VERINURAD WITH FEBUXOSTAT SIGNIFICANTLY REDUCE ALBUMINURIA AND HYPERURICÄEMIA IN PATIENTS WITH TYPE II DIABETES IN PHASE II A TRIAL

Intensive urate-lowering strategy may protect against the progression of diabetic kidney disease.

Madrid, Spain, 13 June 2019: The results of a phase IIa clinical trial presented today at the Annual European Congress of Rheumatology (EULAR 2019) demonstrate a rapid reduction in albuminuria and hyperuricäemia in patients with type II diabetes with combined treatment of verinurad and febuxostat.

The primary endpoint of the study was met; results reveal a 39% reduction in urinary albumin-to-creatinine ratio (UACR) after 12 weeks with combined treatment of verinurad 9mg and febuxostat 80mg versus placebo (p=0.07). The study also shows a 57% reduction in serum urate (sUA) in the treatment group versus a 7% increase in the placebo group (p<0.0001) at 12 weeks. This effect was sustained at 24 weeks with a 62% reduction versus a 5% increase (p<0.0001). The effect on sUA was likely underestimated due to sample collection scheduling. The study also measured estimated glomerular filtration rate (eGFR) but the changes were insignificant.

“Although these are early clinical findings in a limited group of patients, our results show that combined treatment with verinurad and febuxostat in patients with diabetes results in a rapid reduction in hyperuricäemia and albuminuria sustained through week 24,” said Robert Terkeltaub, MD, Professor of Medicine, University of California San Diego, USA. “Further studies are planned to confirm the efficacy of urate lowering strategies combining verinurad and xanthine oxidase inhibitors in slowing progression of chronic kidney disease.”

Verinurad is an inhibitor of the uric acid transporter (URAT1) and is currently under investigation for the treatment of hyperuricäemia and kidney disease. Febuxostat is a potent, selective xanthine oxidase inhibitor used to lower urate levels in patients with gout and hyperuricäemia. It is recommended in patients who do not reach target on, or are intolerant to, allopurinol. It is often used in patients with renal impairment since it is primarily metabolised in the liver.

“We welcome these positive results and look forward to the future clinical development of this novel urate-lowering treatment strategy, particularly in patients with hyperuricäemia and kidney disease,” said Professor Hans Bijlsma, President, EULAR.

The trial included 60 patients with type II diabetes who had a sUA of 6.0mg/dL or above, eGFR of 30mL/min/1.73m² or above, and UACR of 30-3500 mg/g. Patients were randomised to receive either verinurad 9mg and febuxostat 80mg (treatment group) or placebo. Patients were excluded if they had a history of gout or recent treatment with urate-lowering therapy which avoided the need to administer gout prophylaxis. Most adverse events were mild to moderate,
those reported in more than one patient in the treatment group were diarrhoea, dizziness and nasopharyngitis, and only one gout flare-up was reported (in the treatment group).¹

Abstract number: OP0207

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NOTES TO EDITORS
For further information on this study, or to request an interview with the study lead, please do not hesitate to contact the EULAR Press Office:

Email: eularpressoffice@ruderfinn.co.uk
Telephone: +44 (0) 20 7438 3084
Twitter: @EULAR_Press
YouTube: Eular Press Office

About Rheumatic and Musculoskeletal Diseases
Rheumatic and musculoskeletal diseases (RMDs) are a diverse group of diseases that commonly affect the joints but can affect any organ of the body. There are more than 200 different RMDs, affecting both children and adults. They are usually caused by problems of the immune system, inflammation, infections or gradual deterioration of joints, muscle and bones. Many of these diseases are long term and worsen over time. They are typically painful and limit function. In severe cases, RMDs can result in significant disability, having a major impact on both quality of life and life expectancy.³

About 'Don't Delay, Connect Today!'
'Don't Delay, Connect Today!' is a EULAR initiative that unites the voices of its three pillars, patient (PARE) organisations, scientific member societies and health professional associations - as well as its international network - with the goal of highlighting the importance of early diagnosis and access to treatment. In the European Union alone, over 120 million people are currently living with a rheumatic disease (RMD), with many cases undetected.⁴ The ‘Don't Delay, Connect Today!’ campaign aims to highlight that early diagnosis of RMDs and access to treatment can prevent further damage, and also reduce the burden on individual life and society as a whole.

About EULAR
The European League against Rheumatism (EULAR) is the European umbrella organisation representing scientific societies, health professional associations and organisations for people with RMDs. EULAR aims to reduce the burden of RMDs on individuals and society and to improve the treatment, prevention and rehabilitation of RMDs. To this end, EULAR fosters excellence in education and research in the field of rheumatology. It promotes the translation of research advances into daily care and fights for the recognition of the needs of people with RMDs by the EU institutions through advocacy action.

To find out more about the activities of EULAR, visit: www.eular.org
References


3 van der Heijde D, Daikh DI, Betteridge N, *et al.* Common language description of the term rheumatic and musculoskeletal diseases (RMDs) for use in communication with the lay public, healthcare providers and other stakeholders endorsed by the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR). *Ann Rheum Dis.* 2018 Jun;77(6):829-832.

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