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Moleculin Increases Annamycin Production Due to Positive Clinical Trial Activity and Expanded Potential Indications

Expansion of potential indications includes lung-localized tumors

HOUSTON, Oct. 22, 2019 /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, today announced the expansion of Annamycin production commitments in response to management's assessment of positive AML clinical trial activity and the potential expansion of indications for use to include lung-localized tumors. The purchase commitment arranged through Davos Pharmaceuticals includes moving final production of Annamycin to a larger-scale suite within BSP Pharmaceuticals S.p.A. ("BSP") in Latina, Italy. Until now, BSP has been producing the clinical supplies of Annamycin in a smaller pilot-scale suite.

"Our clinical trials of Annamycin in relapsed and refractory acute myeloid leukemia ("AML") have been going better than expected, as it now appears we will be able to reach a higher maximum tolerable dose than what was established in previous clinical trials," commented Walter Klemp, Moleculin's Chairman and CEO. "That not only increases our chances for improved patient outcomes, it places a higher demand on drug supply. Coupled with the recent discovery in animal models that Annamycin may be well suited to treat lung-localized tumors because of its ability in such models to accumulate in the lungs at nearly 6 times the level of the current standard of care anthracycline, we are clearly going to need more drug."

Dr. Donald Picker, Moleculin's Chief Science Officer added: "With management's view of success in clinic and the expectation of wider demand resulting from additional clinical trials in lung-localized tumors, it's time for Moleculin to start preparing for an eventual drug approval process. That requires the development and validation of commercial scale methods and this move with BSP marks the beginning of that process. In addition to increasing the scale of clinical supply production, we will be working with BSP and with our manufacturer of API to develop the commercial scale synthesis and drug production methods we will need to ultimately prepare for New Drug Approval."

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. 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 additional Immune/Transcription Modulators, as well as 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 show safety and efficacy in patients and the ability of the Company and its contractors to develop commercial scale production of Annamycin and to 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 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. The Company cautions investors not to place undue reliance on the interim results announced today.

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