

PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS SU2C CATALYST® RESEARCH GRANT PROGRAM WITH SUPPORT FROM ZENTALIS PHARMACEUTICALS

ABOUT STAND UP TO CANCER

Stand Up To Cancer[®] (SU2C) raises funds to accelerate the pace of research to get new therapies to patients quickly and save lives now. SU2C, a division of the Entertainment Industry Foundation, a 501(c)(3) charitable organization, was established in 2008 by media and entertainment leaders who utilize these communities' resources to engage the public in supporting a new, collaborative model of cancer research, to increase awareness about cancer prevention, and to highlight progress being made in the fight against the disease. As of January 2022, more than 2,000 scientists representing more than 210 institutions are involved in SU2C-funded research projects.

Under the direction of our Scientific Advisory Committee, led by Nobel laureate Phillip A. Sharp, Ph.D., SU2C conducts rigorous competitive review processes to identify the best research proposals to recommend for funding, oversee grants administration, and ensure collaboration across research programs.

Current members of the SU2C Founders and Advisors Committee (FAC) include Katie Couric, Sherry Lansing, Kathleen Lobb, Lisa Paulsen, Rusty Robertson, Sue Schwartz, Pamela Oas Williams, and Ellen Ziffren. The late Laura Ziskin and the late Noreen Fraser are also co-founders. Dr. Russell Chew serves as SU2C's CEO and President.

ABOUT ZENTALIS

Zentalis Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. The Company is developing a broad pipeline of potentially best-in-



class oncology candidates, all internally discovered, which include ZN-c3, a Wee1 inhibitor for advanced solid tumors, ZN-d5, a BCL-2 inhibitor for hematologic malignancies and related disorders, and a heterobifunctional degrader of BCL-xL for solid and hematological malignancies. The Company has licensed ZN-c3, ZN-c5 and ZN-d5 to its joint venture, Zentera Therapeutics, to develop and commercialize these candidates in China. Zentalis has operations in both New York and San Diego.

ZN-c3 is a potentially first-in-class and best-in-class oral inhibitor of WEE1 in development for the treatment of advanced solid tumors. The inhibition of WEE1, a DNA damage response protein, aims to generate sufficient DNA damage in cancer cells, causing cell death, thereby preventing tumor growth and potentially causing tumor regression. ZN-c3 has a broad potential as monotherapy and in combination. We are currently evaluating this candidate in several studies, including two potentially registrational monotherapy trials as well as combination studies such as with chemotherapy in patients with advanced ovarian cancer. We also recently received orphan drug and rare pediatric disease designations from the FDA for pediatric osteosarcoma and have initiated a Phase 1/2 trial in combination with chemotherapy.

For more information, please visit <u>www.zentalis.com</u>. Follow Zentalis on Twitter at @ZentalisP and on LinkedIn at <u>www.linkedin.com/company/zentalis-pharmaceuticals</u>.

SU2C HEALTH EQUITY COMMITMENT STATEMENT

Stand Up To Cancer is committed to eliminating barriers of access to state-of-the-art screening, diagnosis and treatment for all cancer patients. In doing so, with mounting evidence for the need to develop precision medical prevention, treatment and intervention solutions based on diverse patient populations, we are actively engaged in changing the health equity landscape by expanding diversity in the inclusion of historically underrepresented racial and ethnic minority populations into clinical trials that we fund. We are especially interested in supporting clinical trials and research studies that have developed successful strategies, measurable outcomes, and robust outreach plans to feasibly and effectively include these populations into these studies.

PROGRAM MISSION STATEMENT

The SU2C Catalyst Research Grant Program with support from Zentalis Pharmaceuticals endeavors to support research investigating the use of Wee1 inhibitors for treating a variety of cancer types. The most talented and promising researchers across institutions are encouraged to assemble into a collaborative multi-institutional team, forming an optimal configuration of expertise needed to solve key cancer problems that could be supported by foundational knowledge of Wee1 biology. Mechanisms to foster collaborations within and among the Team will be employed – an approach that promotes the sharing of information and a goal-oriented focus on measurable milestones of progress. SU2C believes that this unique Team will advance scientific research in the interests of improved long-term outcomes for patients.

