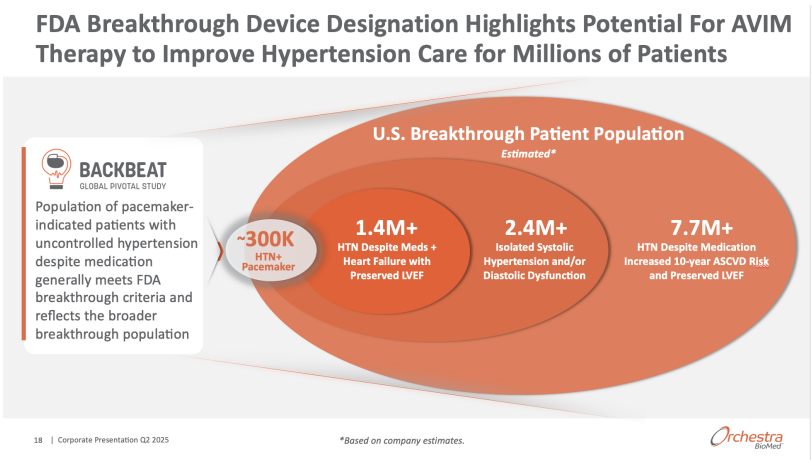
Yesterday, we shared exciting news that Orchestra BioMed has been awarded FDA Breakthrough Device Designation for our novel AVIM therapy. If you missed the announcement, here's a quick overview of this significant clinical and regulatory milestone:



THE NEWS: OBIO announced yesterday that it received FDA Breakthrough Device Designation (BDD) for AVIM therapy.

WHY OBIO'S AVIM THERAPY MATTERS: AVIM therapy offers a potentially powerful solution for uncontrolled hypertension in a broad population of patients with increased cardiovascular risk.

WHY FDA BREAKTHROUGH DEVICE DESIGNATION MATTERS: FDA Breakthrough Device Designation recognizes the potential of OBIO's unique therapy to benefit a significantly expanded number of patients who have uncontrolled hypertension and increased cardiovascular risk, regardless of whether they need a pacemaker for another indication. FDA Breakthrough Device status provides accelerated FDA engagement and reviews for AVIM therapy; it also supports potential pathways to secure higher reimbursement for AVIM-enabled devices in the future.



HOW THIS NEWS CONNECTS TO OBIO'S LARGER CLINICAL AND COMMERCIALIZATION EFFORTS: Patients with uncontrolled high blood pressure despite anti-hypertensive medications who are at increased cardiovascular risk are the core population we are already actively enrolling in the BACKBEAT study in collaboration with Medtronic, our strategic partner for the pacemaker population.

In the words of our Chairman & CEO, David Hochman: "Patients at higher risk for mortality and morbidity associated with high blood pressure are the core of the population we are actively enrolling in the BACKBEAT global pivotal study of hypertensive pacemaker-indicated patients in collaboration with Medtronic. The FDA Breakthrough Device Designation recognizes the potential of this unique therapy to benefit a significantly expanded number of patients who are not indicated for a pacemaker but who also have uncontrolled hypertension and increased cardiovascular risk".

HOW THIS NEWS ALIGNS WITH OUR MEDTRONIC PARTNERSHIP & SHARED GOALS: "Hypertension remains a significant global public health challenge that is especially relevant to the pacemaker population as the most common comorbidity in these patients. Medtronic is committed to collaborating with Orchestra BioMed to advance this innovative, investigational therapy through the BACKBEAT global pivotal study." - *Robert C. Kowal, M.D., Ph.D., Vice President and General Manager of Cardiac Pacing Therapies within the Medtronic Cardiac Rhythm Management operating unit.*

OBIO has a strategic collaboration with Medtronic, the global market leader in cardiac pacing therapies, for development and commercialization

of AVIM therapy for the treatment of uncontrolled hypertension in pacemaker-indicated patients. Under the terms of the existing collaboration agreement, Medtronic holds the right of first negotiation to expand its licensing agreement with OBIO to obtain global rights to commercialize AVIM therapy for the treatment of uncontrolled hypertension in patients that do not have an indication for a pacemaker.

As we noted yesterday, this milestone comes as a result of effective execution of our unique business model, which focuses on optimizing and accelerating clinical and regulatory outcomes with major partners**.**

The bottom line: our opportunity is getting stronger in terms of both market and economic potential. Several of our covering sell-side analysts agree, with multiple positive notes coming out yesterday reiterating positive ratings of OBIO's stock.

Orchestra BioMed is just warming up. Stay tuned!

—Team OBIO