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): July 9, 2018

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.)**
2500 Crosspark Road, Suite E126 **Coralville, IA**		**52241**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (319) 665-2575

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 July 9, 2018, KemPharm, Inc., or the Company, issued a press release announcing top line results from a pivotal efficacy and safety clinical trial of KP415, its investigational attention-deficit/hyperactivity disorder, or ADHD, product candidate that contains serdexmethylphenidate, a prodrug of d-methylphenidate, and d-methylphenidate. Also on July 9, 2018, the Company will conduct a conference call and live audio webcast with slide presentation to discuss these results.

A copy of the press release and presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K. The information set forth in this Item 7.01 and contained in the press release furnished as Exhibit 99.1 and in the presentation furnished as Exhibit 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

In the press release described above, on July 9, 2018, the Company announced top line results from a pivotal efficacy and safety clinical trial of KP415, or KP415.E01. Results from KP415.E01 indicated that KP415 successfully met the primary efficacy endpoint in patients with ADHD between the ages of 6 and 12 years. KP415.E01 was a multicenter, randomized, parallel, double-blind, placebo-controlled analog laboratory classroom clinical trial in 150 children aged 6-12 years old with a diagnosis of ADHD to assess the efficacy and safety of KP415. Subjects who received KP415 met the trial's primary and secondary efficacy endpoint, showing statistically significant improvement on both the Swanson, Kotkin, Agler, M-Flynn, and Pelham, or SKAMP, Scale and the Permanent Product Measure of Performance, or PERMP, scale.

The KP415 capsules contain two active pharmaceutical ingredients: d-MPH hydrochloride as the immediate release, or IR, d-MPH component, and serdexmethylphenidate, or SDX, a prodrug of d-MPH that provides the extended duration component. In terms of d-MPH equivalent amounts, all capsule strengths contain 30% of d-MPH (IR component) and 70% of d-MPH from SDX. Subjects in this trial received daily oral doses (1 capsule/day) of either 28/6 mg SDX/d-MPH, 42/9 mg SDX/d-MPH, or 56/12 mg SDX/d-MPH, corresponding to equivalent d-MPH amounts of 20, 30 and 40 mg, respectively. The dose of KP415 was optimized during a 3-week dose optimization phase with open-label KP415 capsules. After completion of the dose optimization period, subjects were randomized to 7 days of double-blind treatment with their optimized dose of KP415 or matching placebo.

The efficacy evaluation was based on SKAMP and PERMP scores pre-dose, and at 0.5, 1, 2, 4, 8, 10, 12 and 13 hours post-dose during a full laboratory classroom day at Visit 6 (at the end of the seven-day treatment period). The baseline SKAMP score was measured pre-dose at Visit 5 (immediately prior to randomization and the first dose in the seven-day treatment period) due to potential concerns of carryover of methylphenidate into the Visit 6 classroom day which would have disadvantaged KP415, as well as an assumption that placebo would not significantly change from Visit 5 to Visit 6. A post-hoc analysis was conducted using the baseline SKAMP scores measured at pre-dose Visit 6. The SKAMP is a validated rating of classroom behaviors in children with ADHD; the PERMP is an adjusted math test designed to assess attention in children with ADHD through a subject's ability to initiate, self-monitor, and complete the test.

The study met the primary endpoint of mean SKAMP-Combined, or SKAMP-C, change from baseline score (pre-dose Visit 5 as baseline) across all post-dose time points (Visit 6): The least-squares mean post-dose SKAMP-C difference from baseline (150 subjects) was higher for placebo than for KP415 (0.54 vs. -4.87, respectively; $p<0.001$), indicating fewer ADHD symptoms with KP415 therapy than with placebo.

Using pre-dose Visit 5 as baseline (pre-specified), the SKAMP-C change from baseline was statistically significantly better ($p<0.001$) with KP415 versus placebo from 1–10 hours post-dose; using pre-dose Visit 6 as baseline (post-hoc), the SKAMP-C change from baseline was statistically significantly better ($p<0.01$) with KP415 versus placebo from 0.5–13 hours post-dose.

