

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

March 26, 2018

Date of Report (Date of earliest event reported)

Flex Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36812

(Commission File Number)

46-5087339

(IRS Employer Identification No.)

**800 Boylston Street, 24th Floor
Boston, MA**

(Address of principal executive offices)

02199

(Zip Code)

Registrant's telephone number, including area code: **(617) 874-1821**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 8.01 Other Events.

On March 26, 2018, Flex Pharma, Inc. ("the Company") issued a press release announcing the topline data from its exploratory Phase 2 clinical trial of FLX-787 in Multiple Sclerosis patients with frequent muscle cramps/spasms and spasticity. The Company will host a conference call and live webcast with a slide presentation on Monday, March 26, at 8:45 a.m. EDT. A copy of this press release and slide presentation are filed herewith as Exhibits 99.1 and 99.2, respectively, and the information contained therein is incorporated by reference into this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Flex Pharma, Inc. announcing clinical trial results, dated March 26, 2018.
99.2	Flex Pharma, Inc. Slide Presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Flex Pharma, Inc.

Dated: March 26, 2018

By: /s/ John McCabe
John McCabe
Chief Financial Officer

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

- *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. EST*

Boston, MA, March 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 EST to discuss the information in this press release.

Date: Monday, March 26, 2018
Time: 8:45 am EST
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.

Source: Flex Pharma, Inc.

Investors

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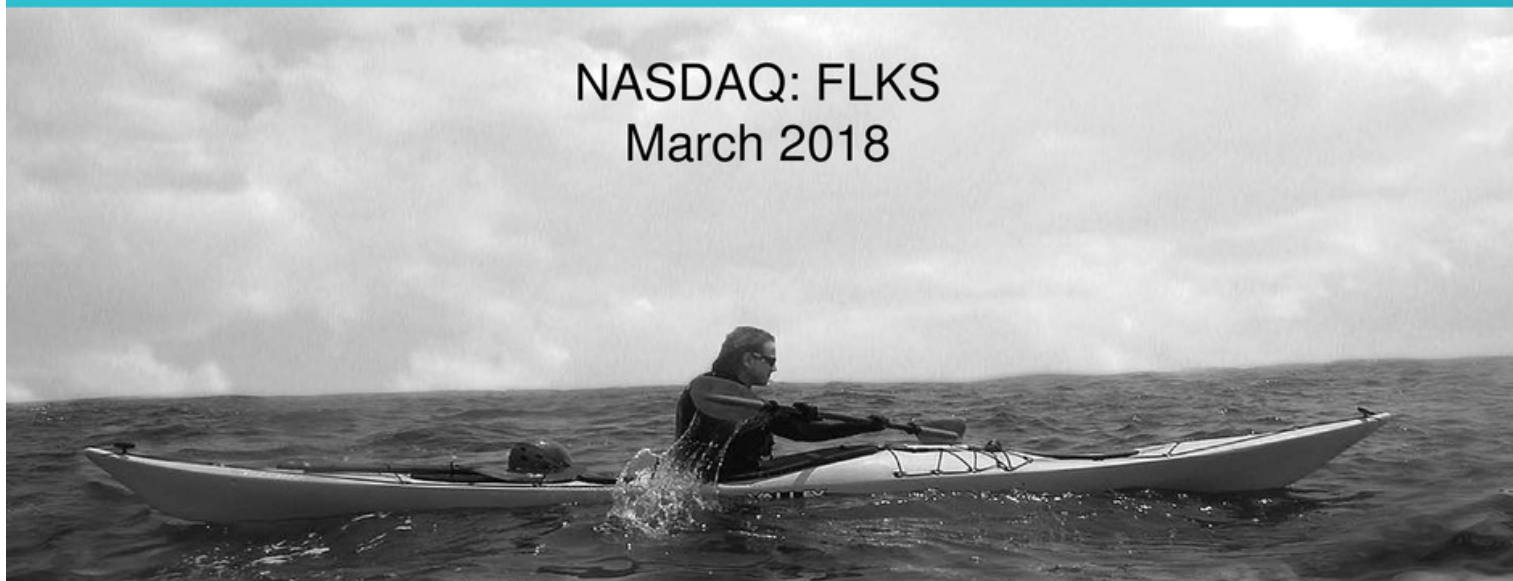
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FLEXPharma

