Orchestra BioMed Announces Upcoming Presentations on BackBeat CNT™ and Virtue® SAB at CRT 2023

February 24, 2023

NEW HOPE, Pa., Feb. 24, 2023 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, “Orchestra BioMed” or the “Company”), a biomedical company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today announced that previously reported data from its BackBeat Cardiac Neuromodulation Therapy ™(CNT™) and Virtue® Sirolimus AngioInfusion™ Balloon (SAB) programs will be featured in upcoming oral presentations at the Cardiovascular Research Technologies (CRT) 2023 Meeting, which is being held in Washington, DC, from February 25 – 28, 2023.

Details on the presentations are shown below.

Presentation Title: Cardiac Neuromodulation Therapy for Medically Refractory Hypertension
Presenting Author: Daniel Burkhoff, M.D., Ph.D., Director of Heart Failure, Hemodynamics and Mechanical Circulatory Support Research at Cardiovascular Research Foundation
Presentation Date: February 26, 2023
Presentation Session Time & Title: 8:00 AM – 12:00 PM ET, *Renal Denervation and Hypertension Therapies*

Presentation Title: Virtue® Sirolimus AngioInfusion Balloon (SAB) Overview
Presenting Author: Dean Kereiakes, M.D., FACC, FSCAI, Medical Director of The Christ Hospital Heart and Vascular Center; Professor of Clinical Medicine at Ohio State University
Presentation Date: February 26, 2023
Presentation Session Time & Title : 2:00 PM – 5:55 PM ET, *BRS, DES and DCH Technologies*

About Orchestra BioMed

Orchestra BioMed (Nasdaq: OBIO) is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading medical device companies. Orchestra BioMed’s partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed’s flagship product candidates include BackBeat Cardiac Neuromodulation Therapy™ (CNT™) for the treatment of hypertension, a significant risk factor for death worldwide, and Virtue® Sirolimus AngioInfusion™ Balloon (SAB) for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Orchestra BioMed has a strategic collaboration with Medtronic, one of the largest medical device companies in the world, for development and commercialization of BackBeat CNT for the treatment of hypertension in pacemaker-indicated patients, and a strategic partnership with Terumo Corporation, a global leader in medical technology, for development and commercialization of Virtue SAB for the treatment of artery disease. Orchestra BioMed has additional product candidates and plans to potentially expand its product pipeline through acquisitions, strategic collaborations, licensing, and organic development. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com.

About BackBeat CNT and the Strategic Collaboration with Medtronic

BackBeat CNT is an investigational bioelectronic treatment designed to lower blood pressure. It is compatible with standard pacemakers as a firmware upgrade and has been evaluated in pilot studies in patients with hypertension who also are indicated for pacemakers. It is estimated that more than 70% of the approximately 1.1 million people globally who are implanted with cardiac pacemakers each year are also diagnosed with hypertension[1].

The recent peer-reviewed, double-blind, randomized pilot study, MODERATO II, showed that patients treated with the BackBeat CNT experienced net reductions of 8.1 mmHg in 24-hour ambulatory systolic blood pressure (aSBP) and 12.3 mmHg in office systolic blood pressure (oSBP) when compared to control patients at six months. Orchestra BioMed plans to conduct a global pivotal trial to further evaluate the safety and efficacy of the BackBeat CNT in lowering blood pressure in a similar target population of patients who have been indicated for, and recently received, a cardiac pacemaker implant. The strategic collaboration with Medtronic will provide Orchestra BioMed with development, clinical, and regulatory support for this planned multi-national study. Upon regulatory approval, Medtronic will have the global rights to commercialize BackBeat CNT-enabled pacing systems for this target population. Orchestra BioMed will share in the revenues generated from Medtronic sales of the BackBeat CNT-enabled pacing systems.

About Virtue SAB and the Strategic Collaboration with Terumo

Virtue SAB is a patented drug/device combination product candidate in development for the treatment of certain forms of artery disease that is designed to deliver a proprietary, investigational, extended-release formulation of sirolimus, SirolimusEFR™, to the vessel wall during balloon angioplasty without any coating on the balloon surface or the need to leave a stent or other permanent implant in the artery. Virtue SAB demonstrated positive three-year clinical data in coronary in-stent restenosis (ISR) in the SABRE trial, a multi-center prospective, independent core lab-adjudicated clinical trial of 50 patients conducted in Europe. Virtue SAB has been granted Breakthrough Device designation by the U.S. Food and Drug Administration for specific indications relating to coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee.

Under the terms of their collaboration agreement, Orchestra BioMed and Terumo plan to execute a global clinical program in an effort to gain regulatory approval for commercial sale of Virtue SAB in multiple markets and indications. Terumo made an upfront payment of $30 million to Orchestra BioMed and Terumo will potentially make additional future clinical and regulatory milestone payments. Orchestra BioMed will share meaningfully in future commercial revenues of Virtue SAB through royalties and per unit payments as the exclusive supplier of SirolimusEFR.

Orchestra BioMed retains the rights to develop and license SirolimusEFR and other technologies used in Virtue SAB for clinical applications outside of coronary and peripheral vascular interventions.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including, without limitation, statements relating to Orchestra BioMed's ability to successfully execute on its late-stage development programs and identify new potential opportunities. These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. The Company cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those identified under the heading "Risk Factors—Risks Related to Orchestra's Business and New Orchestra Following the Business Combination" in the definitive proxy statement/prospectus of Health Sciences Acquisitions Corporation 2 (Orchestra BioMed's predecessor) filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(3) on December 16, 2022 and in the Company's other filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for the Company's management to predict all risk factors, nor can they assess the impact of all factors on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "the Company believes" and similar statements reflect the Company's beliefs and opinions on the relevant subject. These statements are based upon information available to the Company as of the date hereof and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and the Company's statements should not be read to indicate that it has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, the Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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[1] Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES)