|  |  |  |
| --- | --- | --- |
|  | | |
| Cell Therapy External Research Program C:\Users\lhartrich1\Desktop\Gilead_Kite combo_NewLogo_v6_RGB.JPG  Letter of Intent | | |
|  | | |
| Through Medical Affairs, Kite - a Gilead company, supports the research efforts of academic institutions, clinical investigators and research networks to help inform the scientific community about the appropriate use of cell therapy. Kite intends to support investigations focused on:   * Novel combinations * Side effect/safety management combinations * Orphan B-cell malignancies (e.g., Hairy cell leukemia, Burkitt lymphoma, PTLD) * Earlier lines of therapy in high risk lymphoma patients (e.g., high FLIPI/GELF in FL) * B-cell mediated autoimmune disease * Novel conditioning regimens * Real world data * Translational studies characterizing mechanisms of treatment failure, including relapse, pathogenesis of treatment related toxicities, and approaches to support outpatient treatment   Proposed research efforts will be considered out of scope of this program if focused on:   * Studies already planned by or underway at Kite * Approved/authorized indications other than novel combinations * Combinations with: BTK inhibitors, IMiDs, checkpoint inhibitors, and anti-CD20 monoclonal antibodies * Studies of pipeline cell therapies, or malignancies being studied by Kite with pipeline therapies * B-cell mediated autoimmune disease with neurologic involvement * Changes in cell dose * PCNS lymphoma * Safety combinations with: siltuximab or anakinra * Translational research accompanying registrational trials     Please answer all sections below and submit the completed form to [**ERP@gilead.com**](mailto:ERP@gilead.com) with the email subject heading “Cell Therapy 2019 – [Principal Investigator Name, Organization Name].  If you have any questions about the application form, please ask your local Medical Scientist or email [**ERP@gilead.com**](mailto:ERP@gilead.com). | | |
| **Investigator/Institution Information** | | |
| Organization/Institution Name | |  |
| Principal Investigator | |  |
| Degree/Title(s) | |  |
| Department | |  |
| Address | |  |
| City, State, Zip/Province, Postal Code | |  |
| Country | |  |
| Website Address (if available) | |  |
| Telephone | |  |
| Email | |  |
| Has your organization/institution applied for, or previously received, funding from Gilead or Kite? | | Yes No   |  |  | | --- | --- | | If yes, please explain: |  | |
| **Executive Summary** | | |
| Project Title  (Do not exceed 25 words) | |  |
| Estimated Budget Requested  *Must include overhead costs and all applicable taxes if applicable. Overhead in excess of 30% will* ***not*** *be approved.* | |  |
| List of other Supporters to the Project  (Include name and amount in USD currency) | |  |
| Request Type | | Clinical Preclinical Translational  HEOR Other |
| Abstract (Do not exceed 200 words) | | |
|  | | |
| **Letter of Intent Details** | | |
|  | **Organization/Institution Description (e.g., academic institution)**  *(Do not exceed 50 words)* | |
|  | | |
| 1. **Research Plan (Entire plan overview should not exceed two pages)**   *Please provide an abbreviated proposal overview, including: background/ rationale, preliminary studies or data (if applicable), specific aims/objectives, design, primary and secondary endpoints, analytic considerations/ sample size justification, and timeline (if relevant).* | | |
|  | | |
| 1. **Biographical Information**    * *Please submit your CV and include an overview of your research experience*   *(no more than* ***5 pages*** *total)* | | |
| **By entering my name below, I hereby certify that the above statements are true and correct to the best of my knowledge.** | | |  |
| Name & Title Date | | |  |
|  | | |  |