



Organovo To Present FXR314 IBD 3D Model Findings at Upcoming Crohn's and Colitis Congress

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SAN DIEGO, Jan. 09, 2024 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ: ONVO), a clinical stage biotechnology company that is focused on developing FXR314 in inflammatory bowel disease (IBD), including ulcerative colitis (UC), based on demonstration of clinical promise in three-dimensional (3D) human tissues as well as strong preclinical data, today announced that its data on the activity of FXR314 in its proprietary 3D human tissue models of Crohn's disease and ulcerative colitis will be presented at the Crohn's and Colitis Congress to be held January 25-27, 2024 in Las Vegas, Nevada.

The invited oral presentation, entitled "Evaluation of the clinical stage FXR agonist FXR314 in human primary cell 3D models of Crohn's disease and ulcerative colitis", will be made on Friday, January 26, 2024 at 3:00 PM PST by Dr. Fabrice Piu, Vice President, Research & Development.

"We initially identified a strong benefit of FXR agonism in IBD using our internal 3D models, then moved towards development of what we believe to be a best-in-class FXR agonist, FXR314, to treat IBD," said Keith Murphy, Organovo's Executive Chairman. "Our 3D human tissue models rely on primary cells isolated from individual donors with disease, and we believe our findings to constitute a translational research "gold standard" far superior and complimentary to preclinical animal models alone. FXR314 shows excellent results in standard preclinical models as well. In this presentation, data from our 3D models of IBD, especially the effect of FXR314 on multiple endpoints of IBD including epithelial barrier function and fibrosis in a wide set of Crohn's disease and ulcerative colitis donors, will be shown."

Organovo's current development program for FXR314 focuses on inflammatory bowel disease, where the drug's differentiated mechanism of action, as highlighted in Organovo's recently provided mechanism of action video at <http://organovo.com/about>, provides substantial promise that the drug's impact will strongly complement the biology of other successful drugs in ulcerative colitis and Crohn's disease. Organovo plans to begin enrollment for a proof-of-concept Phase 2 ulcerative colitis study in 1H 2024, with targeted completion in 1H 2025. The drug's additional promise in liver fibrosis and NASH makes it a strong candidate for development in that area through partnership collaborations with Organovo.

About Organovo

Organovo is a clinical stage biotechnology company that is developing drugs that are demonstrated to be effective in three-dimensional (3D) human tissues as candidates for drug development. The company's lead molecule, FXR314, is on the path for Phase 2 investigation in inflammatory bowel disease and has potential application in metabolic liver disease and oncology. The company has proprietary technology used to build 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. For more information visit Organovo's website at www.organovo.com.

Forward Looking Statements

Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. These risks and uncertainties and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on July 14, 2023, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on November 9, 2023. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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Source: Organovo, Inc.