Screen to Lead Program (SLP)

INTRODUCTION

The Leukemia & Lymphoma Society (LLS) is sponsoring and issuing this Request for Applications (RFA) from qualified academic laboratories for drug discovery support specifically directed towards medicinal chemistry and/or drug target screening in hematological malignancies. LLS recognizes a significant need for investigators to receive resources for high-throughput screening and optimization of small molecules into drug-like compounds suitable for *in vivo* testing in a disease-relevant model that can be used for further preclinical proof-of-concept testing of the new drug target. Last year, the first year of this new funding mechanism, 6 projects were chosen for funding by an acclaimed peer review panel. This year, new laboratories/projects will be selected to participate in this model of collaboration whereby LLS, grantee, sponsoring institution and appropriate contract service organizations (CROs) or core facilities at academic institutions work together to develop compounds with the potential to change the standard of care for patients with blood cancer. Continued funding/sponsorship will be contingent on available funds and assessments of progress toward the goals outlined in each individual proposal accepted by LLS.

OBJECTIVES

The goal of this RFA is the development of small molecule for *in vivo* proof of concept studies in disease relevant animal models for hematological malignancies. Proposals should include strong scientific rationale for a new drug target in a hematological malignancy; provide information to assess existing intellectual property or the potential for novel chemical space; demonstrate or explain how a screening assay can be developed to accommodate a high volume of compounds; or indicate how a tractable lead compound can be further developed.

ELIGIBILITY

Investigators at academic laboratories are eligible to apply. Investigators must demonstrate that their research environment is equipped and suitable for aspects of the work plan that would be carried out at their facility or in their lab rather than at a CRO. Collaborations between multiple investigators to strengthen the work proposed will be considered favorably, but are not a requirement. Applicants need not be United States (U.S.) citizens nor associated with a U.S.-based institution. Applicants should hold a Ph.D., M.D., D.V.M. or equivalent degree.

APPLICATION and AWARD INFORMATION

LLS plans to sponsor several awards during this year of this program. It is anticipated that each project will be unique and the cost of each work plan variable, depending on the nature of the work required. For this reason, applicants will need to submit a proposed work plan (subject to modification by LLS and collaborators upon review) and a proposed budget with justification for its relationship to the work plan. These factors will be evaluated as part of the peer review application process. As collaborators in CROs or core facilities may conduct the greater portion of the work, LLS will coordinate the appropriate contracting for services according to the work plan. LLS will work with applicants to determine where the work should be conducted and help to manage the process. For any budgeted line items that are specifically related to the PI, for work conducted in their laboratory, indirect costs will be capped at 11.1%. Any new intellectual property created through this collaboration shall be owned and managed by the academic institution. LLS and CRO's subcontractors shall assign all ownership rights to the institution. LLS will put in place, as it does with all its grants, an IP policy that must be executed by the researcher and researcher's academic institution at the time the application is submitted.

Applicants should include the following in their application:

- Scientific rationale for novel target in hematologic malignancies and summary of supportive data;
- Characterization of existing compounds, where appropriate;
- A summary of the intellectual property landscape (to the best of knowledge) on the target/chemical space;
- Description of unmet medical need, i.e., what therapeutic deficiency will this new drug target address; and
- Capabilities of support from laboratory (i.e., describing the level of throughput for assays applicants propose to run in their laboratories)

APPLICATION FORMAT and SUBMISSION

Application templates are web-based and may be obtained on our website at: http://lls.fluxx.io under Screen to Lead Program. Applications are restricted to the capacity of the web forms. The form for budgets allows multi-year entries but only the first year is considered for this award. Please include only costs associated with your institution. Any CRO costs, if needed, will be determined by LLS and added to your budget. If you have had prior discussions with a CRO and have a budget estimate, you are welcome to upload this under the appropriate section but no other supporting documentation is allowed except the signed IP policy which is part of the RFA and must be included with your application.

The cut off for the receipt of applications is on the following date/time schedule:

Call for Proposals:	~September 15, 2013
Deadline:	December 15, 2013, 3:00 p.m., ET
Scientific Peer Review Committee:	April 2014
Notification of Awards:	May 30, 2014
Anticipated Funding Start Date:	October 2014

DESCRIPTION of PEER REVIEW PROCESS

Each application will undergo a thorough review that consists of two parts. There will be an internal review by LLS Research staff for compliance with guidelines, eligibility, and responsiveness of the project to the RFA. The internal review may involve additional requests for more detailed information on the project and direct discussions between the PI and LLS Research staff regarding the proposal to assess the appropriateness of the project.