FLEX-201: Exploratory Study of FLX-787 in
Multiple Sclerosis Patients

NASDAQ: FLKS
March 2018



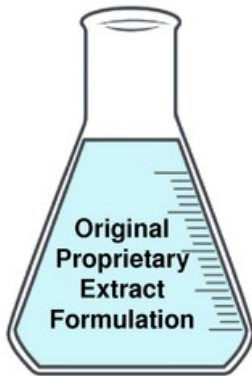
Forward-Looking Statements

Any statements in this presentation and the oral commentary about future expectations, plans and prospects for the company, including statements about the company's strategy, future operations, ongoing clinical trials, development of its consumer and drug product candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "approximately," "development plans," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, design, costs, results and interpretation of the company's 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 commercialize our consumer products; positioning and product attributes of our consumer products; results of early clinical studies as indicative of the results of future trials; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the company's consumer or drug product candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in the Risk Factors set forth in the company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) and in other filings the company makes with the SEC from time to time. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. The forward-looking statements in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

This presentation also contains estimates and other statistical data made by independent parties and by the company relating to market size and growth and other data about the company's industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of the company's future performance and the future performance of the markets in which the company operates are necessarily subject to a high degree of uncertainty and risk.

This presentation contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this presentation, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Origins of FLX-787: A Single Molecule, Dual TRPV1/A1 Activator



Electrically-induced cramp model for:

Optimized Consumer Beverage

Flex R&D

Compositional Analysis
Numerous TRP activators
Isolation of single-agent dual TRPA1/V1 activator, FLX-787

Synthetic pharmaceutical grade FLX-787
Formulation of FLX-787 as an orally disintegrating tablet



US IND open
Well-controlled studies in severe, neurodegenerative diseases

2014

2015

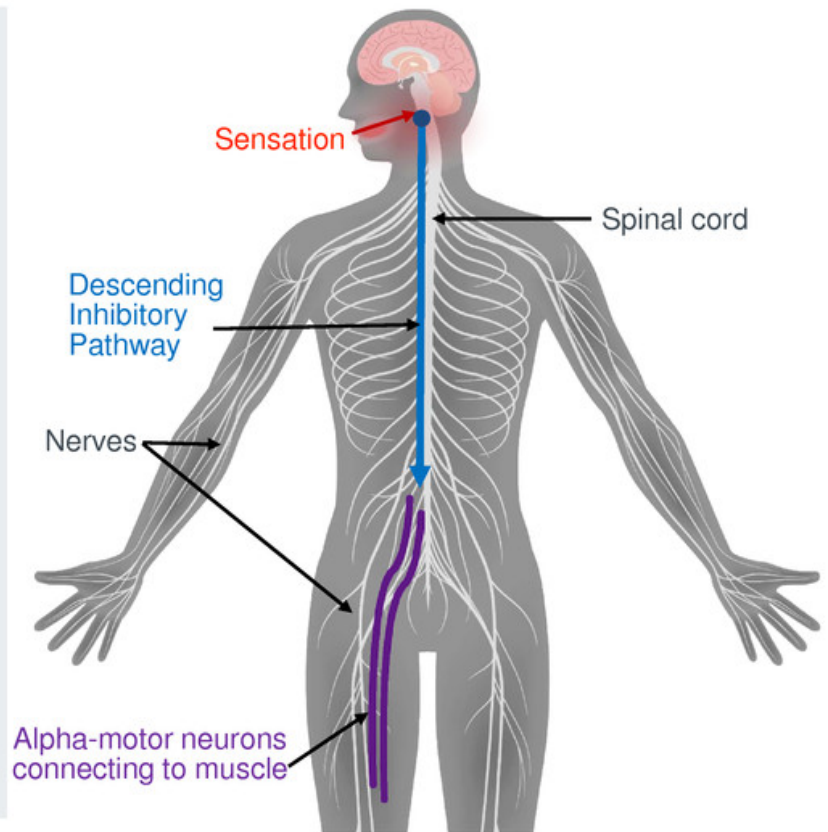
2016

2017

2018

MOA for Topical Modulation of the CNS by FLX-787: Stimulation-Processing-Motor Output

