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Moleculin Announces 100% Survival Achieved in Osteosarcoma Lung Metastases Animal Model

Annamycin shown to reach "sanctuary sites" of cancer

HOUSTON, Feb. 2, 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 a preclinical study in animals demonstrated a potentially significant therapeutic benefit of Annamycin against metastatic osteosarcoma. This appears to be the result of the high cytotoxic potential of Annamycin previously demonstrated in vitro against sarcoma cells in combination with its high uptake by the lungs where the tumors in this study are localized. Computerized tomography (CT) scans demonstrated that animals treated with Annamycin exhibited significant suppression of tumor growth and not a single death was observed in the treated animals, whereas significant tumor burden contributed to the rapid death of 90% of untreated animals. While the study continues, as of day 130, the survival rate for animals treated with Annamycin was 100%, compared with only 10% for untreated animals.

Osteosarcoma is among a class of tumors that initiate in the bone of patients, with bone-related sarcomas representing the second most common form of sarcoma after soft tissue sarcoma. While many bone sarcomas can be addressed through surgical removal, it is estimated that as many as 40% of bone sarcomas will eventually metastasize to the lungs, where treatment can become more problematic. Researchers have more recently referred to the lungs and certain other vital organs as "sanctuary sites" for cancer where tumors can develop out of reach from conventional chemotherapies.

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. Moleculin recently announced findings from its sponsored research showing that doxorubicin has a limited ability to accumulate in the lungs of animals, which may help explain its limited efficacy in this sanctuary site. 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 34 times the level of doxorubicin, which may account for the 100% survival rate attained in this most recent osteosarcoma lung metastases study. Importantly, Annamycin has also demonstrated a lack of cardiotoxicity in recently conducted human clinical trials of Annamycin for the treatment of acute myeloid leukemia, so the use of Annamycin may not face the same dose limitations imposed on doxorubicin.

Moleculin recently announced that the FDA has allowed the Company's request for investigational new drug (IND) status in order to study Annamycin for the treatment of soft tissue sarcoma metastasized to the lungs. In addition, the FDA granted Orphan Drug Designation for Annamycin for the treatment of soft tissue sarcomas.

"Our ongoing sponsored research continues to expand the potential uses for Annamycin," commented Walter Klemp, Chairman and CEO of Moleculin. "We expect that one, and potentially two, clinical trials in sarcoma lung metastases should be up and running this year."

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 and the ability for Moleculin to commence any clinical trials during 2021. 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 Biotech 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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