Moleculin Engages CRO to Begin Clinical Trials of WP1220 for the Treatment of Cutaneous T-Cell Lymphoma

HOUSTON, TX -- (Marketwired) -- 09/13/17 -- Moleculin Biotech, Inc., (NASDAQ: MBRX) ("Moleculin" or the "Company"), a preclinical pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, today announced it has engaged contract research organization ("CRO") Bioscience SA ("Bioscience") to prepare for a proof-of-concept clinical trial in Poland to study its drug candidate WP1220 for the treatment of cutaneous T-cell lymphoma ("CTCL").

"We believe we are in a position to move quickly to develop WP1220," commented Walter Klemp, Chairman and CEO of Moleculin. "We have a complete IND-enabling data package already, so we should be able to make application soon to the Polish regulatory authorities for a clinical trial authorization. In this case, we believe a proof-of-concept trial in Poland can be completed sooner and for less investment than in the US, giving us a very efficient means to develop yet another asset in our portfolio. As well, success with this trial could help us position WP1220 for accelerated approval in the US."

CTCL is a rare life-threatening skin cancer with limited treatment options. Pre-clinical studies have suggested that some CTCL cell lines may be particularly sensitive to inhibition of the activated form of STAT3, something for which the Company believes WP1220 is especially well suited. The Company's initial approach will be to administer WP1220 as a topical drug to Stage 1 through 2a patients in an effort to inhibit the progression of the disease.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a preclinical stage pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on discoveries made at M.D. Anderson Cancer Center. Our lead product candidate is Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML. We also have two preclinical small molecule portfolios in development, one of which is focused on the modulation of hard-to-target tumor cell signaling mechanisms and the recruitment of the patient's own immune system. The other portfolio targets the metabolism of tumors.

For more information about the Company, please visit http://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 potential for WP1220 to become an effective treatment for CTCL and the ability of the Company to obtain Polish regulatory approvals to commence clinical trials. These statements relate to future events, future expectations, plans and prospects. Although Moleculin Biotech 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.

Contacts