Viking Therapeutics Presents Results from Phase 2b VOYAGE Study of VK2809 in Biopsy-Confirmed NASH/MASH at the 75th Liver Meeting® 2024

Oral Late Breaker Presentation Summarizes Positive Results Including Successful Achievement of Study's Primary and Secondary Endpoints

Data Support VK2809's Best-in-Class Profile Highlighted by Robust Liver Fat Reductions, Histologic Results Demonstrating NASH/MASH Resolution and Fibrosis Improvement, and Promising Tolerability and Safety

SAN DIEGO, Nov. 19, 2024 /PRNewswire/ -- Viking Therapeutics, Inc. ("Viking") (NASDAQ: VKTX), a clinical-stage biopharmaceutical company focused on the development of novel therapies for metabolic and endocrine disorders, today announced that final results from the company's Phase 2b clinical trial of VK2809, the company's novel liver-selective thyroid hormone receptor beta agonist, in patients with biopsy-confirmed non-alcoholic steatohepatitis (NASH; also referred to as metabolic dysfunction associated steatohepatitis, MASH) were highlighted in an oral late breaker presentation at the 75th Liver Meeting® 2024, the annual meeting of the American Association for the Study of Liver Disease (AASLD). The presentation summarized the final 52-week data from the VOYAGE study, showing that VK2809 successfully achieved the trial's primary and secondary endpoints while demonstrating excellent tolerability and promising safety.

Highlights from the oral presentation included:

Reduction in Liver Fat Content at 52 Weeks

Patients receiving VK2809 demonstrated statistically significant reductions in liver fat at Week 12, which was the primary endpoint in VOYAGE. Importantly, patients receiving VK2809 continued to demonstrate statistically significant reductions in liver fat content at Week 52, with the mean relative change from baseline ranging from 37% to 55%. The response rate in this study, defined as the proportion of patients experiencing reduction in liver fat ≥30%, ranged from 64% to 88% at Week 52, with all treatment arms demonstrating statistically significant improvement compared to placebo.

Histologic Results at 52 Weeks

On the secondary endpoint of NASH resolution with no worsening of fibrosis, VK2809-treated patients demonstrated NASH resolution ranging from 63% to 75%, compared with 29% for placebo ($p<0.05$ for each VK2809 treatment group). Across the combined VK2809 treatment groups, 69% achieved NASH resolution ($p<0.0001$ vs. placebo). Resolution of NASH was defined as a non-alcoholic fatty liver disease activity score (NAS) of 0 or 1 for inflammation and 0 for ballooning.

On the secondary endpoint evaluating improvement in fibrosis with no worsening of NASH, VK2809-treated patients demonstrated improvement in fibrosis ranging from 44% to 57%, compared with 34% for placebo ($p<0.05$ for the 5 mg and 10 mg QOD cohorts). Across the combined VK2809 treatment groups, 51% achieved improvement in fibrosis with no worsening of NASH ($p=0.03$ vs. placebo). Improvement in fibrosis without worsening of NASH was defined as a ≥1-stage improvement in fibrosis and no increase in NAS for ballooning, inflammation, or steatosis.

On the secondary endpoint evaluating the proportion of patients experiencing both resolution of NASH and improvement in fibrosis, VK2809-treated patients demonstrated improvement ranging from 40% to 50%, compared with 20% for placebo ($p<0.05$ for the 5 mg and 10 mg QOD cohorts). Across the combined VK2809 treatment groups, 44% achieved this endpoint ($p=0.003$ vs. placebo). Resolution of NASH and improvement in fibrosis were defined as described above.

Reduction in Plasma Lipids at Week 52

Patients receiving VK2809 demonstrated placebo-adjusted reductions in LDL-C ranging from 20% to 25% ($p<0.01$ for each arm), as well as reductions in triglycerides and atherogenic proteins such as apolipoprotein B (ApoB), lipoprotein (a) [Lp(a)], and apolipoprotein C-III (ApoC-III), all of which have been correlated with cardiovascular risk. These results support prior data demonstrating that

VK2809 may offer a cardioprotective benefit through its robust reduction in plasma lipids.

Safety and Tolerability

VK2809 demonstrated encouraging safety and tolerability in this study through 52 weeks of treatment, with minimal differences compared with the previously reported results at 12 weeks. The majority (94%) of treatment related adverse events among patients receiving VK2809 were reported as mild or moderate. Discontinuations due to adverse events were low and balanced among placebo and treatment arms. As in prior studies, and at the 12-week timepoint in this study, VK2809 demonstrated excellent gastrointestinal (GI) tolerability throughout the 52-week treatment window in this study. Rates of nausea, diarrhea, stool frequency, and vomiting were similar among VK2809-treated patients compared to placebo.

"The final 52-week data from the VOYAGE study provide compelling evidence of the therapeutic potential of VK2809 in NASH/MASH," said Rohit Loomba, M.D., MHSc, Chief of the Division of Gastroenterology and Hepatology and Director of the MASLD Research Center at University of California San Diego School of Medicine. "The potent reductions in liver fat, impressive NASH resolution rates, and improvements in fibrosis suggest an attractive potential treatment option for patients. In addition, the observed improvements in plasma lipids indicate a potential long-term cardioprotective effect, a valuable benefit in this setting."

