

SUMMARY STATEMENT

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(Privileged Communication)

Release Date: 11/28/2016
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Application Number: 2 R44 AI115877-02

Principal Investigator
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Applicant Organization: THERAPYX, INC.

Review Group: ZRG1 IMM-R (12)
Center for Scientific Review Special Emphasis Panel
Small Business: Non-HIV Microbial Vaccines

Meeting Date: 11/04/2016
Council: JAN 2017
Requested Start: 01/01/2017

RFA/PA: PA16-302
PCC: M37A

Dual IC(s): HD, DK

Project Title: Experimental Gonococcal Vaccine

SRG Action: Impact Score:18
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Project Year	Direct Costs Requested	Estimated Total Cost
2	[REDACTED]	[REDACTED]
3	[REDACTED]	[REDACTED]
<hr/> TOTAL	<hr/> [REDACTED]	<hr/> [REDACTED]

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

Time has passed since the application was reviewed. This sample may not reflect the latest format for summary statements. NIAID posts new samples periodically: <https://www.niaid.nih.gov/grants-contracts/sample-applications>

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2R44AI115877-02 LIU, YINGRU**REVISED 11/28/16****ADMINISTRATIVE NOTE**

RESUME AND SUMMARY OF DISCUSSION: This well-written Phase II SBIR, working to create a novel nanoparticle vaccine combining IL-12 and the outer membrane vesicles from *Neisseria gonorrhoeae*, is an extension of a previously funded and successful Phase 1 application. The panel noted that Gonorrhea is the second-most-frequent, notifiable infectious disease in the United States, and that, if successful, the availability of an effective vaccine could have a significant impact on public health. Reviewers initially expressed an outstanding level of enthusiasm for this application with agreement that the premise was sound, the topic to be addressed is significant, that the outstanding team of investigators has the depth and breadth of experience necessary to carry out the work, that the innovative approach was sufficiently rigorous and was based on standard methods, and that the research environment was exceptionally well suited to support the project. In addition, the commercialization plan was noted to be well developed and sex as a biological variable was appropriately addressed. Minor concerns were expressed that centered on the issues of potential reactogenicity with the prolonged release of IL-12 and the potential for important lipoproteins during the detergent processing of the outer membrane vesicles. However, at the conclusion of the discussion, enthusiasm for the many strengths of the application was not dampened by the potential weaknesses described within the approach and as a consequence, the final potential overall impact of the application remained outstanding.

DESCRIPTION (provided by applicant): Genital tract infection with *Neisseria gonorrhoeae* (gonorrhea) does not induce a state of specific protective immunity and it can be acquired repeatedly. Despite public health measures, the disease persists at an unacceptably high frequency; there is no vaccine against it, and resistance even to the latest generations of antibiotics continues to emerge. Recent findings have revealed that *N. gonorrhoeae* subverts the immune system for its own benefit by eliciting innate responses that it can survive and by suppressing specific adaptive responses that would eliminate it. However, this induced immunosuppression can be reversed by treatments that effectively redirect the immune response against *N. gonorrhoeae*. Proof-of-principle has been established for a novel strategy of prophylaxis against genital gonococcal infection using a mouse model that is accepted as the only currently available animal model. The current vaccine prototype, GvaX12® (a combinatorial formulation of our proprietary sustained-release nanoparticulate interleukin-12 and gonococcal outer membrane vesicles) induces anti-gonococcal T-cell and antibody responses, and generates protection against homologous and heterologous strains for up to 6 months. In this Phase II application, we will define, optimize, and validate a vaccination regimen including route, aiming for intranasal administration. We will determine the basis of cross-protection against diverse strains of naturally occurring *N. gonorrhoeae*, and begin preliminary pharmacokinetics and toxicology studies in preparation for subsequent toxicological testing in nonhuman primates. Along with the preclinical data, toxicology results and future plans will be incorporated into a briefing package that will be submitted to the FDA in a request for a Type C Meeting.

PUBLIC HEALTH RELEVANCE: Gonorrhea is the second-most-frequent, notifiable infectious disease in the United States; the Centers for Disease Control report ~350,000 cases annually, and world-wide incidence is estimated at 78 million new infections per year. No vaccine is available and the emergence of multiple-drug-resistant strains now raises serious and urgent concerns over future treatment options.

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This proposal seeks to develop a novel strategy for prophylactic vaccination against gonorrhea by directing the immune response to generate lasting protective immunity.

