EXPANDED ACCESS POLICY

Lipella Pharmaceuticals, Inc. is a biotechnology company dedicated to the discovery and development of supportive care to cancer survivors who acquire hemorrhagic cystitis. Currently, Lipella's clinical product candidates are in clinical development, not yet approved by health authorities, such as the U.S. FDA, and therefore are "investigational drugs." This phase of development means that more clinical studies are required and that health authorities have not yet found these products to be safe and effective for their specific use. We are focused on enrolling and conducting the clinical trials necessary to gain regulatory approvals to make our products available to patients as quickly as possible.

It is the FDA's position that, whenever possible, an investigational drug should be used as part of a clinical trial. Therefore, Lipella's clinical trial programs are the primary way to access our investigational drugs prior to regulatory approval and we encourage patients to speak with their doctors to determine potential benefits, risks and eligibility to participate in such a clinical trial.

At the same time, we understand that there are patients who will not eligible for our clinical trials and may not have options for effective alternative therapies. In these circumstances, Lipella will consider providing a requesting physician with pre-approval access to a Lipella investigational product for the treatment of an individual patient outside of a clinical trial.

In cases where a clinical trial isn't an option, and the patient has exhausted all available treatment options, FDA may grant permission for us to provide a treating physician with an investigational drug pre-approval. Such individual use of an investigational drug pre-approval is often called "expanded access" or "compassionate use" but may go by other names. Lipella refers to these requests as expanded access.

Expanded Access may be appropriate when certain conditions are met. These conditions include, but are not limited to, the following:

1. Patient has a serious disease or condition, or whose life is immediately threatened.
2. There is no similar or satisfactory alternative therapy to treat the disease or condition.
3. Enrollment in a clinical trial is not possible.
4. Possible patient benefit justifies the possible risks of treatment with investigational drugs.
5. Providing the investigational medical product will not affect the investigational trials.

If you are a patient who is interested in accessing our investigational products, please speak with your physician. You may also learn more about ongoing clinical trials by going to www.clinicaltrials.gov and searching for Lipella Pharmaceuticals.

If you are a physician who is interested in learning more about our investigational products, or participating in our clinical trials, please submit a request to info@lipella.com

Lipella Pharmaceuitcals cannot guarantee access to investigational products. Each request will be given careful consideration by Lipella, whose decisions are final.