The Research Team will benefit from SU2C's structure and oversight through which a multi-disciplinary team will come together with support to focus on a discrete set of aims. The bi-annual progress review practiced by SU2C ensures that milestones and deliverables are met and will keep the project focused on its goals. The Research Team is supported by a grant from Zentalis Pharmaceuticals.

RESEARCH PROJECT CRITERIA

The Research Team represents an unprecedented opportunity to bring together the best scientific minds from diverse fields of research to concentrate on approaches that identify new and unexpected uses of Wee1 inhibition and lower the activation energy required to test new combinations in the clinic for the treatment of solid tumor and hematological cancers. Applications are encouraged from researchers who propose approaches supporting preclinical work on Wee1 which will lead to new ideas and understanding of the biology that will benefit the field in general. Collaborative multi-institution studies are required. A path to clinical trials should be considered although initiation of a clinical trial is not required during the span of the SU2C Catalyst grant. Proposals should show the potential for contributing to significant patient outcomes in solid tumor and/or hematological cancer treatment.

The Team will address key areas of Wee1 biology that should be explored and lead to new insights to better exploit Wee1 inhibition for clinical advances. Projects will be designed to accelerate the development of new treatments and combination therapies and to positively impact patients in the near future. Successful applications will assemble the most impactful multi-disciplinary teams focused on areas of strength along the spectrum of Wee1 biology in basic discovery and pre-clinical studies with the potential to lead to translational studies and clinical trials. Areas of interest are: patient-selection hypothesis, exploration of potential combinations, novel biomarker studies (response or resistance), contribution of replication stress, metabolism and chromatin dysregulation on ZN-c3 sensitivity, exploration of Wee1 mechanism of action and mechanisms of resistance. Fundamental work in immuno-oncology environment and tumor heterogeneity development in patient samples from an ongoing trial would be of interest, as well as investigating the immunomodulatory impact of Wee1. Proposed ideas should be based on perceived opportunities for success as well as high-priority areas with a critical patient need.

APPLICATION DEADLINE

The Full Application shall be submitted by Monday, July 31, 2023, at 11:59pm midnight Pacific Daylight Time. Teams invited to present at the virtual Selection Meeting will be informed on or before Monday, August 28, 2023. The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a virtual selection meeting to be held the week of September 11, 2023. The selected team will be notified October 2023 with anticipated project start dates in January 2024.

See the section "Application Instructions" on page 8 for further information.

TEAM COMPOSITION AND MEMBER ELIGIBILITY CRITERIA

To maximize creativity, innovation, and collaboration, the Research Team must include members with a highly multi-disciplinary range of expertise, perhaps including solid tumor and/or hematological cancers, laboratory sciences, biostatistics, and clinical sciences, with senior and early-career investigators. The Team will consist of a Team Leader, and a Team Co-Leader There will be no more than four additional Team Principals and a Project Manager, *with a minimum of two participating institutions*. Racial and ethnic diversity among Research Team personnel is strongly encouraged.

Team Composition Overview

Definitions

- 1. **Team Leader (TL)** (required): The Team Leader is the person responsible for the scientific and technical direction of the proposed research project, contractual and financial obligations, and other organizational assurances/certifications. The TL must ensure that the Team complies with the terms and conditions of the award, and will be the primary contact person for SU2C science staff.
- 2. **Lead Institution** is the organization at which the Team Leader is employed, and it will be legally and financially responsible for the conduct of Team activities supported by the grant.
- 3. **Team Co-leader (TC)** (required): A Team Co-leader is designated by the Team Leader to assist in directing the scientific and technical work of the Team. A Co-leader serves as an alternate contact person for SU2C science staff.
- 4. **Team Principal (TP)** (required): Team Principal(s) is a senior investigator(s) who will lead a component(s)/subproject(s) of the Team research project.

