



Organovo Highlights FXR314 Combination Therapy Potential and Plan

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SAN DIEGO, Nov. 08, 2023 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ: ONVO), a clinical stage biotechnology company that is focused on developing FXR314 in ulcerative colitis and inflammatory bowel disease (IBD), based on demonstration of clinical promise in three-dimensional (3D) human tissues as well as strong preclinical data, today announced its intention to study combination therapy in inflammatory bowel disease and release data in calendar Q3 2024. The Company believes that the data it can generate can be powerful in establishing a strong use case for FXR314 in patients, and provide support for collaborations with major pharmaceutical companies currently offering IBD treatments.

The differentiated mechanism of action of FXR314, as highlighted in Organovo's recently provided mechanism of action video at <http://organovo.com>, provides substantial promise that the drug's impact will strongly complement the biology of other successful drugs in the space, e.g. TNF-alpha inhibitors (such as Humira), IL-12/23 inhibitors (such as Stelara), and JAK inhibitors (such as Xeljanz). The promise of combination therapy in this space is great, as all of these therapies have impactful safety signals. The ability to enable dosing half or less of the typical dose of these drugs, enabled by a combination with FXR314, could substantially reduce the safety impact and better serve patients. Further, FXR314 combination therapy could enable the successful achievement of clinical remission in a greater percentage of patients.

In both Organovo's proprietary 3D human models and in preclinical animal models of disease, FXR314 treatment demonstrates a reduction in the disruption of the intestinal lining, which protects against bacteria penetrating into the intestinal wall. Further, our models and published literature¹ indicate a role of FXR314 in modulating responses in innate lymphoid cells (ILCs) in the intestine, preventing the cytokine release that triggers a systemic immune-inflammatory response. In so doing, FXR314 can complement the typical drug therapies used in IBD, which themselves inhibit the activity of the cytokines driving the systemic response. Since FXR314 has a target that is upstream of most currently prescribed drugs, it can potentially strongly complement the use of these drugs when used in combination.

Organovo has previously announced plans for a Phase 2a study of FXR314 in ulcerative colitis, with a readout expected in 1H 2025. In addition, the company will now begin preclinical studies with combination therapies using FXR314 and currently approved therapies or equivalent that can benefit from lower dosing. Further, over time the company expects to share data generated in its proprietary 3D human models of inflammatory bowel disease that further demonstrate the potential for combination effects.

"We remain excited about the potential of FXR314 to treat IBD due to its unique mechanism of action, and about our upcoming Phase 2 study to demonstrate its activity in ulcerative colitis," said Keith Murphy, Organovo Executive Chairman. "As we enroll patients and complete the Phase 2, we are eager to explore the drug's potential for combination therapy and share our findings and the opportunities we see to further benefit patients, some of whom don't benefit from existing therapies due to safety limitations or low response rates. There remains great unmet need in inflammatory bowel disease, and we look forward to defining multiple roles FXR314 can play in providing treatment solutions."

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 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 August 10, 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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¹ Fu T, Li Y, Oh TG, Cayabyab F, He N, Tang Q, Coulter S, Truitt M, Medina P, He M, Yu RT, Atkins A, Zheng Y, Liddle C, Downes M, Evans RM. FXR mediates ILC-intrinsic responses to intestinal inflammation. Proc Natl Acad Sci U S A. 2022 Dec 20;119(51):e2213041119. doi: 10.1073/pnas.2213041119. Epub 2022 Dec 12. PMID: 36508655; PMCID: PMC9907109.



Source: Organovo, Inc.