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Moleculin Receives FDA Approval of Fast Track Designation for Annamycin in the Treatment of Sarcoma Lung Metastases

HOUSTON, March 30, 2021 /PRNewswire/ -- Moleculin Biotech, Inc., (Nasdaq: MBRX) (Moleculin or the Company), a clinical stage pharmaceutical company with a broad portfolio of drug candidates targeting highly resistant tumors and viruses, today announced that the U.S. Food and Drug Administration ("FDA") has approved its request for Fast Track Designation for its drug, Annamycin, for the treatment of soft tissue sarcoma (STS) lung metastases.

"We are pleased to receive our second Fast Track Designation from the FDA for Annamycin. We now have potential pathways for accelerated approval in two indications, STS lung metastases, and the treatment of relapsed or refractory acute myeloid leukemia," commented Walter Klemp, Moleculin's Chairman and CEO. "Not only does this make us eligible for accelerated approval and priority review for our NDA submission, but it serves as an important reminder of the unmet need in STS lung metastases. We are now focused on initiating our internally funded clinical trial in the US, possibly prior to mid-year. In addition, we recently announced a $1.5 million grant awarded in Poland for an investigator initiated clinical trial there for this indication which should start later this year."

A drug that receives *Fast Track* designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for *Accelerated Approval and Priority Review, if relevant criteria are met*
- *Rolling Review*, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

Soft tissue sarcomas are the most common form of sarcoma, accounting for an estimated 130,000 incident cases per year worldwide. While many sarcomas can be addressed

through surgical removal, it is estimated that as many 20% to 50% of STS sarcomas will eventually metastasize to the lungs, where treatment can become more challenging.

Once metastasized to the lungs, if tumors cannot be surgically removed, the primary chemotherapy regimen is the anthracycline doxorubicin (also known as Adriamycin). While 10% to 30% of patients with sarcoma lung metastases may initially respond to doxorubicin, most will relapse leaving the majority of these patients without an alternative chemotherapy. Treatment options are further limited because of the inherent cardiotoxicity of currently approved anthracyclines, including doxorubicin, which limits the amount of anthracycline that can be given to patients.

Annamycin is a "next generation" anthracycline that has recently been shown in animal models to accumulate in the lungs at up to 30-fold the level of doxorubicin. Importantly, Annamycin has also demonstrated a lack of cardiotoxicity in recently conducted human clinical trials for the treatment of acute myeloid leukemia, so we believe that the use of Annamycin may not face the same usage limitations imposed on doxorubicin.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses. The Company's clinical stage drugs are: Annamycin, a Next Generation Anthracycline, designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic cancer and hematologic malignancies, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in preclinical development of additional drug candidates, including other Immune/Transcription Modulators, as well as WP1122 and related compounds capable of Metabolism/Glycosylation Inhibition.

For more information about the Company, please visithttp://www.moleculin.com.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability of Annamycin to demonstrate safety and efficacy in patients, the ability of Moleculin to commence a clinical trial in the United States prior to mid-year, the ability of the investigator initiated clinical trial in Europe for STS to commence later this year, the ability of clinical trials to begin recruiting patients on a timely basis, and whether Annamycin will receive New Drug Approval. Although Moleculin believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Moleculin has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words

that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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