

Biocomposites expanded access policy for STIMULAN VG

Biocomposites is dedicated to developing new therapies that have a positive impact on patient health, and to serving patients, patient families and patient communities through education, empathy, and awareness.

Consistent with Biocomposites' mission to bring innovative medicines to patients with serious or life-threatening illnesses or conditions, we are focused on enrolling and conducting the clinical trials necessary to gain regulatory approvals to make our medicines available broadly to patients as quickly as possible. We are privileged to collaborate with clinical investigators and with patients who participate in our studies to develop new, safe and effective therapies. We believe this approach will serve patients who could be helped by the therapies we are developing. At the same time, we understand that there are seriously ill patients who will not be eligible for our clinical trials and may not have options for alternative therapies, including investigational therapies in trials being conducted by other sponsors. In these circumstances, Biocomposites will consider providing a requesting physician with pre-approval access to STIMULAN VG, for the treatment of an individual patient outside of a clinical trial, when certain conditions are met. These conditions include the following:

- The patient has a serious or life-threatening illness or condition and is either no longer responsive to or no longer able to tolerate any available treatment option;
- The investigational drug is in active clinical development with sufficient data available to determine an appropriate dose and schedule for the patient's specific condition;
- A benefit-risk analysis, based on both the available clinical data as well as the requesting physician's assessment of the individual patient's condition and history, supports making the investigational drug available;
- Making the investigational drug available will not negatively impact or delay the conduct of clinical trials or regulatory review or approval of the investigational drug for broader patient access; and
- Adequate supply of the investigational drug is available.

We continually evaluate the benefit-risk profile of each of our investigational drugs based on evolving clinical data. Each compound under development is different and the fact that one investigational drug is made available for the treatment of a particular patient does not mean it will be made available in response to other requests on behalf of other patients whose circumstances and medical histories may be different, or that a different investigational drug will be made available under our policy. Requests will be considered on a case-by-case basis.

Biocomposites is committed to evaluating all requests in a fair and equitable manner. All requests must be submitted by the patient's treating physician; Biocomposites may require more detailed information in order to fully evaluate a request. The requesting physician must agree to obtain appropriate regulatory and ethics committee approvals and comply with regulatory obligations, including obtaining patient consent, patient monitoring and safety reporting. Each request will be given careful consideration by Biocomposites whose decisions are final.

Physicians seeking pre-approval access for patients with no alternative treatment options should submit their requests to expandedaccess@biocomposites.com

We regularly monitor this mailbox and will use our best efforts to respond to each submitted request within 5 business days of receipt.