

## Flex Pharma Presents Results From Three Human Clinical Studies

First Proof-of-Concept in Healthy Volunteers

Data Presented at the Cell Symposium on Translational Neuroscience

Company to Initiate Study in Nocturnal Leg Cramps in Q2 2015

November 14, 2014

Boston, MA – Flex Pharma, Inc., a biopharmaceutical company that is developing innovative and proprietary treatments for nocturnal leg cramps and spasms associated with severe neuromuscular conditions, today presented positive clinical results from its proprietary treatment for preventing muscle cramps at the <u>Cell Symposium on Translational Neuroscience</u> held in Arlington, Virginia.

Flex Pharma's proprietary treatment stimulates transient receptor potential (TRP) channels located in the mouth, esophagus and stomach, activating receptors in the gastrointestinal tract.

The studies evaluating this treatment consisted of three randomized, blinded, placebo-controlled crossover designs including a total of 37 healthy volunteers. The primary endpoint of each study was to evaluate the efficacy of the treatment in preventing muscle cramps. Each of the studies showed statistically significant results, demonstrating that Flex Pharma's treatment reduced electrically induced muscle cramps by 15 minutes, and its effect lasted between six and eight hours compared to subjects taking a vehicle control. When data from the three studies were aggregated, the treatment showed a statistically significant overall treatment effect, reducing cramp intensity by three-fold compared to subjects taking a vehicle control.

"To our knowledge, no marketed products have been shown to be safe and effective in treating leg cramps in well-designed, blinded human clinical studies," commented Flex Pharma Co-Founder, Co-Chair of the Company's Scientific Advisory Board and Nobel Laureate, Rod MacKinnon, M.D. "These study results support the belief that our proprietary treatment has significant potential as a solution for people suffering from muscle cramping and spasms resulting from of a broad range of neuromuscular disorders, including nocturnal leg cramps, multiple sclerosis, spinal spasticity and cervical dystonia."

"Our proprietary treatment is based upon our novel hypothesis regarding neuromuscular physiology – that activation of certain receptors in primary

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sensory neurons reduces the repetitive firing, or hyperexcitability, of alpha-motor neurons, thereby preventing or reducing the frequency and intensity of muscle cramps and spasms," noted Flex Pharma Co-founder and Scientific Advisory Board Co-Chair, Bruce Bean Ph.D. "Moreover, we believe that the physical properties of the TRP activators largely limit their action to sensory neurons in the mouth, esophagus and stomach, with minimal concentrations reaching the bloodstream and, consequently, fewer potential systemic side effects."

"With these positive results in healthy normal volunteers, we plan to initiate at least one proof-of-concept efficacy study in patients with nocturnal leg cramps in the second quarter of 2015," stated Christoph Westphal, M.D., Ph.D., Chairman and Chief Executive Officer of Flex Pharma. "Nocturnal leg cramps can cause distress, interrupted sleep, reduced quality of life and interference with activities of daily living. We estimate that approximately four million U.S. adults over the age of 65 suffer daily from nocturnal leg cramps, a condition for which there is significant unmet need since there are no approved treatments. We are pleased to be partnering with leading academics to advance this innovative science that holds enormous potential for a broad spectrum of cramps and spasms associated with severe neuromuscular conditions."

## **About Flex Pharma**

Flex Pharma, Inc. is a biopharmaceutical company that is developing innovative and proprietary treatments for nocturnal leg cramps and spasms associated with severe neuromuscular conditions. In three randomized, blinded, placebocontrolled studies, Flex Pharma's proprietary treatment has shown a statistically significant reduction in the intensity of muscle cramps in healthy volunteers. In the second quarter of 2015, the Company intends to initiate at least one human proof-of-concept study of its proprietary treatment for individuals with nocturnal leg cramps.

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 Chairman and Chief Executive Officer Christoph Westphal, M.D., Ph.D. Flex Pharma is backed by the Longwood Fund, Bessemer Venture Partners, EcoR1 Capital, Jennison Associates, LLC and a number of additional blue chip investment funds and angels.

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