The PERMP-Attempted and PERMP-Correct scores (secondary endpoints) support the primary endpoint conclusion overall (mean changes; $p<0.01$) and showed statistically significantly better performance with KP415 versus placebo at each time point from 0.5-13 hours ($p<0.05$).

The observed adverse events were mild to moderate in severity and were typical of those seen in other stimulant trials. No serious adverse events were reported.

The information contained in this Current Report on Form 8-K speaks only as the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements include all statements that do not relate solely to historical or current facts, 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. These forward-looking statements include statements regarding the expected features and characteristics of the Company's product candidates, including KP415, as well as the expected timing of the completion of clinical trials or studies related to KP415 and the expected timing of the NDA submission for KP415. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; results of earlier studies and trials may not be predictive of future clinical trial results; the protection and market exclusivity provided by the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; the impact of competitive products and technological changes; and the FDA approval process under the Section 505(b)(2) regulatory pathway, including without limitation any timelines for related approval. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company's business are described in additional detail in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the Securities and Exchange Commission on May 11, 2018, and the Company's other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "KemPharm Announces Top Line Results from KP415.E01 Efficacy and Safety Trial in Children With ADHD" dated July 9, 2018.
99.2	Presentation titled "KP415.E01 Efficacy Trial Results" dated July 9, 2018.

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: July 9, 2018

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

Exhibit 99.1

KemPharm Announces Top Line Results from KP415.E01 Efficacy and Safety Trial in Children With ADHD

Results from Single Classroom-Style Trial Met Pre-Specified Primary and Secondary Endpoints

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today at 8:00 a.m. ET

Coralville, IA – July 9, 2018 – KemPharm, Inc. (NASDAQ:KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced top line results from a pivotal efficacy and safety clinical trial of KP415, its investigational attention-deficit/hyperactivity disorder (ADHD) product candidate that contains serdexmethylphenidate (a prodrug of d-methylphenidate) and d-methylphenidate. Results from the trial (KP415.E01) indicated that KP415 successfully met the primary efficacy endpoint in patients with ADHD between the ages of 6 and 12 years.

The trial was a multicenter, randomized, parallel, double-blind, placebo-controlled analog laboratory classroom clinical trial in 150 children aged 6-12 years old with a diagnosis of ADHD to assess the efficacy and safety of KP415. Subjects who received KP415 met the trial's primary and secondary efficacy endpoint, showing statistically significant improvement on both the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP) and the Permanent Product Measure of Performance (PERMP) scale.

"We are pleased with these top line results from our pivotal trial of KP415. The trial met its pre-specified primary endpoint, which is the mean difference in the SKAMP-Combined score change from baseline across all post-dose time points," said Travis Mickle, Ph.D., KemPharm President and Chief Executive Officer. "Pre-specified secondary endpoints of SKAMP-C change at each time point from the pre-specified, pre-randomization baseline indicated a drug effect from 1 to 10 hours post-dose, and data from the PERMP, PERMP-Attempted and PERMP-Correct all exhibited improvement over placebo from 0.5 hours to 13 hours post-dose. Lastly, KP415 was generally well-tolerated with adverse events (AEs) typical of stimulant therapy"

"The SKAMP-C change from pre-randomization baseline was selected to mitigate a potential carryover effect related to the pharmacokinetics of KP415 and an assumption that placebo should have been more predictable, neither of which actually occurred," added Mickle. "As a result, the endpoint analysis led to an inability to correct for a change of SKAMP-C scores in the placebo group across the analog classroom day. When this bias is accounted for, a similar statistical analysis (post-hoc) of SKAMP-C scores also supports efficacy of KP415 from 0.5 to 13 hours post-dose."

"We anticipate developing additional clinical data for KP415 throughout 2018, including the completion of our ongoing oral and intranasal Human Abuse Potential studies," Mickle concluded. "We believe that completing the analysis of the full data set from KP415.E01 trial and these other studies will allow us to submit our New Drug Application for KP415 with the FDA in the first quarter of 2019."

