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

Date of Report (Date of Earliest Event Reported): April 11, 2019

KemPharm, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL		**34747**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (321) 939-3416

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ 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 ☒

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. ☒

Item 7.01 Regulation FD Disclosure.

On April 11, 2019, KemPharm, Inc., or the Company, issued a press release to announce that the Company concluded a pre-New Drug Application meeting with the U.S. Food and Drug Administration for KP415, as well as information regarding a conference call and live audio webcast with a slide presentation to discuss this meeting and provide a corporate update. A copy of the press release and presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information contained in this Item 7.01, and the press release and presentation furnished as Exhibits 99.1 and 99.2, respectively, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release titled "KemPharm Completes KP415 Pre-NDA Meeting with FDA" dated April 11, 2019.
99.2	Presentation titled "KP415 Pre-NDA Meeting Update Call" dated April 11, 2019.

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 thereunto duly authorized.

KemPharm, Inc.

Date: April 11, 2019

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer

Exhibit 99.1

KemPharm Completes KP415 Pre-NDA Meeting with FDA

KP415 NDA Filing Anticipated in Late Q2 or Early Q3 2019

Conference Call Scheduled for Today, Thursday, April 11, 2019 at 5:00 p.m. ET

Celebration, FL – April 11, 2019 – KemPharm, Inc. (Nasdaq: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that the Company concluded a pre-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA") for KP415, KemPharm's investigational attention-deficit/hyperactivity disorder (ADHD) product candidate that contains serdexmethylphenidate (a prodrug of d-methylphenidate) and d-methylphenidate. Held yesterday, the purpose of the meeting was to discuss the Company's NDA for KP415 and to confirm the clinical and non-clinical requirements for its submission.

At the pre-NDA meeting, representatives from the FDA reviewed KemPharm's summary of the data package being prepared for the KP415 NDA submission, including clinical, non-clinical and human abuse potential studies, as well as regulatory elements. Based on the feedback from the FDA, the Company believes its regulatory data package will be sufficient for submission, with acceptance of the filing subject to the FDA's review of the complete package.

"We are pleased with the collaborative tone of our meeting with the FDA, and we now have a solid understanding of the Agency's requirements for our submission," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "Based on feedback received during this meeting and from previous correspondences, we are confident in moving forward with our NDA package for KP415, which is on track for submission in late Q2 or early Q3 2019."

Dr. Mickle added, "One of the topics discussed with the FDA was the data analysis of the KP415.E01 efficacy trial. The complete KP415.E01 data package will be included in the NDA and provides additional analyses beyond the previously announced top line data that further support our belief that KP415 elicits an onset of action at 30 minutes and a duration of effect of 13 hours. In addition, the FDA stated that no additional efficacy study or data is required to assess KP415's efficacy in treating ADHD."

KP415 is KemPharm's prodrug product candidate being developed for the treatment of ADHD. KP415 consists of serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate-release d-MPH. KP415 is designed to address unmet needs with the most prescribed methylphenidate ADHD treatments, including earlier onset of action and longer duration of therapy. In addition, the results from the Human Abuses Potential program for the SDX component of KP415 suggest that the prodrug may have lower abuse potential than relevant d-MPH comparators.

Conference Call Information:

KemPharm will host a brief conference call and live audio webcast with a slide presentation today, Thursday, April 11, 2019, at 5:00 p.m. ET. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 7191464

An audio webcast with slide presentation will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast and presentation will remain available for 90 days beginning later today, April 11, 2019, at approximately 6:00 p.m. ET.

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT™ (Ligand Activated Therapy) technology. KemPharm utilizes its proprietary LAT technology to generate improved prodrug versions of FDA-approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. KemPharm's prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder. KemPharm's co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of d-methylphenidate, but have differing duration/effect profiles. In addition, KemPharm has received FDA approval for APADAZ®, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com or connect with us on Twitter, LinkedIn, Facebook and YouTube.

