Flex Pharma Reports Positive Topline Data from Exploratory Phase 2 Trial of FLX-787 in Multiple Sclerosis

March 26, 2018

- *FLX-787 reduced cramp/spasm frequency (p=0.0017) and increased cramp-free days (p=0.0457) in MS patients in a pre-specified analysis of the parallel treatment phase*
- *Treating physicians reported improvement in spasticity in patients receiving FLX-787 as measured by the Clinical Global Impression of Change (CGI-C) in pre-specified analyses (p=0.01 parallel period, p=0.0427 both cross-over periods)*
- *FLX-787 was generally well tolerated with no treatment-related serious adverse events reported*
- *Conference Call Scheduled Today at 8:45 a.m. EDT*

BOSTON--(BUSINESS WIRE)--Mar. 26, 2018-- Flex Pharma, Inc. (NASDAQ:FLKS), a clinical-stage biotechnology company that is developing innovative and proprietary treatments for cramps, spasms and spasticity associated with severe neurological diseases such as multiple sclerosis (MS), Charcot-Marie-Tooth (CMT) and amyotrophic lateral sclerosis (ALS) under FDA Fast Track designation today announced positive topline data for FLX-787 from its exploratory Phase 2 trial in MS patients with frequent muscle cramps/spasms and spasticity.

“MS patients frequently complain of cramps, spasms, and spasticity which can dramatically affect their quality of life,” said Anneke van der Walt, MBChB, FRACP, PhD. Associate Professor of Neurology, Royal Melbourne Hospital, University of Melbourne, Australia, and lead investigator of the study. “These new data suggest that FLX-787 may have the potential to address this important unmet medical need.”

FLX-787 at a dose of 19 mg, taken orally twice daily, in a liquid formulation was evaluated in an exploratory Phase 2 randomized, double-blinded, placebo-controlled, cross-over trial in 57 MS patients.

In the evaluation of FLX-787 for its impact on MS patients’ cramps/spasms and spasticity, pre-specified analyses of the parallel portion of the study showed:

- A statistically significant 27.3% reduction in the frequency of cramps/spasms compared with control (p=0.001)
- A 1.4 day increase in cramp/spasm-free days per 14 day period compared with control (p=0.0457)
- Clinician-rated improvement in spasticity with FLX-787 treatment was significantly better than control (p=0.01)
- Treating physicians reported that 7 of 28 (25%) patients on FLX-787 had “Much Improved” or “Very Much Improved” spasticity versus 0 of 26 (0%) on control based upon the Clinical Global Impression of Change in Spasticity

In the evaluation of FLX-787 from data that included both cross-over periods in the intent-to-treat (ITT) population:

- The pre-specified analysis of Clinical Global Impression of Change (CGI-C) in the patient’s spasticity showed statistically significant greater improvement with FLX-787 relative to control (p=0.0427)
- No statistically significant improvement was seen in cramp/spasm frequency, NRS or clinical spasticity scales

FLX-787 was generally well tolerated and resulted in no drug-related serious adverse events. GI-related adverse events (diarrhea and nausea) were infrequently reported with FLX-787.

“We see in these data the clear potential of FLX-787 to improve cramps and spasticity in patients with MS,” stated William McVicar, PhD., Flex Pharma President and CEO. “Based upon these strong data and the learnings from this study, we look forward to the development and execution of a refined phase 2b study as part of our full FLX-787 clinical development program.”

“Late last year, FLX-787 demonstrated a similar efficacy profile in a small exploratory study of ALS patients. Our MS trial results provide a second set of clinical evidence that FLX-787 may provide beneficial activity in patients with underlying neurological disease and demonstrates the potential of chemical neurostimulation in treating symptoms arising from motor neuron and reflex hyperexcitability,” said Flex Pharma Chief Medical Officer Thomas Wessel, M.D., Ph.D.

Data from this study outlined above will be presented at future medical meetings.

Conference Call & Webcast Information

The Flex Pharma management team will host a conference call and live webcast with slides with the investment community today, Monday, March 26, at 8:45 am EDT to discuss the information in this press release.

Date: Monday, March 26, 2018
Time: 8:45 am EDT
Dial-in: 855-780-7202
Replay: 855-859-2056
Conference ID: 1476389

The live webcast and accompanying slides can be accessed under the investor relations section of Flex Pharma’s website at www.flex-pharma.com. A replay of the conference call will be archived under the investor relations section of the Flex Pharma website for three months after the call.

About FLX-787

FLX-787 is an orally disintegrating tablet that is designed to treat cramps, spasms and spasticity associated with severe neurological conditions including ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). FLX-787 is a novel dual transient receptor potential A1/V1 (TRPA1/V1) ion channel activator designed to dampen the underlying hyperexcitability of spinal circuits responsible for cramps, spasms and spasticity. It has shown significant inhibition of electrically-induced muscle cramps (EIC), nocturnal leg cramps (NLC) in healthy adults and cramps in ALS patients. FLX-787 is being developed under Fast Track designation for the treatment of severe muscle cramps associated with ALS.

About Flex Pharma

Flex Pharma, Inc. is a clinical-stage biotechnology company developing innovative and proprietary treatments in Phase 2 randomized, controlled trials for cramps, spasms and spasticity associated with the severe neurological conditions of ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). The Company's lead candidate, FLX-787, is being developed under Fast Track designation for the treatment of severe muscle cramps associated with ALS.

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. These forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the progress, timing, scope and results of ongoing and anticipated clinical studies. 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 interpretation of our clinical studies; the uncertainties inherent in conducting clinical studies; results from our ongoing and planned preclinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; our ability to successfully commercialize our consumer product; results of early clinical studies as indicative of the results of future trials; availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of our consumer or drug product candidates; and the inherent uncertainties associated with intellectual property. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission (SEC), including the "Risk Factors" contained therein. You are encouraged to read our 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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