- 1** Sensory neurons with TRPA1/V1 channels stimulated by FLX-787
- 2** Central processing in brainstem leads to inhibition through descending fibers in spinal cord
- 3** Descending inhibition reduces: 1) alpha-motor neuron hyperexcitability halting muscle cramps and 2) reflex hyperexcitability attenuating spasticity



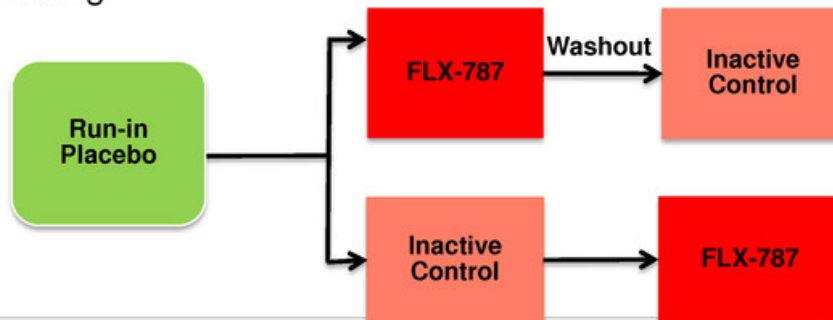
Exploratory MS Study: Proof of Concept

Objectives and Design:

- Explore the potential of chemical neurostimulation with FLX-787 to improve spasticity and decrease cramps/spasms in patients with MS
- Determine the patient characteristics and study design most sensitive to observed clinical improvements by FLX-787 for incorporation into future regulatory trials

Study Design:

- A multi-center trial studying MS patients suffering from spasticity and cramps/spasms
- A randomized, double-blind, placebo-controlled, 14-day per period crossover study
- Evaluated the effects of FLX-787 across multiple MS-associated endpoints including muscle cramp/spasm frequency and spasticity
- Assessed the efficacy of FLX-787 when self-administered BID as an oral solution containing 19 mg



Successful Exploratory MS Study Showing FLX-787 Activity Across Multiple MS-Associated Endpoints

Multiple Signals of Biological Activity:

In pre-specified analyses of the parallel portion of the study, anti-cramp/spasm and anti-spasticity activity was observed:

- **27.3%** decrease in Cramp/Spasm Frequency (**p=0.001**)
- **1.4 day** increase in Cramp-free Days (**p=0.0457**)
- Treating physicians reported that **7 of 28 FLX-787 patients** had “Much Improved” or “Very Much Improved” spasticity versus **0 of 26 on Control** (Clinical Global Impression of Change in Spasticity)

Successful Exploratory MS Study Showing FLX-787 Activity Across Multiple MS-Associated Endpoints

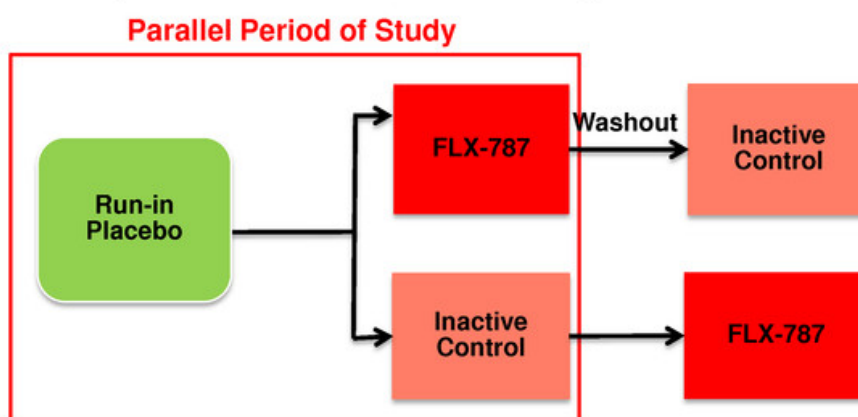
- In a pre-specified analysis that included both cross-over periods, a significant anti-spasticity effect was observed with FLX-787, when compared to Control, as measured by CGI-C for spasticity (**p=0.0427**)
 - CGI-C Responders (defined as “Much Improved” or “Very Much Improved”) were more prevalent on FLX-787 (N=13/54) versus control (N=2/52) (**p=0.004**, post-hoc analysis)
- No statistically significant improvement in cramp/spasm frequency, NRS or clinical spasticity scales from data that included both cross-over periods (ITT)

