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Moleculin Announces Annamycin Receives FDA Orphan Drug Designation for Soft Tissue Sarcomas

HOUSTON, Dec. 29, 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 the US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Annamycin for treatment of soft tissue sarcomas.

Moleculin recently announced that the FDA had allowed its request for Investigational New Drug (IND) status for Annamycin, allowing Moleculin to begin a Phase 1B/2 clinical trial in the US for patients with soft tissue sarcoma (STS) that has metastasized to the lungs after first-line therapy for their disease. The rationale for this clinical trial includes recent animal data, including data presented at the American Association of Cancer Research (AACR) Annual Meeting held June 22nd- 24th, 2020, and data from an independent laboratory announced on October 21, 2020, which demonstrated that Annamycin is capable of reaching 6 to 34-fold higher levels of accumulation in the lungs than that of doxorubicin, the primary first-line chemotherapy for STS. Additionally, clinical data show no cardiotoxicity associated with the use of Annamycin, as well as the ability to avoid multidrug resistance mechanisms, both of which are often treatment-limiting effects of anthracyclines (which includes doxorubicin) in this setting. Taken together, these factors suggest that Annamycin could represent an important treatment to help address a significant unmet need in patients with STS lung metastases.

"This is now the second Orphan Drug designation for Annamycin, as Annamycin previously received ODD for the treatment of relapsed or refractory acute myeloid leukemia," commented Walter Klemp, Chairman and CEO of Moleculin. "We believe this continues to show how the breadth of our pipeline affords us 'multiple shots on goal' and therefore multiple opportunities to create shareholder value."

The FDA grants orphan drug designation to drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including tax credits for qualified clinical trials costs, exemptions

from certain FDA application fees, and seven years of market exclusivity upon regulatory product 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 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 Moleculin to receive the benefits of the Orphan Drug designation, some of which require FDA approval of Annamycin for the Orphan Drug indication, and the ability of Annamycin to demonstrate safety and efficacy in patients. 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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