- 5. **Project Manager** (required): The Team Project Manager (PM) is the administrative leader of the Team and the key administrative contact for the Team with SU2C. The PM is responsible for the coordination of all team efforts to consistently maintain a high level of functionality, collaboration, and communication. The PM coordinates the Patient Advocates and the scientific reporting, and, where appropriate, assists the Team in developing a plan for clinical trial accrual, diversity, and tracking.
- 6. **Investigators:** Senior investigators, other than the TL, TC, and TPs, who are employed at the TL, TC, or TP institutions and contribute substantively to the Team research project, may be included as members of the Team.
- 7. **Early-Career Investigators:** Junior faculty (i.e. independent investigators who have completed their training no more than seven years prior to the start of the grant term), postdoctoral fellows, clinical research fellows, or any other researchers-in-training who are working under the direction of a scientific mentor (i.e., a TL, TC, TP, or Investigator) may be included as members of the Team.
- 8. **Collaborator:** An Investigator who is not employed by a participating institution and is unfunded in this project budget yet makes valuable contributions to the Team.
- 9. **Budget and Contract contact** (required per institution): For each participating institution/clinical trial site, provide at least two officials responsible for grant agreements.
- 10. **Other (Scientific/Technical):** Any person providing scientific or technical support, such as Lab managers and technicians
- 11. Other (Administrative): Any person providing administrative support such as Administrative assistants
- 12. **Public Information Officer (PIO)** (required per institution): The PIO is the communications coordinator or spokesperson for the institution.

Team Member Eligibility Requirements

- 1. The TL, TC, and TPs, must have acquired a doctoral or medical degree and must be independent investigators affiliated with an academic, medical, or research institution. Individuals on the FDA Debarment List may not apply.
- 2. Research may be international. There are no citizenship or residency status restrictions for team members.
- 3. The TL and TC are expected to each dedicate at least 5 percent (or 10 percent combined) of their time and effort to the Team research project.
- 4. TPs must each dedicate at least 5 percent of their time and effort to the Team research project.
- 5. No Team will have more than one Key Personnel (TL, TC, or TP) from any given institution at the time of their initial appointment on the Team. No more than two Key Personnel may be from affiliated institutions. It is expected that additional Investigators from the TL, TC or TP institutions may be involved in the Team research project in some other capacity, and there is no limit to the number of Investigators from each of these institutions that may contribute to the Team project.
- 6. Employees or subcontractors of for-profit industry are not eligible to serve as a TL, TC, or TP; however, their participation as unfunded Collaborators is encouraged, where appropriate, to foster the development of novel strategies.
- 7. Early-Career Investigators are not eligible to serve as a Team Leader, Co-leader, or Principal; however, their participation in the Team research projects is highly encouraged.
- 8. Neither members of the SU2C Scientific Advisory Committee, SU2C Catalyst Executive Committee, SU2C Catalyst Steering Subcommittee, nor members of their individual laboratories are eligible for funding as part of the SU2C Catalyst Grant Program.
- 9. Key Personnel should not be funded on more than one SU2C-sponsored Team grant (Dream Team or Research Team).

Applicants with a question about the eligibility requirements are encouraged to contact SU2C at proposals@su2c.org prior to submitting the proposal.

EVALUATION OF PROPOSALS

The SU2C Catalyst Steering Subcommittee will review the proposals for the SU2C Catalyst Grant Program. The Steering Subcommittee consists of highly accomplished experts in the field of Wee1 biology research and treatment, senior laboratory researchers, and physician-scientists who are respected internationally for their own accomplishments in cancer research and as leaders in the field.