There will be a second review hosted by LLS that is a more extensive external peer review by experts in drug discovery and development, medicinal chemistry, and hematological malignancies.

The application will be assessed upon the following criteria:

Scientific Rationale and Supportive Data

Unmet Medical Need/Scientific Impact

Research Plan & Feasibility

Resources & Qualifications of the PI

ATTACHMENT A

THE LEUKEMIA & LYMPHOMA SOCIETY'S PATENT AND INTELLECTUAL PROPERTY AGREEMENT SPECIFIC TO AWARDEES OF MEDICINAL CHEMISTRY GRANTS THROUGH THE REQUEST FOR APPLICATIONS

Each applicant (PI) and institution applying for funds through this Screen to Lead RFP will be required to sign this attached form noting their understanding and acceptance of the IP terms *before* the proposal will be considered for review.

The Leukemia & Lymphoma Society's ("LLS") primary purpose in funding scientifically meritorious research is to advance its mission to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and to improve the quality of life of patients and their families. In this regard, LLS recognizes that certain Inventions (defined below), potentially having public health, scientific, business, or commercial application or value, may be discovered or made in the course of research or development supported with funds furnished by LLS. LLS desires that such Inventions be effectuated and brought into public use at the earliest possible time, and it recognizes that often this may be best accomplished through patenting and/or licensing of such Inventions.

Each Grantee and their corresponding Sponsoring Institution awarded through LLS's Medicinal Chemistry Request for Applications agrees to the following provisions regarding patent and intellectual property rights and licenses resulting from research conducted by Grantee, contract research organizations and external experts involved in the Medicinal Chemistry Award whether funded in whole or in part by LLS.

This Patent and Intellectual Property Agreement ("IP Agreement") forms part of the accompanying Grant Agreement between LLS, the Grantee and Sponsoring Institution. Although intended to be consistent with the Grant Agreement, the terms of this IP Agreement supersede any conflicting terms of the Grant Agreement, to the extent any conflicting terms exist.

1. The following terms have the meanings set forth below:

    a. "**Funded Invention"** shall mean any Invention conceived, made, validated, developed and/or reduced to practice, in whole or in part, by Grantee, resulting directly or indirectly from, research or development funded in whole or in part by this LLS grant

that may result in a patent or patent application, additional claims for an existing patent or patent application, or patent rights.

b. **"Grantee"** shall mean as applicable to a particular award the PI and Sponsoring Institution.

c. "**Invention"** shall mean any discovery, idea, formula, material, composition, machine, product, apparatus, program, software, work of authorship, use, method, process, or improvement thereof, which is potentially protectable by intellectual property rights, and all intellectual property covering and/or embodied therein including but not limited to associated patents, copyrights, trade secrets, and know-how.

d. "**Revenues"** shall mean any and all receipts and consideration, including any upfront payments, milestone payments, royalties, equity and in-kind payments resulting from but not limited to the licensing, assignment, or optioning of rights to a Funded Invention, less fifteen percent (15%) of such revenues for administrative overhead (the "Administrative Fee"); provided that, the Administrative Fee shall not exceed fifteen thousand dollars ($15,000) in the aggregate.

2. Prior to any work beginning on the Medicinal Chemistry Award, LLS agrees to have any external experts and CROs with whom LLS contracts, assign all and any IP rights to the Grantee/Sponsoring Institution to which such work relates.

3. Title to, and responsibilities for, any Funded Invention, including patent applications and maintenance of intellectual property rights and rights to license Funded Inventions, shall reside in the Sponsoring Institution, unless it requests that LLS assume such responsibilities. All patent and other expenses for obtaining and maintaining rights to intellectual property covering and/or embodied in any Funded Invention shall be borne by the Sponsoring Institution. Should Sponsoring Institution solely decide not to pursue intellectual property protection for a Funded Invention, it shall notify LLS at least ninety (90) days before the deadline for seeking such protection and provide LLS with the opportunity to pursue intellectual property protection on such invention. Sponsoring Institution agrees that if it is to accept the Award through the Medicinal Chemistry

Request for Applications, Institution acknowledges the Institution's waiving of it own Intellectual Property policy in lieu of LLS's policy attached herein. In the event Sponsoring Institution lacks a policy or procedure that requires assignment of ownership by Grantee to Sponsoring Institution of any Funded Invention, then title to any Funded Invention shall automatically reside in LLS. In the event, this is the case, Sponsoring Institution shall confirm this to LLS in writing within ten (10) days of this Award and cooperate with LLS in establishing such rights.