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Conference Call Information

KemPharm will host a conference call and live audio webcast with slide presentation today, July 9, 2018, at 8:00 a.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: 4594415

The live webcast with accompanying slides 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 following the call.

About the KP415.E01 Trial

TREATMENT

The KP415 capsules contain two active pharmaceutical ingredients: d-MPH hydrochloride as the immediate release (IR) d-MPH component, and serdexmethylphenidate (SDX), a prodrug of d-MPH that provides the extended duration component. In terms of d-MPH equivalent amounts, all capsule strengths contain 30% of d-MPH (IR component) and 70% of d-MPH from SDX. Subjects in this trial received daily oral doses (1 capsule/day) of either 28/6 mg SDX/d-MPH, 42/9 mg SDX/d-MPH, or 56/12 mg SDX/d-MPH, corresponding to equivalent d-MPH amounts of 20, 30 and 40 mg, respectively. The dose of KP415 was optimized during a 3-week dose optimization phase with open-label KP415 capsules. After completion of the dose optimization period, subjects were randomized to 7 days of double-blind treatment with their optimized dose of KP415 or matching placebo.

EFFICACY ENDPOINTS:

The efficacy evaluation was based on SKAMP and PERMP scores pre-dose, and at 0.5, 1, 2, 4, 8, 10, 12 and 13 hours post-dose during a full laboratory classroom day at Visit 6 (at the end of the seven-day treatment period). The baseline SKAMP score was measured pre-dose at Visit 5 (immediately prior to randomization and the first dose in the seven-day treatment period) due to potential concerns of carryover of methylphenidate into the Visit 6 classroom day which would have disadvantaged KP415, as well as an assumption that placebo would not significantly change from Visit 5 to Visit 6. A post-hoc analysis was conducted using the baseline SKAMP scores measured at pre-dose Visit 6. The SKAMP is a validated rating of classroom behaviors in children with ADHD; the PERMP is an adjusted math test designed to assess attention in children with ADHD through a subject's ability to initiate, self-monitor, and complete the test.

The study met the primary endpoint of mean SKAMP-C change from baseline score (pre-dose Visit 5 as baseline) across all post-dose time points (Visit 6): The least-squares mean post-dose SKAMP-C difference from baseline (150 subjects) was higher for placebo than for KP415 (0.54 vs. -4.87, respectively; $p<0.001$), indicating fewer ADHD symptoms with KP415 therapy than with placebo.

Using pre-dose Visit 5 as baseline (pre-specified), the SKAMP-C change from baseline was statistically significantly better ($p<0.001$) with KP415 versus placebo from 1–10 hours post-dose; using pre-dose Visit 6 as baseline (post-hoc), the SKAMP-C change from baseline was statistically significantly better ($p<0.01$) with KP415 versus placebo from 0.5–13 hours post-dose.

The PERMP-A and PERMP-C scores (secondary endpoints) support the primary endpoint conclusion overall (mean changes; $p<0.01$) and showed statistically significantly better performance with KP415 versus placebo at each time point from 0.5-13 hours ($p<0.05$).

SAFETY ENDPOINTS:

The observed AEs were mild to moderate in severity and were typical of those seen in other stimulant trials. No serious adverse events were reported.

KP415 – Prodrug Composition of d-MPH for ADHD

KP415 is KemPharm's d-MPH prodrug composition product candidate designed for the broad treatment needs of the ADHD population. KemPharm believes the prodrug may also demonstrate a lower abuse potential as well as less variability in the delivery of d-MPH compared to current methylphenidate products.

