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Moleculin Announces First Subject Enrolled and Dosed in Phase 1b/2 Clinical Trial of Annamycin for the Treatment of Sarcoma Lung Metastases

- Annamycin granted Fast Track Status and Orphan Drug Designation from FDA for the treatment of soft tissue sarcoma lung metastases

- Interim data expected in the second half of 2022

HOUSTON, June 21, 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 it has commenced enrollment and dosed the first subject in its U.S. Phase 1b/2 clinical trial evaluating Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases.

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 of STS sarcomas will eventually metastasize to the lungs, where treatment can become more challenging. Recently published animal data suggests that the efficacy of the current standard of care chemotherapy (doxorubicin) may be limited due to its inability to accumulate sufficiently in the lungs. The use of doxorubicin and other currently approved anthracyclines for STS lung metastases is further limited due to their inherent cardiotoxicity, which limits the amount of anthracycline that can be given to patients.

"We are pleased to have commenced patient enrollment and dosing in this important program evaluating Annamycin, which we believe has the potential to address the limitations with current treatment options for STS lung metastases. Our team is commited to driving continued progress for the development of Annamycin. We look forward to getting the trial well-underway toward interim data and potentially address the unmet medical needs in the treatment of these highly resistant tumors," commented Walter Klemp, Chairman and CEO of Moleculin.

The Phase 1b/2 study is a a U.S. multi-center, open-label, single-arm study that in Phase 1b will determine the maximum- tolerated dose (MTD) or the recommended Phase 2 dose (RP2D) and safety of Annamycin and in Phase 2 will explore the efficacy of Annamycin as a single agent for the treatment of subjects with STS with lung metastases for which chemotherapy is considered appropriate. A minimum of 3 subjects for each dosing cohort will be enrolled in the Phase 1b portion of the study until an MTD is identified. A maximum of 25 subjects will be enrolled at the RP2D to further evaluate efficacy.

"With limitations in the current treatment landscape for STS, there remains significant unmet need for patients and physicians. We are pleased to see the progress of this important study to evaluate Annamycin, which has demonstrated a lack of cardiotoxicity in recent human clinical trials, one of which is ongoing. I continue to be encouraged by the data seen to date and look forward to the continued advancements of this study toward offering potential hope to patients battling this difficult to treat cancer," added Sant P. Chawla MD, Director, Sarcoma Oncology Center, Director, Cancer Center Of Southern California.

Annamycin is the Company's next-generation anthracycline that has 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 (AML), and the Company believes that the use of Annamycin may not face the same usage limitations imposed on doxorubicin. Annamycin is currently in development for the treatment of AML and STS lung metastases.

Annamycin has been granted Fast Track Status and Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of STS lung metastases.

For more information about the Phase 1b/2 study evaluating Annamycin for the treatment of STS lung metastases, please visit clinicaltrials.gov and reference identifier NCT04887298.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of drug candidates for the treatment of highly resistant tumors and viruses. The Company's lead program, Annamycin is a next-generation anthracycline designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity. Annamycin is currently in development for the treatment of relapsed or refractory acute myeloid leukemia (AML) and soft tissue sarcoma (STS) lung metastases.

Additionally, the Company is developing 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 and other cancers, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in the development of a portfolio of antimetabolites, including WP1122 for the potential treatment of COVID-19 and other viruses, as well as cancer indications including brain tumors, pancreatic and other cancers.

For more information about the Company, please visitwww.moleculin.com and connect on Twitter, LinkedIn and Facebook.

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 clinical trials to begin recruiting patients on a timely basis, the timing of the disclosure of interim data in the second half of 2022, 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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