The Steering Subcommittee will consider the following criteria when evaluating the proposals:

- Scientific merit of the proposed research project and translational potential of the research
- Significance of the proposed research
- Novelty of the hypothesis or methodology
- Degree to which the studies have a positive impact on the detection and/or treatment of solid tumor and/or hematological cancers
- Team leadership qualities (TL, TC, TPs): Willingness to collaborate, their research credentials, their unique contributions to the Team research project, demonstrated ability to bring together and lead an interdisciplinary team of experts to a successful conclusion, expertise in the field, and commitment to translational cancer research with clear emphasis on near-term clinical application
- Involvement of patient advocates and/or community members in study design and implementation
- Commitment to diversity, equity, and inclusion: How the project partnership is designed to prioritize different voices and power-sharing with the prioritized communities, the extent to which project leadership is representative of the populations of focus in the grant, the extent to which the proposal captures and effectively disaggregates data in order to determine precise impact (i.e., by race/ethnicity), potential for sustainability in the health equity environment, demographics of the institutions' and project leadership, engagement of experienced and young investigators in the project, track record of collaboration and impact between academic and community partners, and how this project will leverage the learnings
- A clear commitment by the Team that all data resulting from their work will be available to the scientific community at large at the earliest opportunity, as allowed under patient privacy and other applicable laws
- Likelihood that the research project will achieve its stated goals given the budget requested, institutional environments, and other resources available
- Likelihood that patient enrollment to clinical trial(s) will be completed within the timeframe of the grant
- Whether the studies are designed to capitalize upon the unique populations and environments, specialized expertise, new concepts and perspectives, innovative methodologies, and/or emerging technologies that are available as a result of the multi-institutional collaboration
- Plan for broad dissemination, impact, and sustainability of the models created
- Whether adequate institutional and/or financial support exists to sustain the research project
- The cost effectiveness of the budget
- Plan for mentoring and integrating Early Career Investigators and minority team members

GRANT TERMS

Changes to application. Applicants are not allowed to change the project nor the Team members proposed in the application. If changes are necessary, prior written approval from SU2C is required.

Contracts. A Grant Agreement will be executed between SU2C and the Team Leader's Institution, referred to as the Lead Institution. The Lead Institution must serve as the administrator of the grant funds and hold responsibility for the disbursement of the funds, management of the budget, and provision of progress reports. It is expected that the Lead Institution will enter into subcontracts with the institutions of the Team Co-leader and Principals, and assurances that these contractual agreements have been executed will be required for continuation of funding. All contracts with industry are encouraged to use the model contract language for clinical trials of

potential new cancer treatments that have been made available by the CEO Roundtable on Cancer in partnership with the NCI to comply with the requirement of the SU2C founders to expedite the negotiation process. Please visit <u>http://transformingtrials.cancer.gov/initiatives/ctwg/standardization/highlights-start</u> for further details. **Commencement.** The Team Leader will commence upon execution of the contract agreement with the lead institution. SU2C retains the right to terminate the grant if the research project is not commenced in a timely manner.

Budget. Teams may apply for total support up to \$800,000 over a 1-3-year term. A detailed budget should be entered into Proposal Central during the application process. SU2C strongly advises a limited first-year budget as past Teams over-allocate funds in this timeframe. There is no need for all institutions to be funded for the entirety of the grant term. All funding is contingent upon milestones and objectives being appropriately selected and satisfactorily pursued and achieved, as determined by SU2C, the SU2C Catalyst Executive Committee, and the Steering Subcommittee.

Use of Funds. Grant funds may be used for direct research expenses attributable to the proposed research, which may include:

- A percentage of the salary and benefits expenses (limited to 20 percent of the total budget) of senior investigators
- A percentage of salary and benefits expenses of the Early Career Investigators on the Team
- Salary and benefits expenses for research assistants or technicians
- Equipment, supplies, and other laboratory or clinical expenses
- Travel expenses relevant to the Team research project, including travel to the institutions of the Team Leaders/Principals and travel to meetings with the committees, as well as to the annual SU2C Scientific Summit
- Expenses (limited to a total of \$20,000/year) related to publication page charges and/or the presentation of research data at scientific meetings or through other means that will contribute to the dissemination of the scientific knowledge derived from the proposed research

The funds may not be used for salary or benefits of any Collaborators from a government institution/agency or a for-profit industry, or for any research expenses related to the Team project that are incurred by these individuals. Tuition and professional membership dues are not allowable expenses.