CRITIQUE 1:

Significance: 1

Investigator(s): 1

Innovation: 1

Approach: 2

Environment: 2

Overall Impact: This is an excellent proposal to continue to develop a novel prophylactic vaccine against *Neisseria gonorrhoeae* infections, in which a nanoparticulate delivery system is exploited for co-delivery of both gonococcal outer membrane vesicles as well as IL-12; this novel delivery technology is designed to disrupt the normal survival strategies of the pathogen and trigger a protective immune response. The current proposal builds on remarkable data generated from a previous Phase I application, in which, not only is the 1st-generation vaccine conceived and successfully implemented, but the exploration of immune mechanisms involved is exemplary. The current Phase II application is well considered, superbly presented, and logically follows from Phase I progress. The only reservation with the current proposal involves potential back-up strategies for detergent-extracted OMVs; if detergent extraction also removes critical protective lipoproteins, then increasing the number of doses given to correct for any drop in protective immunity may not adequately address this issue; perhaps consideration of genetically engineered LPS-modifications should be considered.

1. Significance:**Strengths**

- *Neisseria gonorrhoeae* poses a significant threat to public health, and the problems with rapidly emerging strains that are becoming resistant to most (or potentially all) classes of antibiotics is of particular concern.
- The fact that infection with *Neisseria gonorrhoeae* offers no protection against re-infection has long complicated the search for an effective vaccine because no correlates of protection were available to guide vaccine development.
- The scientific premise of this proposal is excellent, and is based on ground-breaking work first conducted by this group in which IL-12 was found to shift both innate and adaptive immunity in favor of the host rather than the pathogen. The current proposal will expand upon this key observation, refining the mucosal delivery route and formulation of their candidate vaccine and conducting initial safety studies, in preparation for pre-IND meetings with the FDA.

Weaknesses

- None noted.

2. Investigator(s):**Strengths**

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- This group is among the leaders in this field of research, having discovered the ability of IL-12 to increase the ability of the immune system to target *N. gonorrhoeae* during a primary infection and elicit protective immunity.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The discovery that IL-12 can effectively turn a primary infection with *N. gonorrhoeae* into a “vaccine” is remarkable. Logically extending this observation to co-delivery of OMVs along with IL-12 to develop a prophylactic vaccine is excellent.

Weaknesses

- None noted

4. Approach:

Strengths

- Attempting to move from intra-vaginal mucosal administration to intranasal mucosal administration of GvaX12 is not only appropriate from a vaccine-compliance standpoint, but also introduces the possibility of male vaccination in the future.
- The animal model available for the proposed work is very well defined, and was used to great effect in Phase I.
- The caveats with intranasal versus intra-vaginal routes of immunization are well appreciated by this team.
- The scientific rigor of this proposal is excellent. Sections discussing outcomes, potential difficulties, etc presented in this application are among the best this reviewer has seen in SBIR applications. They are serious and not perfunctory explorations of potential problems with proposed experiments.
- Determination of cross-protection with clinical isolates of *N. gonorrhoeae* is excellent. The proposed screening methodology prior to efficacy testing is well-conceived.
- Proposed pre-clinical safety testing in gestating rats is excellent.
- Extensive familiarity with the process of pre-IND meetings with the FDA is evident.
- Excellent treatment of sex as a variable. The authors correctly point out that no challenge model of gonococcal infection is currently available for male mice.

Weaknesses

- Back-up plans for Task 1C, evaluating deOMVs could fail. If detergent extraction removes critical protective lipoproteins from the preparations, it unlikely that increasing the number of doses given will adequately restore/improve immunogenicity versus conventional preparations. To reduce any unwanted reactogenicity associated with LPS in the OMVs, it may be advisable to look into genetic strategies in which LPS can be deacylated, such as with PagL. Given the ability of OMVs to cross-protect, such a strategy with a given strain of *N. gonorrhoeae* may yield OMVs with optimum homologous protective efficacy that are still able to protect against heterologous strains. As pointed out by the authors, success here will greatly increase the chances of success in the pre-clinical safety studies planned in Aim 2.

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- In the Table 1 study design of Aim 2, why is Group 3 receiving IL-12 IV? Wouldn't this be expected to be toxic? Why not give GvaX12 intravenously instead?

5. Environment:

Strengths

- Excellent environment to successfully complete the proposed work scope.

Weaknesses

- None noted

Phase II (Type 2 R42 and Type 2 R44 applications):

Acceptable

- Well-conceived and presented Phase II proposal that builds upon an excellent set of data generated from Phase I studies.

Protections for Human Subjects:

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Vertebrate Animals:

Acceptable

- Power calculations for of group sizes should be better defined however.

