



RespireRx Pharmaceuticals Inc. Announces Publication of Preclinical Results Supporting the Use of Ampakines in the Treatment of Spinal Cord Injury

Glen Rock, N.J., October 6, 2020 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) (“RespireRx” or the “Company”), a leader in the discovery and development of innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling, is pleased to announce the publication by Dr. David Fuller and his colleagues of a review article entitled “Ampakines Stimulate Phrenic Motor Output after Cervical Spinal Cord Injury” in a special issue of the peer-reviewed journal, *Experimental Neurology* (https://authors.elsevier.com/a/1boWx_L5Mw1dO). In studies funded by grants from the National Institutes of Health, Dr. Fuller, a long-time RespireRx collaborator, describes the ability of CX717, one of the Company’s lead ampakines, to improve motor nerve function in an animal model of spinal cord injury. CX717 improved the electrical activity of the phrenic motor nerve when recorded below the site of the spinal injury, an effect which increased over the course of 8 weeks.

According to Dr. Fuller, “Autonomic and cardiovascular dysfunctions are of paramount concern in persons with spinal cord injury. In our preclinical studies, we have measured the activity of the phrenic motor nerve, which activates breathing by stimulating the diaphragm. Our data shows that ampakines very effectively stimulate neural drive to the diaphragm after spinal cord injury. Ampakines may, therefore, be of use in the treatment of spinally damaged patients, particularly during rehabilitation.”

Arnold Lippa, Ph.D., Chief Scientific Officer and Executive Chairman of the Board of Directors said, “Our ongoing ampakine collaboration with Dr. Fuller is a part our overall neuromodulator program to discover and develop novel drugs for the treatment of psychiatric and neurological disorders. The research results from Dr. Fuller’s laboratory add considerable support for our intention to translationally extend this work to human clinical trials.”

About RespireRx Pharmaceuticals Inc.

RespireRx Pharmaceuticals Inc. is a leader in the discovery and development of medicines for the treatment of psychiatric and neurological disorders, with a focus on treatment options that address conditions affecting millions of people, but for which there are few or poor treatment options, including obstructive sleep apnea (“OSA”), attention deficit hyperactivity disorder (“ADHD”), epilepsy, chronic pain and recovery from spinal cord injury (“SCI”), as well as certain neurological orphan diseases. RespireRx is developing a pipeline of new drug products based on our broad patent portfolios for two drug platforms: (i) pharmaceutical cannabinoids, which include dronabinol, a synthetic form of Δ 9-tetrahydrocannabinol (“ Δ 9-THC”) that acts upon the nervous system’s endogenous cannabinoid receptors and (ii) neuromodulators, which include ampakines and GABAkinines, proprietary compounds that positively modulate (positive allosteric modulators or “PAMs”) AMPA-type glutamate receptors and GABA_A receptors, respectively

The Company holds exclusive licenses and owns patents and patent applications or rights thereto for certain families of chemical compounds that claim the chemical structures and their uses in the treatment of a variety of disorders, as well as claims for novel uses of known drugs.

Pharmaceutical Cannabinoids

RespireRx is developing dronabinol, Δ 9-tetrahydrocannabinol (Δ 9-THC), a synthetic version of the naturally occurring substance in the cannabis plant, for the treatment of OSA, a serious respiratory disorder that impacts an estimated 29.4 million people in the United States according to the American Academy of Sleep Medicine (“AASM”),

published in August 2016. OSA has been linked to increased risk for hypertension, heart failure, depression, and diabetes, and has an annual economic cost in the United States of \$162 billion according to the AASM. There are no approved drug treatments for OSA.

Two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms of OSA and, subject to raising sufficient financing (of which no assurance can be provided) and pending the outcome of an intended meeting with the FDA, RespireRx believes that it will be able to commence a pharmacokinetic study for a to-be-developed new formulation followed by a Phase 3 clinical study for the treatment of OSA with the new formulation. Because dronabinol is already FDA approved for the treatment of AIDS related anorexia and chemotherapy induced nausea and vomiting, the Company further believes that its re-purposing strategy would only require approval by the FDA of a 505(b)(2) new drug application (“NDA”), an efficient regulatory pathway that allows the use of publicly available data.

