

April 6, 2021



Moleculin Engages IQVIA to Manage Potential COVID-19 Clinical Trial

HOUSTON, April 6, 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 the engagement of IQVIA Biotech, a contract research organization (CRO) to manage the Company's effort to begin potential clinical trials of WP1122 for the treatment of COVID-19.



"Our teaming up with IQVIA, a preeminent, global CRO, is intended to facilitate the advancement into possible clinical trials for WP1122 with the objective of determining our drug's potential for treating COVID-19," commented Walter Klemp, Moleculin's Chairman and CEO. "We continue to believe the best possible pathway for development may be outside the US, given the FDA's requirement that we complete an analysis in a COVID-19 animal model before submitting a request for US investigational new drug (IND) status. Unfortunately, validated COVID-19 animal models are in high demand, resulting in a long lead time before that can be done. In the meantime, we believe all of the necessary preclinical safety testing has now been completed to qualify for the equivalent of an IND outside the US. Over the last quarter, we completed our pre-clinical data, interviewed CRO's and decided that IQVIA Biotech has the experience and reach to best serve our clinical needs for this project. In addition, considering that the active ingredient in WP1122 is 2-deoxy-D-glucose (2-DG) and that 2-DG has now shown efficacy in a Phase 2 clinical trial conducted by an unrelated drug developer outside of the US, we believe that a sufficient efficacy rationale for WP1122 already exists to begin clinical trials."

WP1122 is a prodrug of 2-DG, a well-known antimetabolite with the ability to inhibit glycolysis and alter glycosylation, two processes critical to coronaviruses like SARS-CoV-2, the virus responsible for COVID-19. Although 2-DG has shown activity against SARS-CoV-2, other coronaviruses and other non-coronaviruses, we believe its therapeutic potential is limited by its inherent lack of drug-like properties. WP1122 was designed to improve the drug-like characteristics of 2-DG, specifically, increasing circulation time and tissue and organ uptake and concentration (often referred to as improved "pharmacokinetics"). Moleculin has sponsored multiple in vitro analyses showing activity of WP1122 against coronaviruses superior to that of 2-DG alone, as well as preclinical animal tumor models (WP1122 was originally developed as a potential cancer drug) showing the improved pharmacokinetics of WP1122.

For additional information on WP1122 and its potential to treat both viruses and cancers, please visit <http://www.moleculin.com>.

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 visit <http://www.moleculin.com>.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. IQVIA creates intelligent connections across all aspects of healthcare through its analytics, transformative technology, big data resources and extensive domain expertise. IQVIA Connected Intelligence™ delivers powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 70,000 employees, IQVIA conducts operations in more than 100 countries.

IQVIA is a global leader in protecting individual patient privacy. The company uses a wide variety of privacy-enhancing technologies and safeguards to protect individual privacy while generating and analysing information on a scale that helps healthcare stakeholders identify disease patterns and correlate with the precise treatment path and therapy needed for better outcomes. IQVIA's insights and execution capabilities help biotech, medical device and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders tap into a deeper understanding of diseases, human behaviour and scientific advances, in an effort to advance their path toward cures. To learn more, visit www.iqvia.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 obtain approval for the foreign equivalent of an IND for WP1122 and the ability of WP1122 to show safety and efficacy in COVID-19 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 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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