



Flex Pharma Focuses on Phase 2 Clinical Programs in Severe Neurological Diseases

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-- Additional Proof-of-Concept Phase 2 Studies Planned to Initiate in 2017 --

-- Exploratory Phase 2 MS Study Results by Year End 2017 --

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[Flex Pharma, Inc.](#) (NASDAQ: FLKS) today announced that it is prioritizing its clinical programs in the severe neurological diseases of amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS) and peripheral neuropathies such as Charcot-Marie Tooth (CMT). The Company intends to initiate one or two additional proof-of-concept Phase 2 studies in these indications in the US this year with FLX-787, its transient receptor potential (TRP) ion channel activator, formulated as an oral disintegrating tablet. In late 2016, the Company began enrolling MS and ALS patients in two separate exploratory Phase 2 studies in Australia. These randomized, controlled, blinded, cross-over studies are designed to evaluate the safety and efficacy of FLX-787 in patients who suffer from cramps and spasticity as a consequence of their disease. The Company expects to report results from the exploratory MS study by year end 2017.

"By prioritizing our clinical programs to severe neurological diseases ahead of nocturnal leg cramps, we can focus on those patients with the greatest unmet need and accelerate our research efforts for cramps and spasticity," said Flex Pharma Chief Medical Officer Thomas Wessel, M.D., Ph.D. "In 2017, we expect to have multiple Phase 2 studies ongoing with our single agent candidate, FLX-787, with results from our MS study towards the end of the year."

"We believe that topical Chemical Neuro Stimulation, the process whereby small molecules activate TRP ion channels on sensory nerves in the oral mucosa, triggers a reflex response to inhibit the hyperexcitable motor neurons in the spinal cord and reduce muscle cramps," noted Dr. Rod MacKinnon, Nobel laureate and Flex Pharma Scientific Co-Founder, Board Member, and Scientific Advisory Board Co-Chair. "Our approach has a broad range of applications that we believe will ultimately benefit the millions of people that suffer from frequent painful muscle cramps."

"Flex is well funded through early 2019, and we are committed to executing upon our mission of helping people who suffer from painful and debilitating cramps," stated Christoph Westphal, M.D., Ph.D., Chair and CEO of Flex Pharma.

About ALS, MS and CMT

Amyotrophic lateral sclerosis (ALS) is a neurological disease that causes muscle weakness and impacts physical function. ALS often begins with muscle twitching and weakness in an arm or leg, or sometimes with slurring of speech. Eventually, ALS can affect the ability to control the muscles needed to move, speak, eat and breathe. ALS patients commonly experience fasciculations, which are persistent muscle twitches that can interfere with sleep, and over half of all patients with ALS also experience painful muscle cramps that can significantly decrease their quality of life. Based on a report published by the Centers for Disease Control, we estimate that over 12,000 people in the US suffer from ALS.

Multiple sclerosis (MS) is an autoimmune disease in which inflammatory processes cause worsening demyelination and cell degeneration over years, resulting in a variety of neurological deficits such as loss of muscle control, sensation and vision. Spasticity is caused by damage to motor systems in the brain and spinal cord. These lesions cause hyperactive muscle stretch reflexes, which result in increased muscle tone and associated symptoms such as myoclonus which are subsumed under the descriptive term spasticity. The need to treat spasticity increases as the disease progresses and go hand in hand with worsening weakness leading to complications such as contractures, bed sores and severe pain. According to the National Institute of Neurological Disorders and Stroke, between 250,000 and 350,000 people in the US suffer from MS and approximately 84% of patients with MS experience spasticity.

Charcot-Marie-Tooth (CMT) is the most common form of inherited neuromuscular disease, affecting an estimated 150,000 people in the US. It occurs in populations worldwide with a prevalence of about 1 in 2,500 individuals. The primary clinical features of this disorder are slowly progressive distal weakness, muscle atrophy affecting the feet and legs, and sensory loss. The presence of muscle cramps in hands, fingers, and other muscles commonly affected in CMT patients is consistent with the hypothesis that motor nerve dysfunction (hyperexcitability) underlies muscles cramps. A large majority of CMT patients experience muscle cramps frequently, in many muscles, which interferes with sleep, exercise and daily activities. Muscle cramps have been reported as a significant detriment to quality of life.

About Flex Pharma

Flex Pharma, Inc. is a biotechnology company that is developing innovative and proprietary treatments for cramps and spasms associated with the severe neurological diseases of ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). Flex Pharma was founded by National Academy of Science members Rod MacKinnon, M.D. (2003 Nobel Laureate), and Bruce Bean, Ph.D., recognized leaders in the fields of ion channels and neurobiology, along with Chair and CEO Christoph Westphal, M.D., Ph.D.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding current and future studies of our product candidates, including the success and timing of these studies and our beliefs regarding the potential benefits of our current product candidates. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation: the status, timing, costs, results and interpretations inherent in conducting clinical studies, including receiving regulatory approval of our

investigational new drug application required to conduct these studies; the fact that we rely on third parties to manufacture and conduct the clinical studies of our product candidates, which could delay or limit future development or regulatory approval; results from ongoing and planned preclinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; results of early clinical studies as indicative of results of future trials; the inherent uncertainties associated with intellectual property; and other factors discussed in greater detail under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015 and subsequent filings with the Securities and Exchange Commission (SEC). You are encouraged to read Flex Pharma's filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.



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