Caution Concerning Forward Looking Statements:

This press release may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation our proposed development and commercial timelines, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements, including the potential timing and outcome of the NDA submission for KP415, and the potential benefits of KP415, are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning KemPharm's business are described in detail in KemPharm's Annual Report on Form 10-K for the year ended December 31, 2018, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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KemPharm
KP415 Pre-NDA Meeting Update Call
April 11, 2019

Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about our plans to develop and commercialize our product candidates, our planned clinical trials for our prodrug product candidates, the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including expectations about our ability to use the 505(b)(2) pathway and expedited FDA review, the clinical utility of our product candidates and our intellectual property position. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. 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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. These and other risks concerning our business are described in additional detail in our Annual Report on Form 10-K filed with the SEC on March 1, 2019, and our other Periodic and Current Reports filed with the SEC. 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. Further, the information contained in this presentation speaks only as the date hereof. While we may elect to update the information in this presentation in the future, we disclaim any obligation to do so except to the extent required by applicable law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our 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 our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Update Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **Andrew Barrett, Ph.D.** – Vice President, Scientific Affairs

KP415

Pre-NDA Meeting Update

KP415 Pre-NDA Meeting

- KP415 pre-NDA meeting with FDA held yesterday, April 10th
- FDA confirmed that KemPharm's proposed NDA package appears to be sufficient for filing as soon as completed
- KP415.E01 efficacy study is sufficient to assess efficacy in ADHD
  - No additional efficacy study or data is required
  - Division has been well informed of the data and has provided feedback regarding what support they will require to assess the data fully
  - If justified, the Division is not opposed to using analyses similar to other approved products to treat ADHD
  - Specific KP415 efficacy labeling is a matter for NDA review
- KP415 NDA submission in late 2Q 2019 or early 3Q 2019

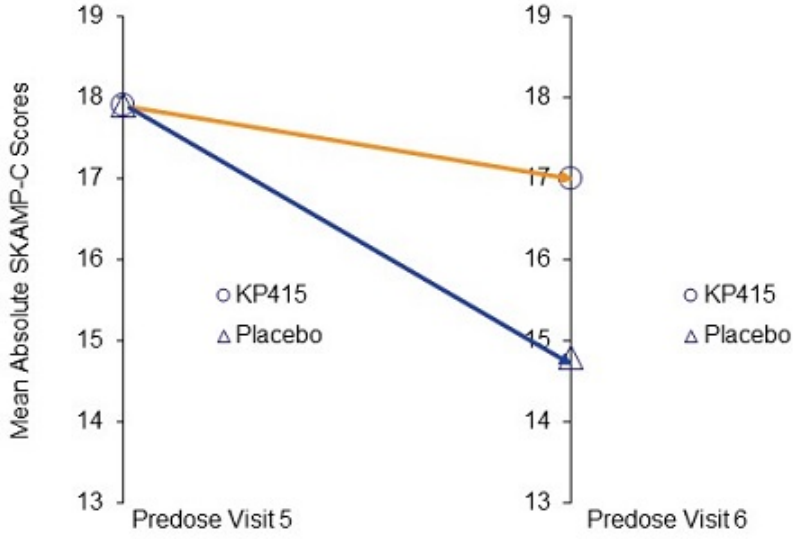
KP415.E01 Efficacy Trial

Final Data Review

KP415.E01 Efficacy Trial Data Review

- A predose KP415 vs. placebo difference in SKAMP-C scores was observed as expected on the classroom day
- The prespecified predose Visit 5 baseline could not mathematically correct for this difference and resulted in a truncated apparent duration of effect from 1 to 10 hours postdose
- After conducting post-hoc and sensitivity analyses, reviewing responses from a Type-C meeting with the FDA, and a Pre-NDA meeting with the FDA, we believe the following can be concluded:
  - Predose Visit 6 is the correct baseline to adjust for predose treatment group differences which is consistent with the statistical model for most approved ADHD products
  - Post-hoc analysis with predose Visit 6 baseline indicates a duration of effect from 0.5 to 13 hours postdose
  - PERMP data and sensitivity analyses support robustness of the 0.5 to 13 hour duration of effect

