Organovo Advances Clinical Timelines for FXR314 and Provides Updates on NASH Phase 2 Data

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SAN DIEGO, Aug. 23, 2023 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (Nasdaq: ONVO) (Organovo), 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 more details about its clinical program for FXR314, 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.

“Phase 1 safety data for FXR314, the data in our 3D human models of ulcerative colitis, and preclinical models all show very positive promise for FXR314 in the treatment of ulcerative colitis,” said Keith Murphy, Organovo’s Founder and Executive Chairman. “We believe strongly that the fact that FXR314 is showing effects on disease in our 3D human cellular models of ulcerative colitis means that it has a greater likelihood of success in Phase 2 than a typical drug program. We are excited to be charting a path to clinical success in ulcerative colitis, while also seeking to unlock the drug’s strong potential in NASH, where it has shown great promise in early clinical trials.”

Organovo’s FXR program announcement updates its previous guidance on clinical trial starts for the company, with the Company accelerating its timeline to first clinical trials by approximately two years. The Company previously announced in March 2023 that it would give guidance on Phase 2 timelines for FXR314 after an internal determination of the best path forward. The Company continues to expect to file INDs starting in 2025 for fully internally developed molecules and expects to issue additional guidance on pipeline programs in the coming months.

In addition, Organovo is anticipating the release of final Phase 2 data on the performance of FXR314 in NASH. Performance of the drug to date in treatment of NASH has been encouraging. Interim results in Phase 2 showed that FXR314 lowered liver fat content, with mean relative reductions of 26.9±27.8 percent in the 3 mg cohort and 9.3±55.8 percent in the 6 mg cohort, compared with 7.5±21.0 percent in the placebo cohort. Median liver fat reduction was 28.6 percent in the 3 mg cohort, 26.9 percent in the 6 mg cohort compared to 1.5% in the placebo arm. A post-hoc comparative assessment of relative liver fat reduction in the interim cohort found the decrease with the 3 mg dose to be statistically significant compared to placebo (p=0.006). FXR314 achieved greater than 30 percent liver fat reduction in 47 percent of patients (8/17) in the 3 mg cohort and 35 percent (6/17) in the 6 mg cohort, compared with 12 percent (2/17) in the placebo arm. To date, the drug has been generally well-tolerated, with no treatment-related serious adverse events. All treatment-related adverse events have been mild-moderate with no apparent dose relationship. Full Phase 2 data is expected to be released in 1H 2024.

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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