Summary of Safety

- FLX-787 at doses up to 19 mg (BID) in an oral solution was generally well tolerated
- No treatment-related SAEs occurred during the study
- The most-commonly reported AEs with FLX-787 were GI-related, mild to moderate, and self-limiting
- 2 subjects (1 Control; 1 Placebo) and 3 FLX-787 subjects discontinued the study due to an adverse event
- No clinically relevant laboratory, vital signs or ECG abnormalities were noted

Parallel Period Analysis Simulates Blinded Parallel Group Design Without Cross-over Limitations

- Cross-over design studies typically have more power to compare within patients but can be subject to confounding factors
- Specifically, FDA has identified the following concerns that could impact the interpretation of cross-over studies with FLX-787:
 - Carryover effects
 - Drop-outs, especially between periods
 - Unblinding
 - Sequence and period effects
 - Learning effects which may be different in each period
 - Interpretability of results from the second period



FLX-787 Significantly Decreased Cramps/Spasms and Increased Cramp-free Days

- In pre-specified Parallel Period Analyses, FLX-787 decreased the number of Cramps/Spasms and increased Cramp-free Days (changes from baseline in cramp/spasm population, over a 14-day treatment period)

Efficacy Endpoint	FLX-787	Control	p-value
Change in Cramp/Spasm Frequency	-9.7	2.9	0.0017
%Change in Cramp/Spasm Frequency	-27.3%	14.2%	0.0010
Change in Cramp Free Days	1.4	0.0	0.0457

- The results from data that included both cross-over periods were not statistically significant

Table 14.2.1.29.2.c

FLX-787 Improved Spasticity by CGI-C (Parallel Period Analysis)

Clinicians were asked to “rate total improvement of Spasticity and whether or not, in your clinical judgement, it is due entirely to drug treatment”.

Score	Placebo (Run-in, n=57)	FLX-787 (n=28)	Inactive Control (n=26)
Very Much Improved (1)	0 (0%)	0 (0%)	0 (0%)
Much Improved (2)	0 (0%)	7 (25%)	0 (0%)
Minimally Improved (3)	6 (11%)	10 (36%)	6 (23%)
No Change (4)	35 (61%)	7 (25%)	10 (38%)
Minimally worse (5)	12 (21%)	3 (11%)	10 (38%)
Much Worse(6)	3 (5%)	1 (4%)	0 (0%)
Very Much Worse (7)	1 (2%)	0 (0%)	0 (0%)

CGI-C
Responders

p=0.01

- 7/28 (25%) on FLX-787 vs 0/26 (0%) on Control were judged by the treating physician as “Much Improved” or “Very Much Improved”
- Comparison of the proportions with Fisher’s exact test confirmed this difference to be statistically significant (p=0.01)

FLX-787 Improved Spasticity by CGI-C (Both Crossover Periods)

Clinicians were asked to “rate total improvement of Spasticity and whether or not, in your clinical judgement, it is due entirely to drug treatment”.

