DaVita Statement on GLP-1 and Potential Implications on Chronic Kidney Disease

DENVER, Oct. 12, 2023 /PRNewswire/ -- DaVita issued the following statement in response to news this week from Novo Nordisk, manufacturer of Ozempic®, a glucagon-like peptide 1 (GLP-1) receptor agonist indicated for type 2 diabetes, related to its FLOW study that sought to demonstrate that Ozempic delays progression of chronic kidney disease (CKD) and lowers the risk of kidney and cardiovascular mortality. The following statement can be attributed to Dr. Jeff Giullian, chief medical officer for DaVita Inc.

"We've been closely monitoring the developments related to GLP-1s, and are excited about the potential benefits this class of drugs could have on society and patients with kidney disease. Like much of the medical community, we're eager to understand the results of the study and whether the results demonstrate improvements over the known effects of SGLT2 inhibitors on kidney disease or the previously announced effects of GLP-1s on cardiovascular mortality.

Although it is nearly impossible to draw any conclusions from the FLOW study at this point because the study results have yet to be released, based on the inclusion criteria for study participants, we believe there may be limited application of the FLOW study findings to the overall CKD patient population.

We will continue monitoring closely as further evidence becomes available to identify the potential benefit of GLP-1s to those afflicted with kidney disease. In the meantime, DaVita remains focused on providing exceptional patient care and advancing the practice of kidney care."

Our understanding of the FLOW clinical trial is the following:

- Patients enrolled in the study were required to have Type 2 diabetes, been diagnosed with CKD, and following a standard of care including ACE inhibitors or ARBs. These patients also needed to demonstrate a requisite amount of proteinuria, i.e., protein in the urine. DaVita estimates that fewer than 10% of all current CKD patients would have this combination of factors.
- The trial sought to demonstrate benefits for the composite endpoint comprised of five separate endpoints: death from kidney disease; death from cardiovascular disease; sustained reduction in GFR by at least 50%; progression to stage 5 CKD; and initiation of chronic kidney replacement therapy. Findings on any single endpoint, or any combination thereof, could be sufficient to halt the trial. It is unknown, however, which endpoint(s) was positive so as to close the study and whether it was a cardiovascular endpoint, a kidney endpoint, or both.

Once released, the detailed results of the FLOW trial will identify which endpoint was proven. If it confirms prior evidence that GLP-1s reduce cardiovascular mortality, since approximately six times more CKD patients die of cardiovascular disease than progress to kidney replacement therapy, any similar findings in the FLOW study would be an additional positive in prolonging life through CKD progression for those taking the therapy.[1] As it relates to CKD progression, if the study proves effective with respect to GFR, it will be interesting to note the efficacy relative to other drugs with similar proven effects such as SGLT2 inhibitors.

- Future trials and research will be required to determine whether any findings derived from the FLOW study could benefit a CKD population beyond those studied in the trial.
- Novo Nordisk's has announced that the FLOW study will be released in the first half of 2024 and the SELECT study will be released on or around November 11, 2023.

About DaVita Inc.
DaVita (NYSE: DVA) is a health care provider focused on transforming care delivery to improve quality of life for patients globally. The company is one of the largest providers of kidney care services in the U.S. and has been a leader in clinical quality and innovation for more than 20 years. DaVita cares for patients at every stage and setting along their kidney health journey—from slowing the progression of kidney disease to helping to support transplantation, from acute hospital care to dialysis at home. As of June 30, 2023, DaVita served approximately 201,000 patients at 2,703 outpatient dialysis centers in the United States. The company also operated 353 outpatient dialysis centers in 11 other countries worldwide. DaVita has reduced hospitalizations, improved mortality, and worked collaboratively to propel the kidney care industry to adopt an equitable and high-quality standard of care for all patients, everywhere. To learn more, visit DaVita.com/About.

Information Concerning the FLOW Study
Statements about the FLOW study are based on publicly available reports from third parties. We have not independently verified the accuracy of this information and such information may be subject to change without notice. These statements involve risks and uncertainties and are subject to change based on various factors, including those discussed under Forward Looking Statements.

Forward Looking Statements
Certain statements in this press release are forward-looking statements that are subject to risks and uncertainties. All statements in this release, other than statements of historical fact, are forward-looking statements. These forward-looking statements could include, among other things, statements about the results of current and future third party clinical trials; the proportion of the CKD population to whom results of the FLOW trial or other clinical trials may apply; and the potential benefits of GLP-1s on individuals with kidney disease, including the potential impacts of such drugs on the development and progression of kidney disease among patients diagnosed with CKD, the onset of dialysis or kidney transplant, and cardiovascular or kidney-related mortality among patients diagnosed with type 2 diabetes and CKD. These forward-looking statements are based on DaVita's current expectations and are based solely on information available as of the date of this press release. DaVita disclaims any obligation to update or revise any forward-looking statement contained in this press release, whether as a result of changed circumstances, new information, future events or otherwise, except as may be otherwise required by law. Actual future events and results could differ materially from any forward-looking statements due to numerous factors that involve substantial known and unknown risks and uncertainties. These risks and uncertainties include, among other things, changes in pharmaceutical practice patterns, including in response to the introduction of new drugs, treatments or technologies; continued increased competition from dialysis providers and others, and other potential marketplace changes, including any decline in the rate of growth of the ESKD patient population, higher mortality rates for dialysis patients or other reductions in demand for dialysis treatments, whether due to the development of innovative technologies, treatments or otherwise; the impact of marketplace conditions on DaVita's revenues and non-acquired growth, treatment volumes, and the CKD population and DaVita's patient population, including on the mortality of these patients; and the other risk factors, trends and uncertainties set forth in our Annual Report on Form 10-K for the year ended December 31, 2022 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, and the risks and uncertainties discussed in any subsequent reports that we file or furnish with the U.S. Securities and Exchange Commission from time to time.

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- Dalrymple, L.S., Katz, R., Kestenbaum, B. et al. Chronic Kidney Disease and the Risk of End-Stage Renal Disease versus Death. J GEN INTERN MED 26, 379–385 (2011). https://doi.org/10.1007/s11606-010-1511-x

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