Absolute SKAMP-C Scores for Visit 5 vs. Visit 6 Predose Statistical Baselines



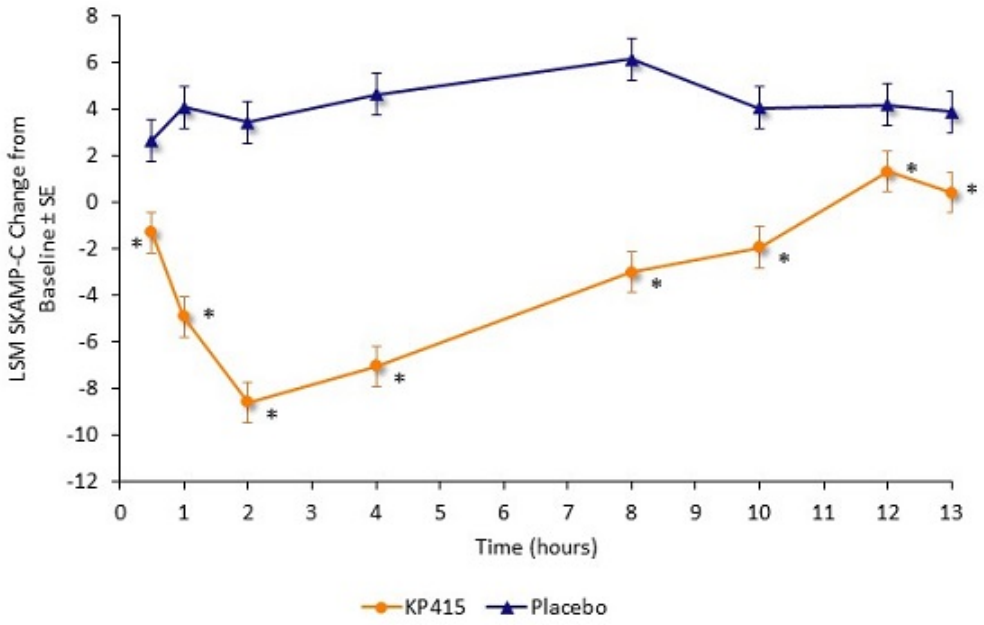
Visit 5: both KP415 and Placebo subjects had taken KP415 for 3 weeks followed by a 2-day washout. After baseline assessment, all subjects received an open-label KP415 dose.

Visit 6: KP415 subjects had taken KP415 for 1 week and Placebo subjects had taken Placebo for 1 week. After baseline assessment, the last double-blind dose of either KP415 or placebo was administered.

KP415.E01 Predose Visit 6 Post-Hoc Analysis

- When using the correct SKAMP-C baseline, predose Visit 6, onset and duration of effect cover 0.5-13 hours postdose
- The post-hoc model is the same as the pre-specified model with the **only** change being the use of predose Visit 6 scores as the baseline rather than predose Visit 5
- A sensitivity analysis with the same model using absolute SKAMP-C scores as endpoint and predose Visit 6 as covariate (similar to, e.g., Cotempla XR-ODT, Aptensio XR) produces identical results as with the change from predose Visit 6 endpoint
- Further sensitivity analyses also support duration of effect from 0.5-13 hours postdose
- Additionally, duration of efficacy is supported by PERMP scores indicating effect for 0.5-13 hours postdose regardless of whether predose Visit 5 or predose Visit 6 is used as the baseline

SKAMP-C Change from Predose Visit 6 (Post-Hoc Analysis)



Statistical model includes predose Visit 6 as covariate

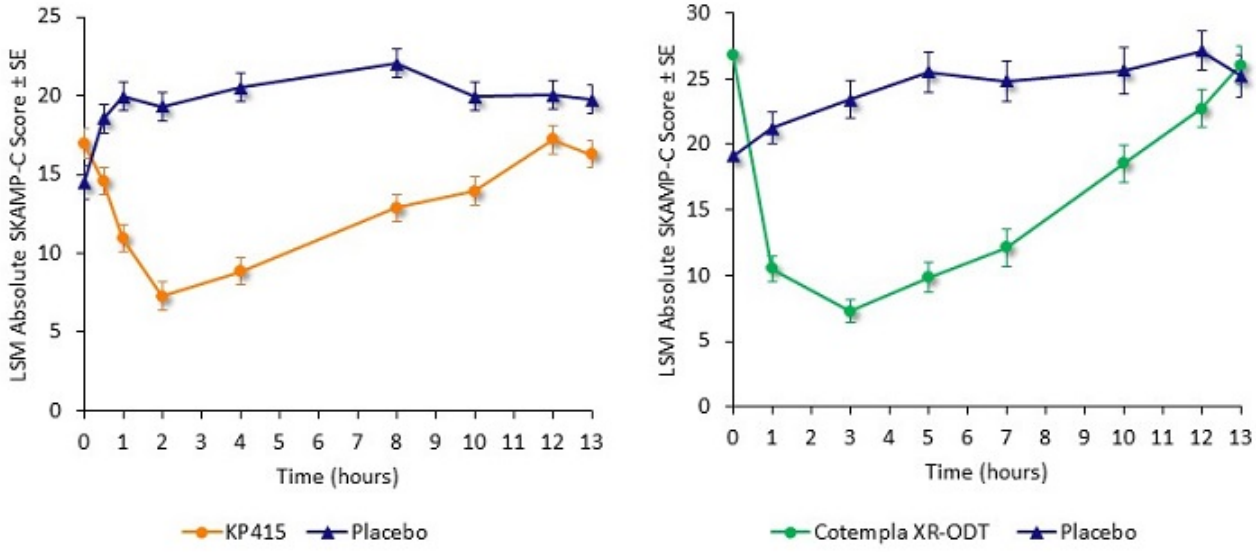
* Indicates time point is statistically significantly different from placebo ($p<0.05$)

