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Pilon, Andre

Proposal To: NIH - BrIDGs *NIH - BrIDGS Program*
Title (Applicant): **Test application to BrIDGs program (AMP) (Pilon, Andre)**

Deadline: **5/30/2012 5:00:00 PM (U.S. Eastern Time)**

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Title Page

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This is not a grant application rather this is an opportunity to collaborate with the BrIDGS Program.

Enter a title for your application, then press Save.
Press Next to save any changes and go to the next proposal section.

* **Project Title**

* **Affiliation**

* **Is this a resubmission** * **Application Type**

* **How did you hear about BrIDGs?**

If you selected Conference or Other, please describe

* **Mechanism of Action**

* **Therapeutic Area**

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Auto Notify: To enable your co-investigators, department or grants administrators to receive system notifications, add them with at least "View" access below and check the box "Auto Notify".

Proposal Access Rights

Del	Auto Notify	Role	Name	E-Mail	Permissions
			Pilon, Andre	pilona@mail.nih.gov	Administrator
Accept Changes					

Proposal Access User Selector

User Selector User ID/E-Mail Enter the E-Mail address or User ID of the User and press the button to select.

[Find User](#)

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Applicant/PI

Person who initially creates the proposal is pre-loaded as the PI. Contact information from PI's profile is shown below. To update profile, click Edit Profile. To change PI, select from list and **click button to confirm selection.**

Principal Investigator

Name: Prefix _____ * First Andre Middle _____ * Last Pilon

* **Institution** National Institutes of Health

Address: MailStop

* **Street** 9000 Rockville Pike

* **City** Bethesda

State/Province MD * **Zip/Postal Code** 20892

* **E-Mail** pilona@mail.nih.gov * **Country** United States

Phone: * **Work:** 301-827-2746 **Fax:** _____

Applicant/PI

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PI's institution is pre-loaded as Lead Institution. To change, select from list below or Search all registered institutions. Press button to confirm selection. Click Edit Profile button to change institution information.

[Instructions](#)

Lead Institution

No Institution Available

Click this button to Change the Lead Institution:

Note: Changing institution will delete currently displayed contacts.

Address

* **Street** 6707 Democracy Blvd
Suite 104

* **City** Bethesda

State/Province MD

* **Zip/Postal Code** 20817

* **Country** United States

If required institution information is missing or appears to be incorrect, please contact the following Administrator(s) of this Profile. The Administrator will make the necessary updates to the Profile.

Administrator	Email	Phone
Miller, Brad	bradmiller123@example.com	703-964-5863

* **Organization Type**

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Key Personnel[Print](#)[<<Previous](#)[Next>>](#)[Cancel](#)[Exit](#)**Provide contact information for key personnel, other than the applicant, in the table below.**

Role	Name	Title	Institution	Email	Phone	Effort	Action
No Personnel Currently Identified							

INSTRUCTIONS:

To add a new contact to the table above, enter the e-mail address of the person you wish to add. Click 'Add'. Complete the contact form. (Note: If the person is already registered in proposalCENTRAL, some information will be pre-loaded into the contact form). To edit the person's contact information, click, 'Edit' (in the far right Action column). To delete a person from the table, click 'Del'. (Note: Changes that you make to the person's contact information will be for this proposal only. Permanent changes must be made in the person's Professional Profile).

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Project Information Category[Save](#)[Print](#)[<<Previous](#)[Next>>](#)[Cancel](#)[Exit](#)**Biology/Efficacy:***** Select the button that describes the stage of your project:**

- Identified target(s), likely pharmacological endpoints & functional assays; defined mechanism of action (MOA) of lead compounds; projected the human efficacy dosage and dosing regimen; developed PK/PD relationship
- Demonstrated in-vivo pharmacology in a key animal model (not necessarily by the route of administration)
- Not yet demonstrated in-vivo pharmacology OR in vivo model not yet available or validated
- Not Sure

Medicinal Chemistry:*** Select the button that describes your project stage:**

- SAR trends exemplified; no significant physiochemical property concerns
- SAR trends have been identified. Modest challenges still exist, including pharmacologic potency-SAR trends are developing
- SAR trends are unclear OR chemistry complexity interferes with the team's ability to advance the SAR OR multiple active platforms remain to be prioritized
- Not Sure

Drug Metabolism and Pharmacokinetics (DMPK) Characterization:**In vivo pharmacokinetic studies and/or in vitro ADME assays (e.g., solubility, permeability, metabolic stability) of lead compounds in this proposal show they have the following DMPK characteristics (select one):***** Select the button that describes your project:**

- High quality DMPK characteristics, thus leads need minimal structure modification

Project Information (cont'd)

Unassigned

$CL_{int} < 0.5$ HBF, $1 \text{ h} < PK \text{ t}_{1/2} < 8 \text{ h}$, or $50\% < \%F < 80\%$)

- Poor DMPK characteristics, thus leads need major structure modification (e.g., solubility $< 10 \mu\text{g/mL}$, $CL_{int} > 0.5$ hepatic blood flow (HBF), $PK \text{ t}_{1/2} < 1 \text{ h}$, or $\%F < 20\%$)
- Unknown DMPK characteristics, because few studies have been performed

Toxicology

*** Select the button that describes your project:**

- Chronic toxicology in two species completed successfully; finished safety pharmacology, mutagenicity, and sub-chronic tox studies
- Conducted acute toxicological studies in rodents; no data generated to date to cause concern
- Literature or experience with this platform indicate that toxicology may be an issue (for peptides, immunogenicity issues have been identified with the lead molecule) OR for pre-lead efforts - in silico & appropriate Tox due diligence not yet complete
- Not Sure

Chemistry, Manufacturing and Controls (CMC)

Select the button that describes the stage of your project most accurately:

- API scale up – no purification issues, all reactions are scalable; Formulation – identified formulation of lead compounds for animal testing and FIH testing; Bioanalytical methods – developed and validated bioanalytical methods
- Have preliminary characterization of API, purity, stability, solvents, for NBE's: chemical composition, glycosylation patterns, payload/protein scaffold ratio, etc.
- Have preliminary formulation and bioanalytical methods for animal studies
- Have not initiated any work on CMC for the lead compounds

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Abstract

Please provide a general audience summary below. 4,000 characters max, including spaces. Text only. No special characters or formatting. See instructions for details.

* General abstract and description of the project should be entered here.

Select the BrIDGs resources that apply. You must select at least 1. If resources required are not listed, please list them in the BrIDGs Proposal document.

*BrIDGS Resources

- Development of analytical methods
- Development of suitable formulations
- Pharmacokinetic/ADME studies including bioanalytical method development
- Product development planning and advice in IND preparation
- Range-finding initial toxicology
- Synthesis

Selected Categories

- [Del](#) IND-directed toxicology
- [Del](#) Manufacture of clinical trial supplies
- [Del](#) Scale-up production

Add

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