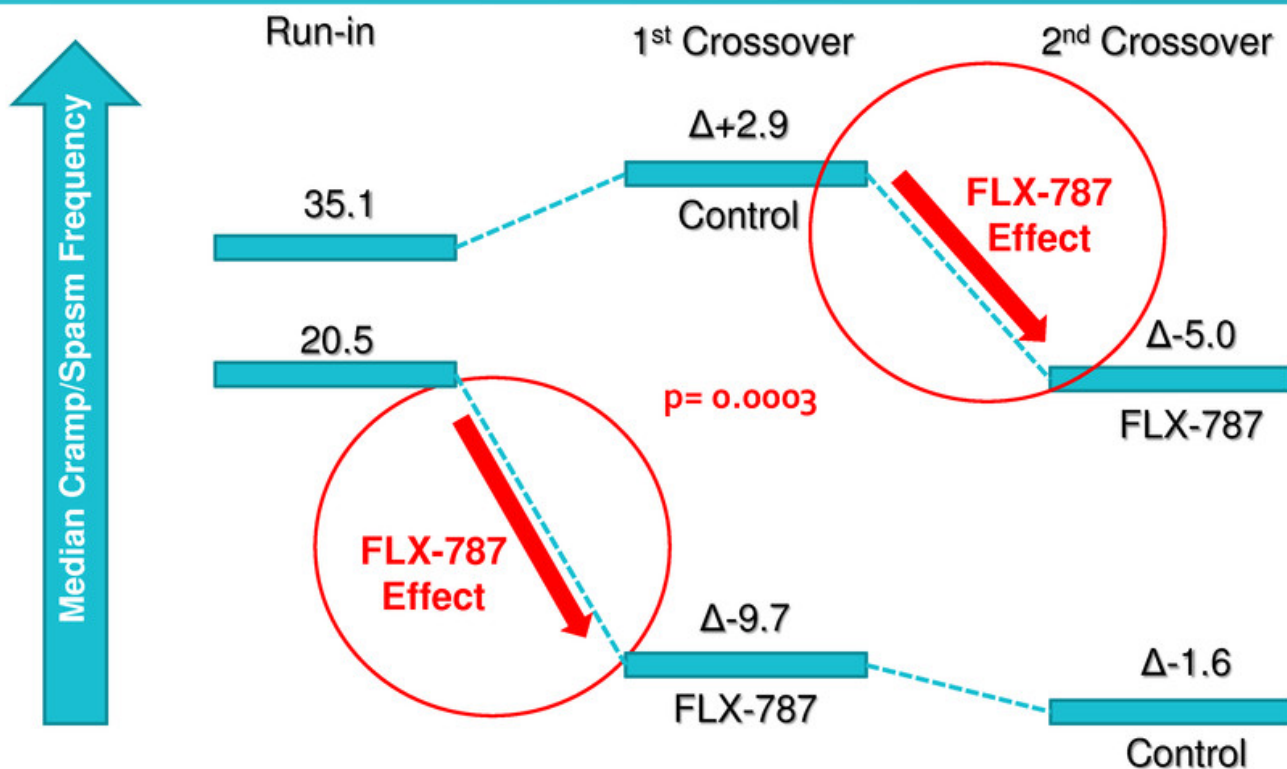
Score	Placebo (Run-in, n=57)	FLX-787 (n=54)	Inactive Control (n=52)
Very Much Improved (1)	0 (0%)	1 (2%)	0 (0%)
Much Improved (2)	0 (0%)	12 (22%)	2 (4%)
Minimally Improved (3)	6 (11%)	14 (26%)	18 (35%)
No Change (4)	35 (61%)	19 (35%)	18 (35%)
Minimally worse (5)	12 (21%)	5 (9%)	12 (23%)
Much Worse(6)	3 (5%)	3 (6%)	1 (2%)
Very Much Worse (7)	1 (2%)	0 (0%)	1 (2%)

CGI-C
Responders

p=0.0427

Source: Table 14.2.1.29.1.a, 14.2.1.23a, file 2018-03-18_ivrsnumtabCA17071_stat)

FLX-787 Reduced Cramps/Spasms in First Treatment Exposure Analysis



To correct for baseline imbalance and potential sequence and temporal effects, post-hoc analyses evaluated **first exposure to drug**, and **change from previous treatment** as baseline (serial period analysis)

Tables 14.2.1.1.2.c

Overall Summary: FLX-787 Improved Cramps/Spasms and Spasticity in MS Patients

- Reduction in Cramp/Spasm Frequency
- Increase in Cramp-free Days
- Greater number of patients assessed with spasticity “Much Improved” or “Very Much Improved”
- FLX-787 was generally well tolerated with minor GI side effects.

Based on this evidence of FLX-787-mediated biological activity in MS patients, we are planning our Phase 2b program

Future Phase 2b MS Cramping and Spasticity Trial

- ✓ Longer run-in to account for disease variability
- ✓ Longer treatment periods to allow greater time to achieve maximal drug effect
- ✓ Parallel treatment design
- ✓ Increased dosing frequency (BID→TID)
- ✓ Explore dose range (higher doses e.g.)
- ✓ Use orally-disintegrating tablet with longer oral residence time
- ✓ Optimized patient characteristics

FLEXPharma

Novel Treatments for Neuromuscular Conditions

NASDAQ: FLKS