Statistical Analysis Model Comparison

Analysis Parameter	Cotempla XR-ODT (pre-specified)	KP415 (post-hoc)
Endpoint	postdose SKAMP-C	• postdose SKAMP-change from predose • postdose SKAMP-C
Model	mixed model repeated measures (MMRM)	
Fixed Effects/ Covariates	• treatment • predose SKAMP-C • time • treatment-by-time • site	
Random Effects	Subject	
Test Sequence	Fixed-sequence: 5, 3, 7, 1, 10, 12, 13 hour	Chronological sequence: 0.5, 1, 2, 4, 8, 10, 12, 13 hour

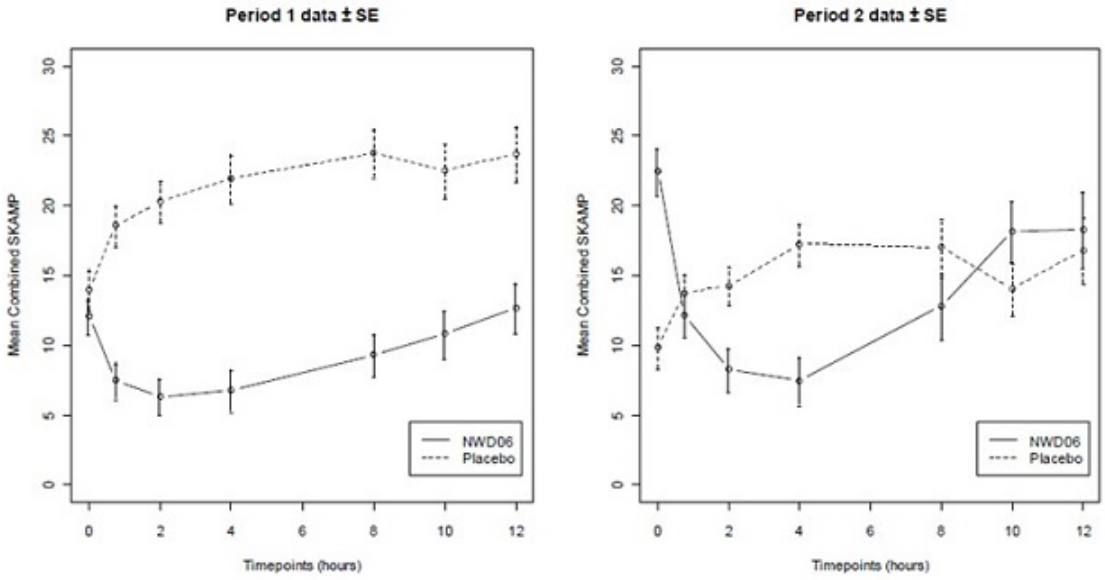
The KP415 pre-specified model/analysis were identical to the post-hoc model/analysis with the exception of using predose Visit 6 (post-hoc) as opposed to predose Visit 5 as the SKAMP-C baseline

Statistical Analysis Model Comparison



Statistical model includes predose Visit 6 (KP415) and predose Visit 8 (Cotempla XR-ODT) as covariate, respectively.

Quillivant XR Statistical Analysis of Efficacy Study Data



FDA implemented post-hoc modification of statistical plan, using only Period 1 data due to a sequence effect that invalidated Period 2 data.

