

Expanded Access Policy

Lipocine Inc. is a biopharmaceutical company focused on developing innovative therapy options for metabolic, endocrine, and central nervous system disorders using its proprietary drug delivery technologies. The company has advanced one of its clinical candidates LPCN 1148, an oral prodrug of bioidentical testosterone, for the treatment of sarcopenia in patients with decompensated cirrhosis through a Phase 2 clinical trial.

Lipocine is currently in the planning stages of a Phase 3 clinical study; therefore, clinical trial programs are the primary way to access the Lipocine investigational medicine, LPCN 1148. We recognize that there may be situations where a patient with a serious or life-threatening condition will not qualify for upcoming LPCN 1148 clinical trial(s) and may seek access to an investigational medicine outside of a clinical trial setting. This process is known as expanded access, treatment use, or compassionate use. Per FDA, Expanded Access may be appropriate when all the following apply:

- A patient has a serious disease or condition, or a patient's life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefits justify the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

Currently Lipocine is not making its investigation drug, LPCN 1148, available on an Expanded Access basis prior to FDA approval. Lipocine may reconsider making LPCN 1148 available through an Expanded Access Program in the future.

As authorized by the 21st Century Cures Act, Lipocine may revise this Expanded Access Policy at any time. The posting of this policy by Lipocine shall not serve as a guarantee of access to any specific investigational medicine by any individual patient.

If you have additional questions, please speak with your treating physician or contact Lipocine at EAP@Lipocine.com.