Neuromodulators

AMPAkines. Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the Company has developed a family of novel, low impact ampakines, including CX717, CX1739 and CX1942 that may have clinical application in the treatment of CNS-driven neurobehavioral and cognitive disorders, spinal cord injury, neurological diseases, and certain orphan indications. From our ampakine platform, our lead clinical compounds, CX717 and CX1739, have successfully completed multiple Phase 1 safety trials. Both compounds have also completed Phase 2 proof of concept trials demonstrating target engagement, by antagonizing the ability of opioids to induce respiratory depression.

Ampakines have demonstrated positive activity in animal models of ADHD, results that have been extended translationally into statistically significant improvement of symptoms observed in a Phase 2 human clinical trial of CX717 in adults with ADHD. At present, the major pharmacotherapies available for ADHD are made up of two types of drugs. Stimulants, such as amphetamine, rapidly produce robust effects, but suffer from side effects typical of stimulants, including tolerance, dependence, withdrawal and abuse. For these reasons, stimulants are scheduled by the FDA. Non-stimulants, such as Strattera® (atomoxetine) tend to be less effective than stimulants, with a much longer (approximately 4 – 8 week) latency to onset of action. In a number of animal and human studies, CX717 and other ampakines did not display any stimulant properties typically associated with drugs like amphetamine. In the Phase 2 ADHD clinical trial, statistically significant therapeutic effects were observed within one week. Therefore, we believe ampakines may represent a novel, non-stimulant treatment for ADHD with a more rapid onset of action than alternative non-stimulant treatment options.

GABAkines. Under a License Agreement with the University of Wisconsin-Milwaukee Research Foundation, Inc. (“UWMRF”), an affiliate of the University of Wisconsin-Milwaukee, RespireRx has licensed rights to certain selectively acting GABAkines that have shown impressive activity in a broad range of animal models of refractory/drug resistant epilepsy and other convulsant disorders, as well as in brain tissue samples obtained from epileptic patients. Epilepsy is a chronic and highly prevalent neurological disorder that affects millions of people world-wide. While many anticonvulsant drugs have been approved to decrease seizure probability, seizures are not well controlled and, in as many as 60-70% of patients, existing drugs are not efficacious at some point in the disease progression. We believe that the medical and patient communities are in clear agreement that there is desperate need for improved antiepileptic drugs. In addition, these GABAkines have shown positive activity in animal models of migraine, inflammatory and neuropathic pain, as well as other areas of interest. Because of their GABA receptor subunit specificity, the compounds have a greatly reduced liability to produce sedation, motor incoordination, memory impairments and tolerance, side effects commonly associated with non-specific GABA PAMs, such as Valium® and Xanax®.

Additional information about the Company and the matters discussed herein can be obtained on the Company's website at www.RespireRx.com or in the Company's filings with the Securities and Exchange Commission at www.sec.gov.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act. In some cases, you can identify forward-looking statements by the following words: "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words, and such statements may include, but are not limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company's product candidates, (iv) reorganization plans, and (v) the need for, and availability of, additional financing. Forward-looking statements are not a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this report.

These factors include but are not limited to, regulatory policies or changes thereto, available cash, research and development results, issuance of patents, competition from other similar businesses, interest of third parties in collaborations with us, and market and general economic factors, and other risk factors.

We caution investors not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to risks and uncertainties described in our reports filed with the Securities and Exchange Commission (the "SEC") and others that we may consider immaterial or do not anticipate at this time. These forward-looking statements are based on assumptions regarding the Company's business and technology, which involve judgments with respect to, among other things, future scientific, economic, regulatory and competitive conditions, collaborations with third parties, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. For more information about the risks and uncertainties the Company faces, see "Item 1A. Risk Factors" of the RespireRx Pharmaceuticals Inc. Annual Report of Form 10-K as of December 31, 2019. For more current information about the Company, see the Company's Quarterly Report on Form 10-Q as of June 30, 2020 as well as on our Forms 8-K filed or furnished in our filings with the SEC. Forward-looking statements speak only as of the date they are made. The Company does not undertake and specifically declines any obligation to update any forward-obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

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