Quillivant XR (NDA 202100). Summary Basis of Approval

Partnership Process Update

KP415 and KP484 for ADHD

KP415 and KP484 – NDA and Partnering Process Update

- Anticipated NDA submissions
  - KP415 pre-NDA meeting completed
  - KP415 NDA submission late Q2 or early Q3 2019
  - KP484 NDA planned for 2020
- Strategic Partnering Process
  - Process continues as previously disclosed on last quarterly update call
  - Multiple parties are engaged in a competitive process
  - Continuing to pursue the best proposal to maximize long-term value
    - Not all proposals are created equal
    - Each partner's commercial plans and current capabilities must be understood to ensure commercial potential is optimized

KemPharm Value Proposition

KP415/KP484 potentially provide near-term, high value opportunities

- Partnership
- NDA submission
- Approval
- Launch with partner into a large market

Building future value

- KP879 – for the treatment of stimulant use disorder (SUD)
- APADAZ® commercial launch
- Continue to advance our development product pipeline
- R&D collaborations (e.g., twoXAR, Genco)

Appendix

Final SKAMP-C Change from Predose Visit 5 (Pre-specified)

Time Point	Change in SKAMP-C from Predose Visit 5*					
	LS Mean (SE)		Difference in LS mean (SE)	95% Confidence Interval		
Visit 6	KP415	Placebo	KP415 – Placebo	KP415 – Placebo		p-Value
Predose	-0.50 (0.85)	-2.87 (0.87)	2.37 (1.18)	0.07	4.68	0.0437
0.5 hours postdose	-3.10 (0.85)	-0.82 (0.87)	-2.28 (1.18)	-4.58	0.03	0.0531
1 hours postdose	-6.72 (0.85)	0.68 (0.87)	-7.40 (1.18)	-9.70	-5.09	<.0001
2 hours postdose	-10.39 (0.85)	-0.25 (0.87)	-10.14 (1.18)	-12.45	-7.83	<.0001
4 hours postdose	-8.84 (0.85)	0.92 (0.87)	-9.76 (1.18)	-12.07	-7.46	<.0001
8 hours postdose	-4.80 (0.85)	2.25 (0.87)	-7.05 (1.18)	-9.35	-4.74	<.0001
10 hours postdose	-3.73 (0.85)	0.18 (0.87)	-3.91 (1.18)	-6.22	-1.60	0.0009
12 hours postdose	-0.47 (0.85)	0.49 (0.87)	-0.96 (1.18)	-3.27	1.34	0.4119
13 hours postdose	-1.39 (0.85)	0.23 (0.87)	-1.63 (1.18)	-3.93	0.68	0.1665
Mean difference in change from baseline across all postdose time points	-4.44 (0.557)	0.089 (0.653)	-4.53 (0.797)	-6.09	-2.97	<.0001

* Statistical model includes predose Visit 5 as covariate.

Final SKAMP-C Change from Predose Visit 6 (Post-Hoc Analysis)

Time Point	Change in SKAMP-C from Predose Visit 6*					
	LS Mean (SE)		Difference in LS mean (SE)	95% Confidence Interval		
Visit 6	KP415	Placebo	KP415 – Placebo	KP415 – Placebo		p-Value
0.5 hours postdose	-1.30 (0.88)	2.67 (0.91)	-3.97 (1.22)	-6.37	-1.57	0.0012
1 hours postdose	-4.92 (0.88)	4.08 (0.91)	-9.00 (1.22)	-11.40	-6.60	<0.0001
2 hours postdose	-8.60 (0.88)	3.43 (0.91)	-12.03 (1.22)	-14.43	-9.63	<0.0001
4 hours postdose	-7.04 (0.88)	4.62 (0.91)	-11.66 (1.22)	-14.06	-9.26	<0.0001
8 hours postdose	-3.00 (0.88)	6.15 (0.91)	-9.15 (1.22)	-11.55	-6.75	<0.0001
10 hours postdose	-1.93 (0.88)	4.05 (0.91)	-5.99 (1.22)	-8.39	-3.59	<0.0001
12 hours postdose	1.32 (0.88)	4.17 (0.91)	-2.85 (1.22)	-5.25	-0.45	0.0200
13 hours postdose	0.40 (0.88)	3.90 (0.91)	-3.49 (1.22)	-5.89	-1.09	0.0044
Mean difference in change from baseline across all postdose time points	-3.13 (0.61)	4.13 (0.71)	-7.27 (0.88)	-9.00	-5.53	<0.0001

* Statistical model includes predose Visit 6 as covariate