# Clinical Trials Data EGFR - Document 34

# AURA-LV: Aurinia Urinary Protein Reduction Active - Lupus With Voclosporin (AURA-LV)

## Clinical Trial: https://clinicaltrials.gov/study/NCT02141672

"eligibilityCriteria": "Inclusion Criteria:\n\nMale or female subjects aged 18 to 75 years.\n\nDiagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology criteria.\n\nKidney biopsy within 6 months prior to Screening (Visit 1) with a histologic diagnosis of lupus nephritis (International Society of Nephrology/Renal Pathology Society 2003 classification of lupus nephritis) Classes III, IV-S or IV-G, (A) or (A/C); or Class V, alone or in combination with Class III or IV.\n\nLaboratory evidence of active nephritis at screening, defined as:\n\n\* Class III, IV-S or IV-G: Confirmed proteinuria \u22651,500 mg/24 hours when assessed by 24 hour urine collection, defined by a UPCR of \u22651.5 mg/mg assessed in a first morning void urine specimen (2 samples).\n\* Class V (alone or in combination with Class III or IV): Confirmed proteinuria \u22652,000 mg/24 hours when assessed by 24 hour urine collection, defined by a UPCR of \u22652 mg/mg assessed in a first morning void urine specimen (2 samples).\n\nExclusion Criteria:\n\nEstimated glomerular filtration rate (eGFR) as calculated by the Chronic Kidney Disease Epidemiology Collaboration equation of \u226445 mL/min/1.73 m2.\n\nCurrently requiring renal dialysis (hemodialysis or peritoneal dialysis) or expected to require dialysis during the study period.\n\nA previous kidney transplant or planned transplant within study treatment period.\n\nIn the opinion of the Investigator, subject does not require long-term immunosuppressive treatment (in addition to corticosteroids).\n\nCurrent or medical history of:\n\n\* Pancreatitis or gastrointestinal hemorrhage within 6 months prior to screening.\n\* Active unhealed peptic ulcer within 3 months prior to screening. If an ulcer has healed and the subject is on adequate therapy, the subject may be randomized.\n\* Congenital or acquired immunodeficiency.\n\* Clinically significant drug or alcohol abuse 2 years prior to screening.\n\* Malignancy within 5 years of screening, with the exception of basal and squamous cell carcinomas treated by complete excision. Subjects with cervical dysplasia that is cervical intraepithelial neoplasia 1, but have been treated with conization or loop electrosurgical excision procedure, and have had a normal repeat PAP are allowed.\n\* Lymphoproliferative disease or previous total lymphoid irradiation.\n\* Severe viral infection (such as CMV, HBV, HCV) within 3 months of screening; or known human immunodeficiency virus infection.\n\* Active tuberculosis (TB), or known history of TB/evidence of old TB if not taking prophylaxis with isoniazid.\n\nOther known clinically significant active medical conditions, such as:\n\n\* Severe cardiovascular disease including congestive heart failure, history of cardiac dysrhythmia or congenital long QT syndrome.\n\* Liver dysfunction (aspartate aminotransferase, alanine aminotransferase, or bilirubin greater than 2.5 times the upper limit of normal) at screening and confirmed before randomization.\n\* Chronic obstructive pulmonary disease or asthma requiring oral steroids.\n\* Bone marrow insufficiency unrelated to active SLE (according to Investigator judgment) with white blood cell count \\<2,500/mm3; absolute neutrophil count \\<1.3 x 103/\u03bcL; thrombocytopenia (platelet count \\<50,000/mm3).\n\* Active bleeding disorders.\n\* Current infection requiring IV antibiotics.\n\nAny overlapping autoimmune condition for which the condition or the treatment of the condition may affect the study assessments or outcomes. Overlapping conditions for which the condition or treatment is not expected to affect assessments or outcomes are not excluded.\n\nSubjects who are pregnant, breast feeding or, if of childbearing potential, not using adequate contraceptive precautions.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
This trial is specifically for Systemic Lupus Erythematosus (SLE) with active lupus nephritis. The eligibility criteria do \*\*not\*\* mention anything about EGFR gene mutations. Therefore, having an EGFR mutation does \*not\* automatically exclude a patient, but they would still need to meet \*all\* other inclusion criteria and \*not\* meet any of the exclusion criteria to be eligible.