Biohazards:

Acceptable

Resource Sharing Plans:

Unacceptable

- No plans presented.

Authentication of Key Biological and/or Chemical Resources:

Unacceptable

- No verification of key strains or integrity of IL-12 presented. No analysis of specific compositions to verify/establish reagent identities presented.

Budget and Period of Support:

- Recommend as requested. Completely appropriate for a two year project of this scale.

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CRITIQUE 2:

Significance: 1

Investigator(s): 1

Innovation: 2

Approach: 2

Environment: 1

Overall Impact: This is a R44 grant application from Drs Liu and Auci which proposes to develop a novel prophylactic vaccine, GvaX12, against gonorrhea. The vaccine strategy consists of a proprietary sustained release nanoparticulate IL-12 formulation delivered with gonococcal outer membrane vesicles (OMV). Strengths of the application include the investigators who have a track record of collaboration in developing various therapeutic and prophylactic strategies against N. gonorrhea infection and the successful completion of all of the aims in the Phase 1 grant with a submitted manuscript to report their results. The goals of the phase II application are a logical extension of the Phase I efforts with a focus in preparing an IND application for a clinical trial to evaluate the efficacy of their prophylactic vaccine in humans. There is strong scientific premise in moving forward with the project based on the results of the Phase 1. They provide alternative strategies which include use of a detergent extracted OMV to minimize any potential reactogenicity from the presence of LOS. A weakness noted is the order of the subaims given the possibility that changing the OMV formulation with detergent extraction can impact its immunogenicity and, thus, the possibility that the intranasal versus intravaginal immunization comparison may need to be repeated with the newly extracted OMV product. Overall, there is enthusiasm for the potential impact of this proposal.

1. Significance:

- Scientific Premise: Preclinical data is shown which demonstrates that intra-vaginal immunization with GvaX12 protects against genital gonococcal infection through adaptive and humoral immune responses which provide cross strain protection and immunologic memory. Thus, there is scientific premise to evaluate the efficacy of GvaX12 in humans.
- Commercial Potential: This product would fill a current void in the field and would be of interest not only in the US but in other countries.

Strengths

- Gonorrhea is the second most common infectious disease in the US
- Antibiotic resistance against gonorrhea is a major public health concern and prophylactic vaccination strategies may alleviate the disease burden in the US
- The group completed all aims from the Phase I grant and demonstrate feasibility and scientific premise for moving GvaX12 forward into the clinic

Weaknesses

- None noted.

2. Investigator(s):**Strengths**

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- Dr. Liu has a background in immunology and long standing track record of collaboration with Dr. Russell in the area of understanding N gonorrhea infections.
- Dr. Russell is an expert in mucosal immunology.
- Dr. Auci has experience with scale up efforts for commercialization.
- Dr. Furtado has expertise in microencapsulation.

Weaknesses

- Although there is a need for multiple fields of expertise, the need for multi-PIs on this application is unclear.

3. Innovation:

Strengths

- Development of a sustained release nanoparticulate IL-12 formulation delivered with OMV prepared from various gonococcal strains.

Weaknesses

- None noted.

4. Approach:

- Scientific Rigor: Propose to repeat murine experiments at least twice with a sufficient number of mice per group per experiment.
- Consideration of Relevant Biological Variables: Protective immunity experiments are being proposed in female mice only given that there is no animal model for male tract gonococcal infection. The group proposes that if i.n. immunization generates serum and salivary Ab responses, then they will repeat the experiments in male mice to evaluate applicability to both sexes.

Strengths

- The comparison of intranasal versus intravaginal immunization is important because the former represents a more clinically acceptable route of vaccination.
- Inclusion of reproductive toxicology studies given the use of IL-12 delivery intravaginally if i.n. route is not effective.

Weaknesses

- Aim 1C is to evaluate whether detergent extracted OMV induces protective immune responses since this may address any potential reactogenicity from the presence of LOS. However, this aim should be performed first or simultaneously as the intra-vaginal versus i.n. immunization studies since all of these experiments may need to be repeated with the detergent extracted OMV. Since the detergent extracted OMV may be less immunogenic this has important implications for testing i.n. administration with this newly altered product.

5. Environment:

Strengths

- The resources and equipment are available to complete the aims of the study

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Weaknesses

- None noted.

