September 9, 2020

Moleculin Announces Successful Completion of Pre-IND Meeting with the FDA

Intends to file an IND using Annamycin for the Treatment of Soft Tissue Sarcomas with Lung Metastases by Year-End

HOUSTON, Sept. 9, 2020 /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 it successfully completed a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding the development plan for Annamycin, including the clinical study design and dosing strategy for the initial phase 1b/2 protocol for soft tissue sarcomas with lung metastases.

Moleculin submitted a proposed clinical protocol for FDA review entitled, "Phase 1b/2 Study of Liposomal Annamycin (Annamycin) in Subjects with Previously Treated Soft-Tissue Sarcomas with Pulmonary Metastases." The proposed study is an open-label, multicenter, single-arm, dose escalation and expansion study to evaluate single-agent Annamycin in up to 55 patients with soft tissue sarcoma (STS) with lung metastases for whom chemotherapy is considered appropriate. The primary objectives of the dose escalation phase are to evaluate the safety of Annamycin and identify the maximum tolerated dose (MTD) or the recommended Phase 2 dose (RP2D).

In summary, the FDA, among other items:

- did not object to the proposed clinical study design while providing guidance on additional assessments
- agreed the proposed dose escalation schedule appeared reasonable
- commented regarding the consideration for including adolescents in oncology clinical trials
- stated that a repeat dose toxicology study of 3 months is required before initiating a registration study
- recommended an EOP1 meeting after completion of the RP2D.

"We are pleased to complete the pre-IND meeting with the FDA, and will move forward with our plans to file the IND by the end of 2020 and initiate a Phase 1b/2 trial of Annamycin for the treatment of soft tissue sarcomas metastasized to the lungs," said Wally Klemp, Chief Executive Officer of Moleculin. "We appreciate the FDA's guidance as we endeavor to find a cure for certain cancers metastasized to the lungs."

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, being studied for brain tumors, pancreatic cancer and hematologic malignancies; and WP1220, an analog to WP1066, being studied for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as compounds capable of Metabolism/Glycosylation Inhibition, such as WP1122. Moleculin has the exclusive worldwide rights (subject to certain territories for which it has issued sublicenses) to all of the above technologies.

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 Company's ability to obtain an IND for Annamycin and the ability of Annamycin to be shown safe and effective for the treatment of STS with lung metastases. 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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