Expanded Access to Moleculin Biotech Investigational Agents Form

Please download the Expanded Access form, answer each question, acknowledge the certification, and email the completed form to: expandedaccess@moleculin.com. PLEASE DO NOT INCLUDE ANY PATIENT MEDICAL RECORDS WITH THIS APPLICATION.

Physician Information

a. Country:

b. Requesting physician's Name:

c. Title:

d. Organization/Affiliation:

e. Medical field:

f. Medical license # (if applicable in physician's country):

g. DEA # (if applicable):

h. Requesting physician's address:

i. Requesting physician's phone number:

j. Requesting physician's email:

k. Investigational product requested (and dose/length of therapy?):

l. Has the patient received the requested product previously in a clinical trial setting: ☐ Yes ☐ No

m. Rationale (Please include your medical opinion about the medical benefit the investigational product may provide to the patient):

Patient Eligibility

Have you read the criteria below and to the best of your knowledge, you believe this patient and medicine being requested meet these criteria?

☐ Yes ☐ No

- *The patient suffers from a life threatening or serious disease or condition, where there is an unmet medical need that cannot be met by existing products.*
- *The patient is ineligible or unable to participate in any ongoing clinical study of the investigational product.*
- *The investigational product is under active development and has not been placed on regulatory or any other hold.*
- *The benefit-risk profile of the drug in the indication and the patient population is deemed, to date, to be positive.*
- *The use of the investigational product in an expanded access protocol is compliant with local rules and regulations.*

Certification

- I certify that I am a treating physician.

- I certify the information provided in this application is complete and accurate to the best of my knowledge, and that once the investigational product requested under the Moleculin Biotech Expanded Access Program is approved for release to this patient, I will be responsible for supervising the patient's treatment. I understand and certify that all units of any investigational product shipped to me pursuant to this application will be provided to the above-named patient only, for his or her treatment, and will not be sold or otherwise distributed and that no patient or third party (including, but not limited to, Medicare (in the US) and any other governmental programs) shall be charged for such product. Additionally, no units of this investigational product will be submitted to Medicare/Medicaid in the US, or to any public or private third-party for reimbursement, or returned for credit. I understand eligibility under this program is subject to the Moleculin Biotech Expanded Access Program's approval and the patient's continuing compliance with all eligibility requirements, as set by Moleculin Biotech.

- For those in the European Union (EU), we would like to inform you about the introduction of the new European regulation (law) about personal data. This is known as the General Data Protection Regulation (GDPR). We are required to provide you with the following information under the new regulation:
  - Under the General Data Protection Regulation (GDPR) and specifically in relation to your personal information, we would like to provide you the following additional information:
    - The processing of your personal information is carried out under the responsibility of the data controller which is Moleculin Biotech, Inc.
    - If you have any questions or concerns about your personal data protection rights or a complaint about the use of your personal information direct your questions to the Data Representative, when necessary:

Moleculin Biotech, Inc.

5300 Memorial Drive, Suite 950

Houston, TX, 77007

(713) 300-5160

- If you feel that any of your concerns have not been addressed to your satisfaction, you also have the right to complain about the processing of your personal information to your national data protection authority.
- In addition, you also have the right to request information about the data stored about you and to request correction in case you discover errors.

☐ Agree ☐ Disagree