



Horizon Pharma plc Presents Multiple Retrospective Analyses Showing Kidney Transplant Recipients Have Higher Rates of Gout and Increased Disease Severity

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-- Data presented at the American Society of Nephrology Kidney Week 2018 --

DUBLIN--(BUSINESS WIRE)--Oct. 25, 2018-- Horizon Pharma plc (Nasdaq: HZNP) today announced multiple presentations showing that people who have undergone a kidney transplant experience higher rates of uncontrolled gout compared to other renal disease patients, and mortality rates were higher in kidney transplant recipients diagnosed with gout. In addition, a retrospective analysis indicates that gout prevalence remains high among solid organ transplant patients, independent of the use of cyclosporine as an immunosuppressant. These data will be presented at the American Society of Nephrology (ASN) Kidney Week, Oct. 23-28, in San Diego, Calif.

"The remarkable increase of gout in renal transplant patients is concerning," said Richard J. Johnson, M.D., one of the authors on four ASN analyses discussing solid organ transplant and gout, and professor, Division of Renal Diseases and Hypertension, University of Colorado Denver - Anschutz Medical Campus. "The potential for gout to stimulate inflammatory processes, as well as concern that elevated serum uric acid may have additional effects on blood pressure and kidney function, suggest that this is an important area for further study in the transplant recipient. Treatment of gout in the transplant patient needs more attention."

Gout is a chronic, progressive inflammatory form of arthritis that is caused by excess uric acid in the body, and needs to be managed aggressively.¹ If uric acid levels in the blood remain elevated, thin rod-like crystals can form and deposit in the joints, which can lead to severe pain, tenderness, stiffness, swelling and joint damage. In addition to the joint damage, urate crystals can also deposit in other organs of the body,² and if left unmanaged, gout can lead to significant tissue damage.³ Uncontrolled gout occurs when people living with gout continue to have high levels of uric acid and gout symptoms despite the use of standard oral urate-lowering therapies.

"The increased prevalence of visible tophi among people who have had a kidney transplant, as well as their failure rates on oral medicines, underscore the need for education about the potential for uncontrolled gout among this patient population," said Jeffrey Kent, M.D., senior vice president, medical affairs and outcomes research, Horizon Pharma plc. "The urate burden associated with gout begins before the appearance of visible tophi – in fact, by the time the first gout flare occurs, a patient will have years of urate deposition and urate deposits can cause structural joint damage almost anywhere in the body. It's important that physicians are aware of this increased risk for any patient who has undergone a kidney transplant."

Data Summaries Presented at ASN 2018

Gout Severity in Kidney Transplant Recipients ([abstract #TH-PO159](#))

A retrospective analysis was conducted based on an online survey of 100 board certified U.S. nephrologists who were asked to pull de-identified patient charts for their most recent gout patients. Of 299 total treated patients reported in the survey, 23 had a history of kidney transplant. Compared to patients who did not have a solid organ transplant, those who had been transplanted were more likely to meet criteria for severe uncontrolled gout (25% vs. 7%, $P < 0.05$). Solid organ transplant patients also had higher prevalence of visible tophi and increased rates of failure with standard oral urate-lowering treatments.

Early Evidence of the Association between Gout and Higher Mortality Rates in the Prevalent Solid Organ Transplant Population ([online abstract](#))

Gout prevalence was analyzed among the solid organ transplant population in two administrative claims databases, one Medicare and one commercial. In the Medicare solid organ transplant population, mortality was higher among kidney transplant patients who had gout than those without gout (9.6% vs. 7.1%, $p = 0.013$). In the commercially insured population, mortality was higher among patients with gout for both kidney (3.0% vs. 2.3%, $p = 0.022$) and heart (5.3% vs. 3.2%, $p = 0.045$) transplant recipients. The study authors note that further risk-adjusted studies are warranted to determine whether gout is an independent driver of mortality.

Prevalence of Gout in the Surviving U.S. Solid Organ Transplant Population ([abstract #TH-PO158](#))

Analysis of Medicare and commercial claims database identified gout in 11 percent of the 637,231 U.S. patients who received a primary kidney, liver, heart, or lung transplant from 1988 and 2017. The highest rates of gout were seen in kidney and heart transplant recipients, 13 percent of whom had active gout compared to 1.1 percent of the general population using the same definition for active gout.

Immunosuppressant Use and Gout in the Prevalent Solid Organ Transplant Population ([abstract #TH-PO160](#))

The use of the immunosuppressant cyclosporine is often considered the main cause of gout for patients who have had a solid organ transplant. As most transplantation guidelines and institutions have replaced cyclosporine with tacrolimus, this retrospective patient claims data analysis sought to understand how many solid organ transplant recipients continue to use cyclosporine, and whether this use fully explains high rates of gout in solid organ transplant patients. The study found that, while cyclosporine use has declined and tacrolimus use has increased, gout diagnosis continues to be prevalent even in patients receiving tacrolimus, and that among solid organ transplant patients with gout, cyclosporine was only used in 21.5 percent. In addition, the prevalence of gout was found to be 16 percent among patients receiving cyclosporine and 8 percent for those receiving tacrolimus – both higher than the accepted general population prevalence of 3.9 percent⁴.

- 1 Keuhn, B. Chronic Disease Approaches Needed to Curb Gout's Growing Burden. Journal of the American Medical Association. 2018; 319(13):1308-1309.
- 2 Park J, Roudier M, Soman D, Mokada N, Simin P. Prevalence of birefringent crystals in cardiac and prostatic tissues, an observational study. BJM Open. 2014; 4:e005308. doi:10.1136/bmjopen-2014-005308
- 3 Edwards NL. Treatment-failure gout: a moving target. Arthritis Rheum. 2008;58(9):2587-2590.
- 4 Zhu, Y. Prevalence of Gout and Hyperuricemia in the US General Population. Arthritis and Rheumatism. 2011; 63(10): 3136-3141.

About Horizon Pharma plc

Horizon Pharma plc is focused on researching, developing and commercializing innovative medicines that address unmet treatment needs for rare and rheumatic diseases. By fostering a growing pipeline of medicines in development and exploring all potential uses for currently marketed medicines, we strive to make a powerful difference for patients, their caregivers and physicians. For us, it's personal: by living up to our own potential, we are helping others live up to theirs. For more information, please visit www.horizonpharma.com, follow us [@HZNPplc](https://twitter.com/HZNPplc) on Twitter, like us on [Facebook](#) or explore career opportunities on [LinkedIn](#).

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