Any indirect costs charged by the institutions will be negotiated to a minimum, but in no event will there be permitted a charge of more than 25 percent of the total budget.

Payments. The payment schedule between the Team and SU2C will be delineated in the contract agreement after awarding of the grant.

Reporting Requirements. Progress reports, submitted each year on July 15 and January 15, shall highlight the accomplishments of that specific time period bearing in mind the pre-defined Milestones and Deliverables of the Team. Progress Reports will be reviewed by SU2C and a Review Team drawn from the Steering Subcommittee.

SU2C may withhold release of any or cancel future Grant Funds until the reports have been filed and approved. Failure to address deficiencies, meet grant requirements, or achieve the pre-defined Milestones and Deliverables may result in discontinuation of the grant.

Teams must meet three times a year, either in person, by teleconference, or by videoconference, to review progress and, if necessary, adjust research plans. Two of the required meetings can be fulfilled prior to the semiannual reviews, where Team Leaders meet with the Review Team and all other Team members, following the submission of Progress Reports, to thoroughly discuss the Teams' progress. The review meeting schedule will be an appendix to the Team contract. A final written progress and financial report shall be submitted no later than sixty (60) days after the ending date of the grant term. The reporting materials must include all project components.

SU2C will share copies of interim and final progress reports and may provide these materials, at their discretion, to other funders that have provided financial support for the grant and also may use all or portions of the report for public dissemination, such as within SU2C newsletters or websites, or in other similar manners.

Publications and Acknowledgment of Support. Any publications resulting from research funded in whole or in part by the grant must cite SU2C as funders in the acknowledgment. The contract between SU2C and the Lead Institution will contain exact wording. Copies of such publications shall be forwarded to SU2C after acceptance but before publication.

Intellectual Property. SU2C must be notified of any discovery that is protectable under applicable law (e.g. patentable), that is discovered in the course of the research funded through this grant. SU2C shall have no responsibility or interest in the protection of, commercialization, or licensing of intellectual property resulting from the Team. The Team Leader and the Lead Institution shall notify SU2C of the granting of each patent or other legal protection and of all commercial exploitation of any Invention.

Insurance. Insurance shall be maintained by the Team Members and Institutions for professional liability and comprehensive general liability insurance, on an "occurrence" basis, against claims for "personal injury" liability, including bodily injury, death or property damage liability. Such insurance shall be primary and noncontributory with any other insurance carried by SU2C and shall provide appropriate waivers of subrogation against SU2C, and its directors, committee members, employees, affiliates, and agents.

Notification of Changes. The Team Leader is responsible for notifying SU2C immediately of any changes in the composition of the Team and changes in the position or institution of any of the Team Members. SU2C may not accept proposals to change the research project from that described in the application and may terminate the grant.

Organizational Assurances. The Team Leader and Lead Institution are responsible for ensuring that organizational assurances/certifications from all Team Member Institutions are obtained.

For research involving human subjects, the appropriate Team Member(s) and U.S. Institution(s) shall certify that:

- a. Prior to the initiation of human research, the proposed research project has been reviewed and approved in writing by an Institutional Review Board ("IRB") constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services ("HHS") and registered with HHS.
- b. The Team Member(s) shall secure a legally acceptable informed consent from all human subjects taking part in any research funded in whole or in part by SU2C in accordance with and to the extent required by current regulations promulgated by the United States Department of Health and Human Services and approved by HHS. IRB approval for human subjects research should be submitted to SU2C, and funds for human subjects research will not be released unless and until proof of all IRB certifications is received by SU2C. Prior IRB approval for another project cannot be substituted but can be officially amended to include the proposed project.

For research involving animals, the Institution(s) shall ensure compliance with applicable chapters of the Public Health Service Animal Welfare Policy, the NIH Manual for Grants and Contracts, and any and all requirements of the Institution concerning animal welfare. Certification by the Institution Animal Care and Use Committee

(IACUC) or equivalent shall be documented by submitting a copy of the institutional letter of approval, which identifies the Team Member(s) responsible for the project, the Team research project title, SU2C as the funding agencies, and the date of approval, and is signed by the IACUC Chair or equivalent Institution official. Prior IACUC certification for another project cannot be substituted but can be officially amended to include the proposed project.

