Horizon Therapeutics plc Highlights the Systemic Implications of Gout and the Need for Improved Patient Care Strategies with a Series of Presentations at EULAR 2019

June 12, 2019

- Poster presentations raise critical systemic correlations central to optimizing patient care -
- Oral presentation illustrates novel monitoring tool designed to track response to treatment -

DUBLIN--(BUSINESS WIRE)--Jun. 12, 2019-- Horizon Therapeutics plc (Nasdaq: HZNP) is elevating the dialogue on gout within the medical and scientific community during the Annual European Congress of Rheumatology (EULAR 2019) with a series of data presentations on gout and its systemic implications. Oral and poster presentations reinforce the increasingly robust evidence linking gout to renal and cardiovascular health risks and raise important clinical considerations in monitoring and tracking patient status beyond joint health over time.

"Across a number of independent evaluations, we're finding important links between gout and other organ system diseases," said Jeffrey Kent, M.D., senior vice president, medical affairs and outcomes research, Horizon. "Gout is a complex, multi-system disease that should be treated with rigor to manage both the arthritis components as well as other important comorbidities over time. Our work represents a growing dialogue that calls for a more focused approach to managing this chronic disease, including improved monitoring efforts that can inform the use of novel therapeutic solutions to better manage the disease."

Evidence reinforces correlation of gout to kidney and cardiovascular disease

A series of poster presentations illustrate the true burden of gout in the U.S. population, with recent statistics linking gout to a heightened risk of both cardiovascular and renal disease. The body of evidence reinforces the need for greater consideration of gout diagnosis and management, particularly among patients with kidney disease, to optimize treatment strategies for both diseases.

- **Significantly higher rates of hospitalizations among gout patients for cardiac or acute renal events**

  Previous research indicated a significant increase in all-cause hospitalizations among patients with gout, far exceeding trends in hospitalization rates among the general population. Now, a broad hospital database analysis found significant differences in the events requiring hospitalization among this population as compared with the general population, including "hypertensive complications and secondary hypertension" (4.0% vs. 1.7%, respectively) and acute renal failure (4.5% vs. 2.1%, respectively). *Gout in the US: Significant Associations with Cardiovascular and Renal Disease Hospitalizations (SAT0446)*

- **Diagnosis of gout prior to and following kidney transplantation may be linked to mortality**

  A retrospective review of data from more than 6,000 people who have had a kidney transplant showed an important connection about the onset of gout before and after transplantation. The analysis found that in total, one-fourth of the renal transplant population had a diagnosis of gout: 15 percent prior to the transplant and another 10 percent who developed gout following the transplant. *Analysis of the Prevalence and Timing of Gout Co-Morbidity in Patients Undergoing Kidney Transplant (SAT0428)*

  Evidence linking kidney transplantation and gout diagnosis thus raises the question of whether gout may contribute to increased mortality among renal transplant patients. A retrospective study among Medicare patients with a history of kidney transplant found that gout may serve as an early indicator of declining health, warranting additional research to improve identification and intervention strategies. *Impact of Gout on All-Cause Mortality Among Medicare Beneficiaries with a History of Kidney Transplantation: A Retrospective Cohort Study (SAT0430)*

- **Marked increase in comorbidities among uncontrolled gout patients compared with controlled patients**

  A large analysis of more than 6,500 gout patients finds important differences between gout patients who are well controlled and those whose disease remains uncontrolled as defined by sUA levels above 6 mg/dL. This analysis compared gout patients with sUA levels <6 mg/dL to those with sUA levels >8 mg/dL. Specifically, patients who have not achieved their treatment goals with respect to lowering uric acid have:
  - A higher prevalence of chronic kidney disease (49.4% vs. 32.4%, respectively)
  - Higher rates of hospitalizations for congestive heart failure (20.0% vs. 7.0%, respectively)
  - More frequent hospitalizations due to acute kidney failure (20.0% vs. 8.0%, respectively)

  *Comorbidities in an Early Diagnosed Cohort of Uncontrolled versus Controlled Gout: Analysis of a Large Payer Database (SAT0429)*
Composite measure captures multi-variable changes in disease status

The complex pathology of gout, with its wide range of signs and symptoms, complicates physicians’ ability to assess effectiveness of therapy. Most assessments evaluate change in serum urate and rates of flares, but composite measures may more accurately reflect a patient’s status, particularly among those with uncontrolled gout. Now, a newly designed gout composite measure, the multivariable improvement measure (GMIM) captures a broader spectrum of gout manifestations and trends over the course of treatment, focusing on those that best correlate with time to maximum treatment benefit. This includes not only serum urate, absence of tophi and flares, and level of pain, but also swollen or tender joints. This measurement approach assesses the degree of improvement associated with treatment, scoring based on a 20, 50, or 70 percent improvement in at least four of the six clinical evaluations. Evaluation of the GMIM indicates sensitivity to changes in disease severity and an ability to distinguish persistent versus transient response to therapy. As such, the GMIM may serve as a compelling, evidence-based tool to assess response to therapy either during clinical trials or in the course of medical practice. Development of a Multivariable Improvement Measure for Gout (OP0051, June 12, 16:15)

About Horizon

Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, please visit www.horizontherapeutics.com, follow us @HorizonNews on Twitter, like us on Facebook or explore career opportunities on LinkedIn.

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