

Investigator-Sponsored Studies (ISS)

Pharmacosmos Therapeutics, Inc. (PTI) may support investigator-sponsored research that promotes the advancement of medical and scientific knowledge relating to our products and/or therapeutic areas of interest. This type of research would expand the understanding of PTI products and their potential applications and may spark new ideas for further disease-related research.

Academic and community-based Investigators (e.g., researchers, healthcare providers, physicians, pharmacists, advanced practice providers, nurses) interested in conducting an ISS can apply for support on behalf of their institution/organization in the form of funding, drug product, or both. An ISS may be an interventional or non-interventional study.

PTI welcomes unsolicited proposals from qualified Investigators with promising ideas in PTI areas of strategic interest that will contribute to advancing knowledge in the medical and scientific community, addressing unmet needs, and communicated in an appropriate scientific forum (including congresses and peer-reviewed publications).

How to Apply

If you are an Investigator with an ISS proposal to submit on behalf of your institution/organization, the first step is to share your proposal with your regional Medical Science Liaison (MSL), who will provide you with an Application Form for completion and submission. If you do not know your regional MSL, please reach out to our Medical Information department via email (MedInfo@Pharmacosmos.us) or phone ([888-828-0655](tel:888-828-0655)), 9:00 am – 5:00 pm Eastern, Monday to Friday.

Process

Once PTI receives the initial proposal, the PTI ISS Review Committee will review it based on objective criteria and factors, such as, but not limited to:

1. Scientific, clinical, and medical robustness and merit
2. Safety and ethical integrity
3. Feasibility of study protocol
4. Alignment with existing PTI strategy
5. Availability of PTI resources

Applications are typically reviewed monthly and may require multiple rounds of review. PTI may approve or reject an application in its sole and absolute discretion. Your MSL will be your best source for updates as the application moves through the review process. PTI reserves the right to request additional information and documentation to evaluate an application. Please note that missing or inaccurate information may delay the review of the application.

Responsibilities

The Investigator assumes responsibility for all aspects of the ISS, including, but not limited to, study design, initiation and conduct, monitoring and safety reporting, analysis, and publication of the results. If the ISS application is approved, the requesting institution/organization will need to enter into a duly executed agreement with PTI governing the terms and conditions of its support for the ISS

before any support will be provided by PTI. The requesting institution/organization and investigator will be responsible for complying with the terms and conditions of such agreement.

Support of an ISS is not intended to encourage or reward the prescription, supply, administration, recommendation, purchase, use, order or sale of any PTI product or otherwise generate business for or between PTI or the requesting institution/organization or investigator. PTI is committed to compliance with all applicable laws, rules, and regulations as well as both data and financial transparency. To ensure compliance with relevant laws, rules, regulations, and industry codes, all transfers of value (e.g., payments and product supply) will be reported in accordance with such requirements. As the study sponsor, the Investigator is also responsible for complying with all applicable regulatory requirements and guidance, including, without limitation, registering the study with relevant government agencies and websites (e.g., clinicaltrials.gov). In addition, Investigators must share and report any support provided to them.

Areas of Interest

Currently, PTI is interested in ISS proposals in the following areas of interest. Please note that this list does not guarantee an ISS proposal in these areas of interest will be approved. Investigators may still submit ISS proposals in other areas of interest.

Established Areas of Interest	Ferric derisomaltose	Trilaciclib
Real-World Evidence, including:		
- Health Economics and Outcomes Research	Submissions Preferred	Submissions Preferred
- Improving Patient Quality of Life	Submissions Preferred	Submissions Preferred
- Reducing Logistical Toxicity	Submissions Preferred	Submissions Preferred
Safety of IV Iron, including:		
- Hypophosphatemia		
- Infusion Reactions		
- Hypersensitivity Reactions		
Special Populations with Iron Deficiency with or without Anemia:		
- Hereditary Hemorrhagic Telangiectasia	Submissions Preferred	
- Heart Failure		
- Chemotherapy-Induced Anemia Treatment	Submissions Preferred	
- Abnormal Uterine Bleeding		
- Pregnancy		
- Postpartum Hemorrhage		
- Perioperative and Patient Blood Management	Submissions Preferred	
Prevention of Chemotherapy-Induced Myelosuppression (CIM):		
- In patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with new(er) therapies where trilaciclib has not been previously studied		Submissions Preferred
- Other tumors in which trilaciclib has not been previously studied		Submissions Preferred
Effect on Overall Survival, Progression Free Survival, or other marker:		
- In combination with treatments for tumors where trilaciclib has not been previously studied		Submissions Preferred

If you have additional questions about the ISS program, please contact your local MSL or email PTI at ISS@Pharmacosmos.us