Proposed Expanded Access Policy

We are deeply committed to developing a new class of regenerative tissue products that accelerate healing of large bone defects, bone non-union and spine fusion in a single treatment. To bring these innovative investigational therapies to patients we conduct rigorous clinical trials. This is to enable us to obtain marketing approval by the FDA and other regulatory authorities.

Whenever possible, an investigational medical product should be used as part of a clinical trial. However, if patient enrolment is not possible or enrolment in a clinical trial is not feasible, expanded access offers a possible route for gaining access to an investigational medical product.

Expanded access may be appropriate when all the following apply:

- Patient has a serious or immediately life-threatening disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrolment in a clinical trial is not possible.
- Potential patient benefit justifies 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.

At the present time, Novadip believes that the best way for patients to access our investigational products is through clinical trials designed to evaluate their safety and efficacy. Accordingly, we are currently not accepting expanded access use requests. We will re-evaluate this policy in the future.

For information our clinical trials, please visit www.clinicaltrials.gov

If you have any questions about the Expanded Access Policy, please email info@novadip.com We anticipate replies may be provided within five business days.

NOVADIP Biosciences s.a.
Rue Granbonpré 11
1435 Mont-Saint-Guibert
Belgium
T +32 10 77 92 20
www.novadip.com