# The Pediatric Lupus Nephritis Mycophenolate Mofetil (PLUMM) Study

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 8 years to 20 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion

1. Male or female aged 8 to < 21 years;
2. Must meet Classification Criteria for SLE as per the criteria of the American College of Rheumatology (ACR)/ European League Against Rheumatism
3. Diagnosed with proliferative LN as per the International Society of Nephrology/Renal Pathology Society4 based on kidney biopsy done within 90 days prior to enrollment into the study;

Subjects may have been previously diagnosed with LN. For study inclusion, the kidney biopsy must be interpreted as one of the following classes: Class 3, Class 3/5, Class 4, or Class 4/5.
4. Treatment of LN with twice daily MMF as per the decision of the treating physician.

The subject will have taken MMF as prescribed by their treating physician for a minimum of 4 days (or 8 doses).
5. Subject tolerates MMF as per the treating physician's opinion;
6. Able to swallow MMF tablets and capsules;
7. If subject is treated with belimumab, must be IV or SQ;
8. Subjects who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures;
9. Evidence of a personally signed and dated Informed Consent document and Assent document (as appropriate) indicating that the subject and a legally acceptable representative/ parent(s)/legal guardian has been informed of all pertinent aspects of the study.
10. Parent or legal guardian must have a smart phone available and able to support the PLUMM smart phone application.
11. Must be able to complete study questionnaires in English or Spanish.

Exclusion Criteria:

1. Perceived or stated inability to adhere to the study protocol;
2. Hypersensitivity to MMF or any component of the drug product;
3. Presence of features (from SLE or other chronic disease) that a-priori suggest that the subject benefits from other therapies than that suggested or allowable by the study protocol; These disease features include but are not limited to severe, progressive, or uncontrolled hepatic, hematologic, gastrointestinal, metabolic, endocrine, pulmonary, cardiac or neurologic disease.
4. History of other kidney disease besides LN or prior to the diagnosis of SLE;
5. Need for renal replacement therapy within 2 weeks from Baseline Subjects can have required short-term renal replacement therapy prior to Baseline, for example due to preceding acute kidney injury.
6. Infections:
    1. Untreated latent or active tuberculosis (TB);
    2. Chronic infections requiring treatment;
    3. A subject known to be infected with Human Immunodeficiency Virus (HIV), Hepatitis B;
    4. Diagnosis of any infection requiring hospitalization, parenteral antimicrobial therapy or judged to be opportunistic by the investigator within 4 weeks prior to Baseline visit;
    5. Any treated infections within 2 weeks of Baseline visit;
    6. History of infected joint prosthesis with prosthesis still in situ;
7. Blood dyscrasias, including:
    1. Hemoglobin <8.5 g/dL or Hematocrit <22%;
    2. White Blood Cell count <2.6 x 109/L;
    3. Neutrophil count <1.2 x 109/L;
    4. Platelet count <100 x 109/L;
    5. Lymphocyte count <0.5 x 109/L.
8. 8) Estimated glomerular filtration rate [GFR] <40 mL/min/1.73 m2 calculated using the CKiD U25 equation (see Appendix 4);
9. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >1.5 times the upper limit of normal;
10. Vaccinated or exposed to a live or attenuated vaccine within the 4 weeks prior to Baseline visit;
11. History or current symptoms suggestive of lymphoproliferative disorders (e.g., Epstein Barr Virus [EBV] related lymphoproliferative disorder, lymphoma, leukemia, myeloproliferative disorders, or multiple myeloma);
12. Current malignancy or history of any malignancy with the exception of adequate treated or excised basal cell or squamous cell or cervical cancer in situ;
13. Recent (within 4 weeks prior to Baseline visit) significant trauma or major surgery;

14. Herbal supplements with pharmaceutical properties must be discontinued at least 1week prior to Baseline visit, unless there are sufficient data available regarding the duration of an herbal medication's pharmacokinetic and pharmacodynamic effects to allow a shorter or longer washout to be specified (e.g., 5 half-lives).
15. Oral or intravenous cyclophosphamide must be discontinued 12 weeks prior to Baseline visit
16. Use of prohibited prescription medication as listed in Appendix 3 within the specified time frame prior to Baseline visit
17. Participation in other studies involving investigational drug(s) within 4 weeks or 5 half-lives (whichever is longer) prior to Baseline visit and/or during study participation; Exposure to investigational biologics should be discussed with the Sponsor.
18. Pregnant female subjects; breastfeeding female subjects; male subjects with partners currently pregnant; male subjects able to father children and female subjects of childbearing potential who are unwilling or unable to use two highly effective methods of contraception or are abstinent for the duration of the study;
19. Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.

## Conditions & Interventions

Interventions:
DRUG: Mycophenolate Mofetil, DRUG: Mycophenolate Mofetil
Conditions:
Lupus Nephritis

## More Information

Description:
The study is a 1-year 2-part double-blinded placebo controlled 2-arm clinical trial. Treatment arms are (1) MMF dosed as per body-surface area (MMFBSA; 600mg/m2 body surface area per dose about every 12 hours) and (2) pharmacokinetically-guided precision-dosing of MMF (MMFPK; MMF dosed twice daily to achieve an area under the concentration-time curve (AUC0-12h) of MPA \>60-70 mg*h/L. The study goal is to determine the safety and efficacy of MMFPK compared to MMFBSA for the treatment of proliferative LN in subjects 8 to \<21 years.

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