4. Sponsoring Institution agrees to notify LLS in writing of the filing of all patent applications and all issuances to it of any and all patent(s) directed to a Funded Invention within thirty (30) days following such application and issuance. This obligation shall continue throughout the term of this IP Agreement and no less than ten (10) business days before any patent application for a Funded Invention is filed by Sponsoring Institution, it agrees to confirm to LLS and other partners to the Medicinal Chemistry Award the names of all inventors to be listed on any patent application. LLS will provide any proposed changes to the names of inventors within five (5) business days.

5. Sponsoring Institution also agrees to notify LLS in writing thirty (30) days prior to any license, lease, sale, or assignment of a Funded Invention (collectively an "Assignment"), and to provide LLS with the name of any assignee, the subject matter of the assignment and in the case of a license, the terms of the license, and whether such license is exclusive or non-exclusive. Sponsoring Institution agrees that until such time an LLS Funded Invention is exclusively licensed or designed, and subject to completing intellectual property protection, it shall be made available to other researchers and LLS for non-commercial research purposes only as a non-exclusive, royalty-free, technology transfer, should a request be made to use the invention for research purposes.

6. No pending patent application, issued patent, or other intellectual property covering and/or embodied in the Funded Invention shall be abandoned without first notifying LLS at least thirty (30) days in advance of such decision. At such time, Sponsoring Institution shall provide LLS with the reasonable opportunity to pursue IP protection and to be

assigned such patent or patent application. This opportunity shall be subject to the Grantee's obligations to all other sponsors of research, including the Federal Government.

7. Sponsoring Institution shall pay to LLS a share of Revenues derived by Sponsoring Institution from any Funded Invention, as follows:

   a. Twenty-five percent (25%) of all Revenues.

   b. LLS shall have the right to have a third party CPA audit the books and records of Sponsoring Institution, no more than once per year during the term of this IP Agreement, in order to verify the Revenues derived annually from the Funded Invention. Sponsoring Institution shall make the relevant books and records available to LLS within thirty (30) days of such request from LLS.

   c. If the parties are unable to agree on the amount of Revenues payable to LLS pursuant to this paragraph, the dispute shall be resolved as follows:

      (i) One of the parties shall request ("the Resolution Request") that each of the parties appoint a designated executive management representative to meet for the purpose of attempting to resolve such dispute. The parties' designated executive management representatives shall meet and negotiate in good faith in an effort to resolve the dispute.

      (ii) If the parties' designated executive management representatives are unable to resolve the dispute within thirty (30) days after the Resolution Request is made, the parties shall engage in a mediation with a mutually acceptable mediator.

      (iii) If the mediation does not resolve the dispute within sixty (60) days (unless this time is extended by written agreement of the parties) after the Resolution Request is made, the dispute shall be settled by appropriate legal remedy.

8. Sponsoring Institution agrees to exert its best efforts to commercialize, license or cause to be commercialized the Funded Invention(s), consistent with sound and reasonable business practices and judgment.

9. In the event Sponsoring Institution assigns a Funded Invention to a third party for commercialization, Sponsoring Institution shall include in the Assignment a requirement obligating the licensee to diligently pursue commercialization of the Funded Invention and requirements for the Sponsoring Institution to receive progress reports at least annually, which report promptly shall be disclosed to LLS after they are received by Sponsoring Institution. The agreement shall also provide that in the event that the assignee has failed to commercialize the technology in accordance with such diligence provisions, Sponsoring Institution shall have the right to a) require assignment back (if previously assigned) of any Funded Invention to Sponsoring Institution, b) terminate any outstanding licenses, c) convert an exclusive license to a non-exclusive license so that Sponsoring Institution may seek other licensees, d) grant non-exclusive licenses on terms that are reasonable under the circumstances, or e) make other reasonable disposition of rights.

10. Grantee agrees to complete all required disclosure and progress forms supplied by LLS as set forth in the underlying Grant Agreement.

11. The Term of this IP Agreement begins as of the Effective Date (i.e., the date payment for the accompanying Grant commences) and continues until or for so long as Sponsoring Institution has paid to LLS its full share of all Revenues from any Funded Invention.

_____
Investigator Name and Degree

_____
Investigator Title

_____
Date

_____
Institutional Technology Official

_____
Institutional Title

_____
Date