Lupus Nephritis Trials Network

Membership Meeting Washington DC, November 14, 2012

Executive Summary

Main Goals for the Meeting

- 1. Update on progress since our last meeting at EULAR in June
- 2. Presentation and discussion of the first six concept proposals that have been submitted for consideration by members of LNTN.
- 3. Introduction of Patti Tosta, who will begin work on January 1, 2013 as the Executive Director of the LNTN
- 4. Discussion of next steps

Attendees

Attendance at the meeting was compromised by two factors: (1) most of our nephrologist members do not attend the ACR meeting; and (2) there was a conflicting meeting on lupus biomarkers that involved participation by many of our members. Nonetheless, there was a reasonable representation of rheumatologists from Europe, from North, Central and South America, and from Asia, as well as a few nephrologists and pediatric rheumatologists. The attendance was more than sufficient to support lively discussion of LNTN procedures and the six concept proposals. Although few nephrologists were present for this meeting, Brad Rovin had been able to present an LNTN progress report to our nephrology colleagues at the ASN meeting one week earlier.

Brief Summary

- 1. <u>Interim Report</u>: There has been major progress over the past five months.
 - a) <u>Start-Up Funding:</u> Generous contributions have been forthcoming from numerous sources to help jump start the LNTN. The ACR provided the facilities for our meeting as well as outstanding and substantial staff support over many months to coordinate the process of submitting and evaluating concept proposals. The Lupus Research Institute (LRI), the Lupus Foundation of America (LFA) and the Alliance for Lupus Research (ALR) have all made meaningful contributions.
 - b) Staff: As a result of the contributions we have received, we have been able to hire an Executive Director who will begin work on January 1. Patti Tosta is ideally suited for this role. Many members of LNTN have worked closely with Ms. Tosta in her capacity as Associate Director of the Immune Tolerance Network (ITN). In that role, Patti has been responsible for guiding protocol development and then overseeing the conduct of large-scale, international, investigator-initiated trials. She will continue to devote 80% of her time to ITN trials, while devoting 20% time to providing the same talent, experience, and expertise to LNTN.

- c) Submission and Review of Concept Proposals; In response to a request for proposals that followed our meeting at EULAR, LNTN received six concept proposals. These proposals were reviewed by members of the Project Review Committee, who then returned suggestions to each of the investigators. The second step in the process of project development was the presentation of the concepts to the membership meeting (see below), after which the investigators will now revise and expand their proposals for distribution to the entire membership.
- 2. <u>Concept Proposals</u>: The following concept proposals were presented and discussed at the meeting:

<u>Title</u>: Maintenance Lupus Nephritis Treatment with Azathioprine Guided Escalation Dosing

Presenter: Eloisa Bonfa (on behalf of her colleagues)

<u>Title</u>: Rituximab in Lupus Nephritis with Remission as a Goal Presenter: Frédéric Houssiau (on behalf of his colleagues)

<u>Title</u>: Rituxilup Trial: An Open Label Randomized Multicentre Controlled Phase III Trial of Rituximab and Mycophenolate Mofetil (MMF) Without Oral Steroids for the Treatment of Lupus Nephritis

Presenter: Ian Bruce (on behalf of Liz Lightstone and colleagues)

Title: Outcome Measures in Lupus Nephritis

Presenter: Meggan Mackay (on behalf of her colleagues)

Title: Thrombotic Microangiopathy (TMA) in Lupus Nephritis

Presenter: Kyriakos Kirou

<u>Title</u>: Rituximab Plus Cyclophosphamide Followed by Belimumab for the Treatment

of Lupus Nephritis

<u>Presenter</u>: Betty Diamond (on behalf of colleagues)

Next Steps and Timeline

- Concept proposals will be expanded to full proposals by November 30
- The full proposals will be packaged by the Executive Committee (primarily for uniformity and clarity) and then distributed to LNTN members for comment in January.
- LNTN members will have an opportunity to convey a level of enthusiasm for each project and express their interest in participating in one or more of the projects. We anticipate that this process will be complete by the end of February.

- Once it has been determined that there is sufficient enthusiasm and commitment from members of the network to participate in the project, and there are sufficient resources to support it, a project development team will be assembled consisting of the key investigators, Patti Tosta, a member of the Executive Committee and, if necessary, other individuals who may be required to bring specialized expertise to the group.
- After the New Year, we will establish a system of communications that will include quarterly newsletters and a user-friendly website.
- It is our hope that some of our projects will lead to publications relatively quickly. With this in mind, we will soon be looking for volunteers to serve on a Publication Committee that will review our draft publication policy (distributed previously) and discuss standard operating procedures.

Summary prepared by:

David Wofsy (on behalf the LNTN Executive Committees)