



## Organovo Announces FXR Program

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### Lead Molecule Poised for Phase 2 in IBD

SAN DIEGO, March 21, 2023 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ: ONVO), a clinical stage biotechnology company that is focused on developing novel human therapies with demonstrated function in high fidelity three-dimensional (3D) tissues that recapitulate key aspects of human disease, today announced a clinical program for FXR 314, an FXR agonist that has completed initial clinical trials. FXR314 is a drug with safety and tolerability after daily oral dosing in Phase 1 and Phase 2 trials. Further, FXR314 has FDA clinical trial authorization for a Phase 2 trial in ulcerative colitis.

"We believe FXR314 to be a best-in-class FXR agonist with high potency and the potential to avoid dose-limiting toxicity issues found in other FXR-directed compounds," said Keith Murphy, Organovo's Founder and Executive Chairman. "Our 3D human tissue models will allow us to find the most effective clinical and commercial development strategy for this drug in inflammatory bowel disease patients, and we expect FXRs to have a widening set of therapeutic applications over time."

Organovo's FXR program announcement updates its previous guidance that it would first begin Phase 1 trials in 2025. The Company plans to give guidance on Phase 2 timelines after an internal determination of the best path forward. The Company continues to expect to file INDs starting in 2025 from fully internally developed molecules and expects to issue additional guidance on clinical plans in the coming months.

#### 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 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](http://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 June 10, 2022, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on February 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.*

#### Investor Contact

Amato and Partners, LLC  
Investor Relations Counsel  
[admin@amatoandpartners.com](mailto:admin@amatoandpartners.com)



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