Organovo Presents Clinical Data of FXR314 in Phase 2 MASH in an Oral Presentation at The Liver Meeting

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SAN DIEGO, Nov. 20, 2024 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (Nasdaq:ONVO), a clinical stage biotechnology company focused on developing novel treatment approaches in inflammatory bowel disease (IBD) including ulcerative colitis, today announces that its oral presentation of its lead clinical stage drug FXR314 by Dr. Eric Lawitz of the Texas Liver Institute and the University of Texas Health San Antonio was featured at The Liver Meeting, sponsored by the American Association for the Study of Liver Diseases (AASLD). The meeting was held November 15-19, 2024 in San Diego, California.

The presentation entitled “Pharmacokinetics, Safety and Efficacy of the Novel Non-bile Acid FXR Agonist FXR314 in Patients with Metabolic Dysfunction-Associated Steatohepatitis: Results from a Phase 2 Study” was presented on Sunday, November 17 in the MASLD and MASH – New therapies session.

Dr. Lawitz shared the complete details of the 16-week, randomized, placebo-controlled, multi-center Phase 2 study of FXR314 in MASH patients. A total of 214 patients were randomized in a 1:1:1 ratio to either 3 mg or 6 mg of FXR314, or placebo. Study results demonstrated statistically significant reduction in liver fat content from baseline in patients receiving FXR314 compared to placebo, and a safety profile demonstrating significantly lower pruritus rates than seen with other FXR agonists.

Study subjects receiving FXR314 achieved statistically significant reduction in liver fat content from baseline, with LS mean percent reduction at end of treatment of 22.8% (p=0.0010) with 3 mg and 17.5% (p=0.0267) with 6 mg doses of FXR314 compared to 6.1% in the placebo group. The proportion of subjects with >30% magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF) reduction was 29.2% (p=0.0023) and 32.2% (p=0.0020) for 3 mg and 6 mg FXR314, respectively, compared to 9.5% with placebo. Investigators observed improvements in hepatocellular damage and liver function based on serological measures, with no evidence of worsening of liver fibrosis.

FXR314 was also found to be safe and well tolerated. Treatment-emergent adverse events were mostly mild to moderate in severity, with incidence comparable between FXR314 3 mg, 6 mg, and placebo. Drug-related treatment discontinuation was low in frequency and similar across groups. FXR314 did not demonstrate significant adverse events typical of the FXR class, including pruritus (3 mg 2.8%, 6 mg 4.2% and placebo 2.8%) and LDL-C levels (change from baseline of 1.5%, 4.5% and -3.6% for 3mg, 6mg, and placebo groups respectively).

	FXR314 3 mg	FXR314 6 mg	Placebo
Liver fat reduction (LS mean reduction from baseline, SE)	22.8 + 3.6% p=0.0010	17.5 + 3.7% p=0.0267	6.1 + 3.5%
Subjects with >30% MRI-PDFF reduction	29.2% p=0.0023	32.2% p=0.0020	9.5%
Pruritus	2.8%	4.2%	2.8%
Pruritus-related treatment discontinuation	0%	0%	0%

“These results are encouraging as we saw FXR314 treatment resulting in liver fat reduction but did not demonstrate the expected toxicities of this class,” stated Dr. Lawitz. “Due to this unique profile, I am excited about the prospects of further evaluating FXR314 for the treatment of MASH. The intestinal activating specificity is intriguing.”

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 May 31, 2024, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on November 8, 2024 and the Registration Statement on Form S-1 (File No. 333-282841). 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.

Contact

CORE IR
pr@coreir.com

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