Phase II (Type 2 R42 and Type 2 R44 applications):

Acceptable

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Vertebrate Animals:

YES, all four points addressed

Biohazards:

Acceptable

Authentication of Key Biological and/or Chemical Resources:

Unacceptable

- No authentication of key biological and/or chemical resources.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Significance: 1

Investigator(s): 1

Innovation: 1

Approach: 2

Environment: 1

Overall Impact: This 2 year application is an R44 extension from a phase I award. The prior data are excellent and submitted for publication. The PI has laid out an excellent application with expected plans for commercialization. The new research proposed is a logical extension from phase I and seeks to expand the *Neisseria gonorrhoeae* vaccination studies as tested in mice, the only available animal model. The PI's premise will test mucosal vaccination, vaginal and nasal against a novel vaccine consisting of outer membrane vesicles plus nanoparticles with IL-12. Then the PI will examine protection against a large battery of strains, test for toxicity and teratogenicity of the vaccine, and test for detergent removal of LOS from the vaccine, which would prevent its use in humans. Finally, the PI will prepare materials for a pre-pre-IND meeting with FDA. The goals are well presented with pitfalls

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and alternatives listed. The rigor and reproducibility standards have been met. I have high enthusiasm for these studies.

1. Significance:

Strengths

- *Neisseria gonorrhoeae* infections, so far, cannot be managed by vaccination. These studies raise the possibility. This is important also because of the antibiotic resistance developing in the organism.
- The PI has novel vaccine technology that has proven effective in mice, supporting his overall premise.
- The data from phase I studies are strong.
- The prior studies show cross-protection from multiple *N. gonorrhoeae* strains.

Weaknesses

- Minor: The PI has to use mice as the model. There is no other choice, but only future studies in humans will show the value of the mouse tests.

2. Investigator(s):

Strengths

- Strong collection of investigators with each assigned an important task.
- Investigators have a track record in the proposed areas of study.
- They have submitted a manuscript on phase I studies.

Weaknesses

- None noted.

3. Innovation:

Strengths

- There are no effective vaccines against *N. gonorrhoeae*. This study uses a novel vaccination method that appears to function well in mice to generate protective Th1 and Antibodies. The immunity is cross-protective. Thus, the study premise raises the hope that a functional vaccine can be developed.
- A useful vaccine is needed.

Weaknesses

- None, except the same qualifier on use of mice.

4. Approach:

Strengths

- The PI will first compare intravaginal versus intranasal vaccination of female mice, testing T cell response and antibodies. The use of female mice is justified. Since this was done intravaginal in phase I, the studies should pose no difficulties. These studies are an expansion of the phase I studies. They should yield interesting and important data.

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- The PI will next examine cross-protection from challenge with diverse strains. The strains are available, so these studies should pose no problem.
- The PI plans next to detergent extract the LOS from the OMVs and assess vaccination potential. These studies are critical and likely must be successful to make the vaccine useful in humans. There is no guarantee the studies will work.
- The PI will examine bioavailability and pharmacokinetics of IL-12 since this cytokine could be toxic to humans. These studies should be easily do-able.
- The PI will farm out tests to determine reproductive toxicity in rats to a company that has the ability to do the studies.
- Finally, the PI will prepare materials for a pre-pre-IND meeting with FDA. These studies should pose no problem.
- I think rigor and reproducibility and authentication of chemical standards have been met.

Weaknesses

- The ability to remove LOS from OMVs may pose a significant problem.

5. Environment:

Strengths

- Strong

Weaknesses

- None noted

Phase II (Type 2 R42 and Type 2 R44 applications):

Acceptable

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Vertebrate Animals:

YES, all four points addressed

Biohazards:

Acceptable

Resource Sharing Plans:

Unacceptable

- I did not see any plan

Authentication of Key Biological and/or Chemical Resources:

Acceptable

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Budget and Period of Support:

Recommend as Requested

VERTEBRATE ANIMAL (Resume): ACCEPTABLE**COMMITTEE BUDGET RECOMMENDATIONS:** The budget was recommended as requested.**THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:****ADMINISTRATIVE NOTE:**

Applications submitted for due dates on or after January 25, 2016 are required to include a new PDF attachment describing plans for Authentication of Key Biological and/or Chemical Resources that will be used in that research study (see [NOT-OD-16-011](#)). Reviewers were asked to consider information provided in this attachment as part of their evaluation of your application. This attachment was missing from your application and could not be assessed.

VERTEBRATE ANIMALS (Resume): ACCEPTABLE**REVISION NOTE:**

Roster correction 11/28/2016

Footnotes for 2 R44 AI115877-02; PI Name: Liu, Yingru

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER
Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW
Small Business: Non-HIV Microbial Vaccines
ZRG1 IMM-R (12)
11/04/2016

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.