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) platform technology. KemPharm utilizes its proprietary LAT™ platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of ADHD, pain and other central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415 and KP484, both based on a prodrug of methylphenidate, but with differing extended-release/effect profiles for the treatment of ADHD. In addition, the company has received FDA approval for Apadaz™, an immediate-release combination product candidate of benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. The company is also advancing KP201/IR, an acetaminophen-free immediate-release formulation of the company's benzhydrocodone prodrug candidate. Both Apadaz™ and KP201/IR are intended for the treatment of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 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 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. These forward-looking statements include statements regarding the expected features and characteristics of KemPharm's product candidates, including KP415, as well as the expected timing of the completion of any clinical trials or studies related to KP415 and the expected timing of the NDA submission for KP415. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements 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. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with: KemPharm's financial resources and whether they will be sufficient to meet KemPharm's business objectives and operational requirements; results of earlier studies and trials may not be predictive of future clinical trial results; the protection and market exclusivity provided by KemPharm's intellectual property; risks related to the drug discovery and the regulatory approval process; the impact of competitive products and technological changes; and the FDA approval process under the Section 505(b)(2) regulatory pathway, including without limitation any timelines for related approval. KemPharm's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning KemPharm's business are described in additional detail in KemPharm's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the Securities and Exchange Commission on May 11, 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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KP415.E01 Efficacy Trial Results

July 9, 2018

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 Quarterly Report on Form 10-Q filed with the SEC on May 11, 2018, 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.

KP415.E01 Efficacy Trial Results Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **R. LaDuane Clifton, CPA** – Chief Financial Officer, Secretary & Treasurer
- **Gordon K. "Rusty" Johnson** – Chief Business Officer
- **Dan Cohen, M.A.L.S.** – EVP, Government & Public Relations

KP415 Product Overview

- Prodrug of d-methylphenidate (MPH) with extended release properties, co-formulated with immediate release d-methylphenidate
- Potential KP415 features and benefits
  - Early onset of action
  - Potential longer total duration than current MPH therapies
  - Active metabolism may offer more predictable therapeutic effect
  - Lower abuse potential
  - Patient-friendly dosage form
    - Small capsule size (same as Vyvanse), easily swallowed
    - May be opened and contents sprinkled on food or mixed into liquids for easier ingestion
- No generic equivalent product
- Granted composition-based patent expires in 2032, pending applications potentially would expire in 2037; potentially NCE eligible

KP415.E01 Efficacy Trial Results

- Met primary endpoint of the trial: mean difference in SKAMP-C score change from baseline across all post-dose time points ($p<0.001$)
- Trial results, based on a prespecified analysis of SKAMP-C scores using the Visit 5 pre-dose value as baseline, support a 1 hour post-dose onset of action and a duration of efficacy of 10 hours post-dose
  - A period effect occurred between Visit 5 and Visit 6 where observed placebo SCAMP-C scores changed unexpectedly from Visit 5 to Visit 6
- We believe our post hoc analysis of SKAMP-C scores based on using the Visit 6 pre-dose value as baseline supports a 30 minute post-dose onset of action and a duration of efficacy of 13 hours post-dose
- Secondary endpoints supportive of a 30 minute post-dose onset of action and a duration of efficacy of 13 hours post-dose include:
  - PERMP (Total Score), PERMP-A and PERMP-C change from baseline
- Additional secondary endpoints appear supportive of overall efficacy