Team Members at non-U.S. institutions must adhere to ethical standards for the protection of human and animal subjects that are at least equivalent to U.S. standards and to the legal requirements of the country of origin. Certification of ethical standards review and approval should be documented by submitting a letter, which cites all relevant approval and license numbers and dates required by the country of origin. In the absence of an official ethical review board (or equivalent) or legal requirements, the Team Member(s) must agree in writing to adhere at minimum to the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

APPLICATION INSTRUCTIONS

APPLICATIONS:

The Full Application shall be submitted by Monday, July 31, 2023, at 11:59pm midnight Pacific Daylight Time. Teams invited to present at the virtual Selection Meeting will be informed on or before Monday, August 28, 2023. The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a virtual selection meeting to be held the week of September 11, 2023. The selected team will be notified October 2023 with anticipated project start dates in January 2024.

The Full Application includes the following elements:

- Title Page
- Signatures Pages: Signature pages must be submitted for every Institution requesting SU2C Catalyst funds through this grant application. The Team Leader, Team Co-Leader, and every Team Principal must be included in the Signature Pages.
- Lay Abstract (limited to 1/2 page)
- Scientific Abstract (limited to 1/2 page)
- Research Proposal (limited to 3 pages; include the following information)
 - o Background and Rationale
 - o Specific Aims
 - o Research Design and Methods
 - Statistical Plan
 - Projected Timeline and Milestones
 - o Significance and Therapeutic Impact
 - o Collaboration/Team Members
 - Data Sharing Plan
- Facilities (limited to 1 page per Institution)
- References (no page limit)
- Other Support
- Budget Justification: Limited to three (3) pages per institution. Detailed justification of the separate budget requests for expenses related to the research components/subprojects conducted by the Team leader, Team Co-Leader, and Team Principals is required for all items of the equipment costing over \$1,000, and the need for personnel, supplies, and other items. Provide the names of individuals whose salaries will be supported by the grant funds and justify the amount of support requested. If requesting "Other Expenses," a thorough list of these expenses along with the justification is required.
- Milestones and Deliverables Timeline

- Requested funding and required regulatory approvals per Specific Aim
- Budget (should not exceed \$800,000 USD): See sections "Budget" and "Use of Funds" on p. 6-7 for additional information.
 - Total Budget per Year
 - Budget per Institution (complete for every institution)
 - Total Budget per Institution
 - Budget by Specific Aim
- Personnel Tracker: See section "Eligibility Criteria" on p. 3-5 for additional information.
- CVs for Team Leadership (Team Leader, Team Co-Leader, Team Principals; NIH Biosketch preferred but not required; no template is provided; do not exceed five (5) pages per individuals)
- Letters of Support
 - \circ $\;$ Letters from Leadership at each Institution involved in the Team
 - Letters from other Company(ies) collaborating with the Team

Other Application Information

Teams are required to have a Team Leader and a Team Co-Leader. Teams must include a Project Manager. Projects should be planned for three years. The proposed budget should not exceed \$800,000 US dollars total.

Application Submission

Full Applications will be submitted through the ProposalCentral portal (proposalcentral.com) using the instructions, fields and templates provided there. An email will be sent to confirm receipt of your online submission.

Changes to the Application

Following the submission of an application, the Team Leader should notify SU2C in writing of (1) any changes of address, email, or phone number for any Team member, (2) any changes in institution for any Team member, or (3) withdrawal of the application for any reason.

NOTIFICATION

The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a virtual selection meeting to be held the week of March 13, 2023. The selected team will be notified April 2023 with anticipated project start dates in June 2023.

INQUIRIES

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to the SU2C Science Office at:

Phone: 818-262-1168 Email: proposals@su2c.org