



Organovo Presents FXR314 3D Human Tissue Model Findings That Show Improved Epithelial Barrier Function and Fibrosis Reduction at Crohn's and Colitis Congress

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SAN DIEGO, Jan. 25, 2024 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (Nasdaq: ONVO), a clinical stage biotechnology company focused on developing FXR314 in inflammatory bowel disease (IBD), including ulcerative colitis, based on demonstration of clinical promise in three-dimensional (3D) human tissues, today announced the presentation of preclinical data related to the company's FXR314 development program in its proprietary 3D human tissue models of Crohn's disease and ulcerative colitis at the Crohn's and Colitis Congress being held January 25-27, 2024 in Las Vegas, Nevada.

FXR314 is a clinical-stage potent, selective, orally administered non-bile acid FXR agonist being developed as a novel therapeutic approach for IBD.

"There is a critical need for novel approaches to treat inflammatory bowel disease (IBD) that extend beyond modulating the immune response targeted by current pharmacological therapies. These data underscore the potential of FXR314 as a unique treatment approach to IBD given its demonstrated multifaceted activity profile, especially in directly improving the intestinal barrier function and controlling fibrosis," said Dr. Fabrice Piu, Vice President, Research & Development. "The Crohn's and Colitis Congress is a unique opportunity to demonstrate this potential among key thought leaders in the field and as we continue to drive our program forward."

The presentation highlights preclinical data characterizing the activity of FXR314 in 3D models of human Crohn's disease and ulcerative colitis. FXR314 broadly improved measures of epithelial barrier function in a subset of donors, and fibrotic markers in all Crohn's disease donors. In ulcerative colitis, FXR314 improved epithelial barrier function and fibrotic activity in all donors.

"Organovo's primary multicellular 3D human IBD models constitute a powerful tool to more accurately predict the relevance of specific targets and assess the efficacy of therapeutic candidates. We strongly believe these results increase the probability of success with FXR314 when conducting IBD clinical trials, due to its demonstrated comparability to known disease," added Keith Murphy, Organovo's Executive Chairman.

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 <https://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 2024, with targeted completion in 2025. The drug's additional promise in liver fibrosis and NASH makes it a strong candidate for development in that.

Details of the presentation at the Crohn's and Colitis Congress in Las Vegas are shown below:

Title: Evaluation of the clinical stage FXR agonist FXR314 in human primary cell 3D models of Crohn's disease and ulcerative colitis
Presenter: Dr. Fabrice Piu, Vice President Research & Development
Date: Friday January 26, 2024 at 3 PM (Pacific)

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.