Northwestern INVO



REQUEST FOR APPLICATION Drug Target Advancement Program

NewCures Accelerator November 2021

Objective: To capture the value of new innovations from Northwestern laboratories, strengthen Northwestern's therapeutic pipeline, and ultimately expedite the translational process of early-stage research discoveries into next generation medical treatments.

NewCures is Northwestern University's biomedical accelerator that focuses on advancing the development of novel therapeutics. NewCures supports projects through pre-clinical stages, in particular, proof-of-concept validation and pharmacological de-risking. By aligning with industry standards, NewCures fills a translational gap in therapeutic development and aims to enhance and de-risk discoveries by:

- (1) identifying potential assets in faculty laboratories;
- (2) providing expertise and resources to formulate a strategic, project-specific development plan;
- (3) developing robust, validated preclinical data; and
- (4) translating research to industry-ready assets to attract external partnerships and investment from the private sector.

For the 2021 Request for Application (RFA), the focus is Target Advancement, such as Target validation, Target Optimization and Target Prioritization, to translate basic research and enable novel therapeutic development. To this end, NewCures is seeking early-stage studies that can bridge the critical gap between basic biology and drug development. The proposed studies will build robust

evidence to rationalize biological pathways and targets for further translation into new therapeutics.

For this round, NewCures will <u>not</u> consider proposals focused on validation of established targets or proposing discovery studies to identify new targets (i.e., large-scale screening or genomic/transcriptomic analyses).

Contact Information

NewCures@northwestern.edu

Key Dates

Applications due: November 22, 2021

Area of Interest

All molecular-based therapeutic projects with an identified biological target with a translational/commercialization trajectory are encouraged to apply. At this time, NewCures does <u>not</u> support projects involving therapeutic delivery/formulation, diagnostics, devices, research tools or healthcare information.

Eligibility

Applicant: Northwestern University principal investigator (PI) with a full-time faculty appointment.

Intellectual property (IP) related to the application must meet the following criteria (if applicable):

- Owned by or will be disclosed to Northwestern University;
- If IP is jointly owned, NU must be the lead, and joint owner/collaborator must be a non-profit organization;
- Not licensed to a third party.

All projects will be reviewed for IP protection for NewCures eligibility.

Funding/Benefits

Projects will be supported at a level deemed necessary to achieve carefully evaluated objectives. After project selection and PI agreement, NewCures will:

- Work with the PI and external experts to formulate a development plan, outlining key experiments for proof-of-concept validation;
- Execute milestone-driven project plans, which will mainly consist of outsourcing experimental work to third party contract research organizations (CROs) – outsourced work will be managed and paid for by NewCures (up to \$50K)*; and
- Work with INVO and the PI to build IP portfolio (if applicable) and engage potential private sector partnership and/or investment, contingent on the achievement of desired experimental outcomes/milestones.

*NewCures serves the role of project manager and makes direct payments to the CROs. NewCures does <u>not</u> provide direct funding to a PI's laboratory (NU chartstring).

Evaluation Criteria

The goal of NewCures Accelerator is to advance molecular-based technologies to the point where technology transfer is achieved or additional funding/partnership is secured from the private sector. Thus, *applications will be evaluated on overall potential for technology transfer, including scientific/technical merit, unmet medical need and commercial potential.*

APPLICATION DIRECTIONS

Send the application as a single PDF file to <u>newcures@northwestern.edu</u> by 5:00 PM CST on November 22, 2021. Please do not include appendices.

Prepare a project description (1 title page, 2 project pages including figures and references, 11-point font, 1" margins) as follows:

Title Page (1 page)

- 1. PI name and affiliation
- 2. Project title
- 3. Project team (if applicable): *name, affiliation and area of expertise of the research scientists*
- 4. Project area: *small molecules, biologics, gene therapy, protein therapy, cell therapy, others*
- 5. Intellectual property: *list if there are patents covering the project or invention disclosures with INVO, i.e., Northwestern reference number*

- 6. All prior, current and pending sources of support related to the application
- 7. IRB/IACUC approval number (if applicable)
- 8. Non-confidential executive summary (≤ 150 words), which may be shared with industry partners with permission from the PI: *describe the biomedical need or opportunity and the significance of the proposed technology; state the major research findings and how they will advance therapeutic potential; describe the potential commercial market for the technology*

Project Pages (2 pages)

- A. Project description and clinical need Summary of the project including:
 - i. Scientific merit and significant findings
 - ii. Current stage of development
 - iii. Description of the medical need and desired indication
- B. Competitive landscape

Brief description of the current standard of care and how the potential therapeutic of this project, if developed, will be an improvement over currently available treatment

C. Project needs

Briefly summarize the resources and expertise that are needed to progress the project towards target advancement with an estimated cost. Please note NewCures does <u>not</u> provide funding towards personnel, equipment, materials or reagents (see **Funding/Benefits** section, page 2).

Review Process

Each application will be judged on the basis of translational and commercialization potential, scientific merit, and medical need.

Applications will be initially reviewed for basic eligibility and feasibility, followed by a review and prioritization by NewCures and INVO team members experienced in therapeutic technology assessment and development. **NewCures may request for additional data and information during the prioritization process.** Prioritized applications will be presented to the NewCures <u>External</u> Board of Advisors (EAB) for final evaluation.

NewCures EAB consists of experts from outside of the Northwestern community who are highly recognized leaders in therapeutic development from

pharmaceutical, biotech and investment communities; all external members have signed confidentiality agreement with Northwestern. Only external members will be involved in the final selection and funding of NewCures projects to avoid a potential conflict of interest.

Project Execution and Management

NewCures project team will work with the PI, external consultants and subject matter experts to develop a pre-clinical development plan for the technology. The experimental work will be coordinated and managed by NewCures, either through internal resources (Northwestern Core Facilities) or third party CROs.

NewCures and INVO will work with the PI to generate a "pitch deck" to facilitate engagement with the private sector for potential licensing, collaboration and/or investment.

NOTE

NewCures is dedicated to fostering ongoing molecular-based therapeutic technology development at Northwestern. For the applications that are not accepted this round, NewCures will continue to engage and interact with PIs to provide guidance and support, as needed, for future development.

APPLICATION DEADLINE: MONDAY, NOVEMBER 22 by 5:00 PM CST NEWCURES@northwestern.edu