Brian Lian, Ph.D., chief executive officer of Viking, added, "VK2809, along with our ongoing clinical activities with subcutaneous and oral VK2735 in obesity, as well as our preclinical program targeting amylin receptor agonists, provides Viking with one of the industry's most exciting and complementary therapeutic pipelines in the field of metabolic disorders. We look forward to continued advancement of our pipeline programs in important metabolic disorders."

Study Design

The VOYAGE study was a randomized, double-blind, placebo-controlled, multicenter, international trial designed to assess the efficacy, safety and tolerability of VK2809 in patients with biopsy-confirmed NASH/MASH and fibrosis. Enrollment included patients with at least 8% liver fat content as measured by MRI-PDFF, as well as F2 and F3 fibrosis. The study allowed for up to 25% of enrolled patients to have F1 fibrosis provided they also possessed at least one additional risk factor, such as diabetes, obesity or hypertension, among others. The primary endpoint of the study evaluated the change in liver fat content from baseline to Week 12 in patients treated with VK2809 as compared to patients receiving placebo. Secondary objectives include the evaluation of histologic changes assessed by hepatic biopsy after 52 weeks of treatment.

About VK2809

VK2809 is an orally available, tissue and receptor-subtype selective agonist of the thyroid hormone beta receptor (TRβ) that possesses selectivity for liver tissue, as well as the beta receptor subtype, suggesting promising therapeutic potential in a range of lipid disorders. The Phase 2b VOYAGE study of VK2809 in patients with biopsy-confirmed non-alcoholic steatohepatitis (NASH; also referred to as metabolic dysfunction associated steatohepatitis, MASH) and fibrosis successfully achieved both the trial's primary and secondary endpoints. VK2809 also successfully achieved primary and secondary endpoints in a Phase 2a study for the treatment of patients with elevated LDL-C and non-alcoholic fatty liver disease (NAFLD). Selective activation of the thyroid hormone beta receptor in liver tissue is believed to favorably affect cholesterol and lipoprotein levels via multiple mechanisms, including increasing the expression of genes associated with lipid metabolism and clearance.

About Viking Therapeutics, Inc.

Viking Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development of novel first-in-class or best-in-class therapies for the treatment of metabolic and endocrine disorders, with three compounds currently in clinical trials. Viking's research and development activities leverage its expertise in metabolism to develop innovative therapeutics designed to improve patients' lives. Viking's clinical programs include VK2735, a novel dual agonist of the glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) receptors for the potential treatment of various metabolic disorders. Data from a Phase 1 and a Phase 2 trial evaluating VK2735 (dosed subcutaneously) for metabolic disorders demonstrated an encouraging safety and tolerability profile as well as positive signs of clinical benefit. Concurrently, the company is evaluating an oral formulation of VK2735 in a Phase 1 trial. Viking is also developing VK2809, a novel, orally available, small molecule selective thyroid hormone receptor beta agonist for the treatment of lipid and metabolic disorders. The compound successfully achieved both the primary and secondary endpoints in a recently completed Phase 2b study for the treatment of biopsy-confirmed non-alcoholic steatohepatitis (NASH; also referred to as metabolic dysfunction associated steatohepatitis, MASH) and fibrosis. In a Phase 2a trial for the treatment of non-alcoholic fatty liver disease (NAFLD) and elevated LDL-C, patients who received VK2809 demonstrated statistically significant reductions in LDL-C and liver fat content compared with patients who received placebo. The company's newest program is evaluating a series of internally developed dual amylin and calcitonin receptor agonists (or DACRAs) for the treatment of obesity and other metabolic disorders. In the rare disease space, Viking is developing VK0214, a novel, orally available, small molecule selective thyroid hormone receptor beta agonist for the potential treatment of X-linked adrenoleukodystrophy (X-ALD). In a Phase 1b clinical trial in patients with the adrenomyeloneuropathy (AMN) form of X-ALD, VK0214 was shown to be safe and well-tolerated,

while driving significant reductions in plasma levels of very long-chain fatty acids (VLCFAs) and other lipids, as compared to placebo.

For more information about Viking Therapeutics, please visit www.vikingtherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding Viking Therapeutics, Inc., under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including statements about Viking's expectations regarding its clinical and preclinical development programs, anticipated timing for reporting clinical data and cash resources. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and adversely and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of Viking's product candidate development activities and clinical trials, including those for VK2735, VK0214, VK2809, and the company's other incretin receptor agonists; risks that prior clinical and preclinical results may not be replicated; risks regarding regulatory requirements; and other risks that are described in Viking's most recent periodic reports filed with the Securities and Exchange Commission, including Viking's Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q, including the risk factors set forth in those filings. These forward-looking statements speak only as of the date hereof. Viking disclaims any obligation to update these forward-looking statements except as required by law.

SOURCE Viking Therapeutics, Inc.

For further information: CONTACTS: Viking Therapeutics, Inc., Greg Zante, Chief Financial Officer, 858-704-4672, gzante@vikingtherapeutics.com; Vida Strategic Partners, Stephanie Diaz (Investors), 415-675-7401, sdiaz@vidasp.com; Tim Brons (Media), 415-675-7402, tbrons@vidasp.com

---