KP415.E01 Primary Endpoint Result

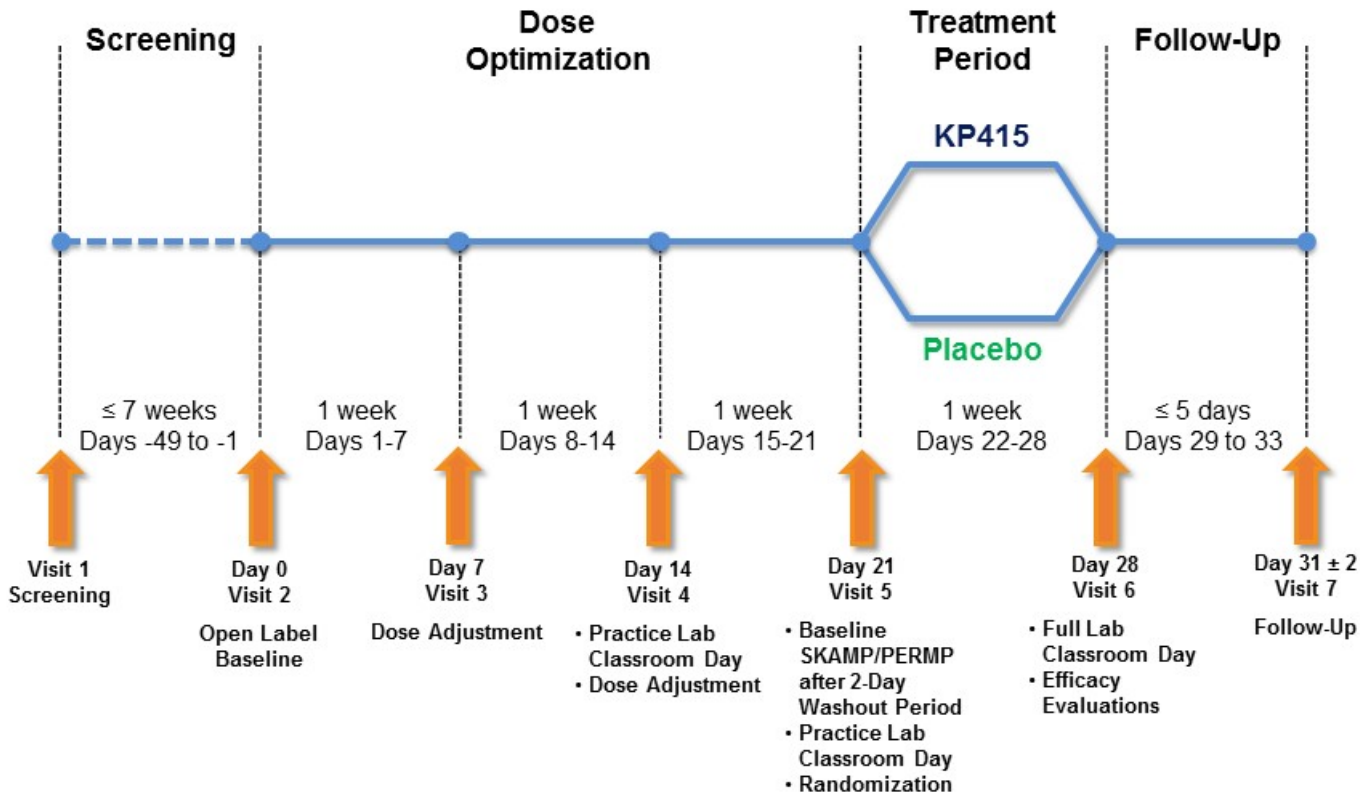
- KP415.E01 met the primary endpoint of mean difference in change from baseline (pre-dose Visit 5) across all post-dose time points for the SKAMP-C score ($p<0.001$)

Change in SKAMP-C from Pre-dose Visit 5						
	LS Mean (SE)		Difference in LS mean (SE)	95% Confidence Interval		
Statistical Measure	KP415	Placebo	KP415 – Placebo	KP415 – Placebo		p-Value
Mean difference in change from baseline across all post-dose time-points	-4.87 (0.62)	0.54 (0.70)	-5.41 (0.87)	-7.10	-3.71	<0.001

KP415.E01 Efficacy Trial Overview

- Double-blind, placebo-controlled, randomized, parallel, analog classroom trial
- Children 6 to 12 years with ADHD (150 completers)
- 5 U.S. trial sites, 2-3 cohorts each; 5-18 subjects per cohort/per site
- 3-week open-label KP415 dose optimization period ending with 2-day drug washout period
- On Visit 5 (Day 21), baseline SKAMP-C scores were collected at pre-dose, patients were given their last open-label dose and then they were randomly assigned to either placebo or their optimized dose of KP415 once daily in the morning for 1 week
- On Visit 6 (Day 28), SKAMP-C scores were collected at pre-dose and post-dose efficacy assessments were taken at 0.5, 1, 2, 4, 8, 10, 12 and 13 hours

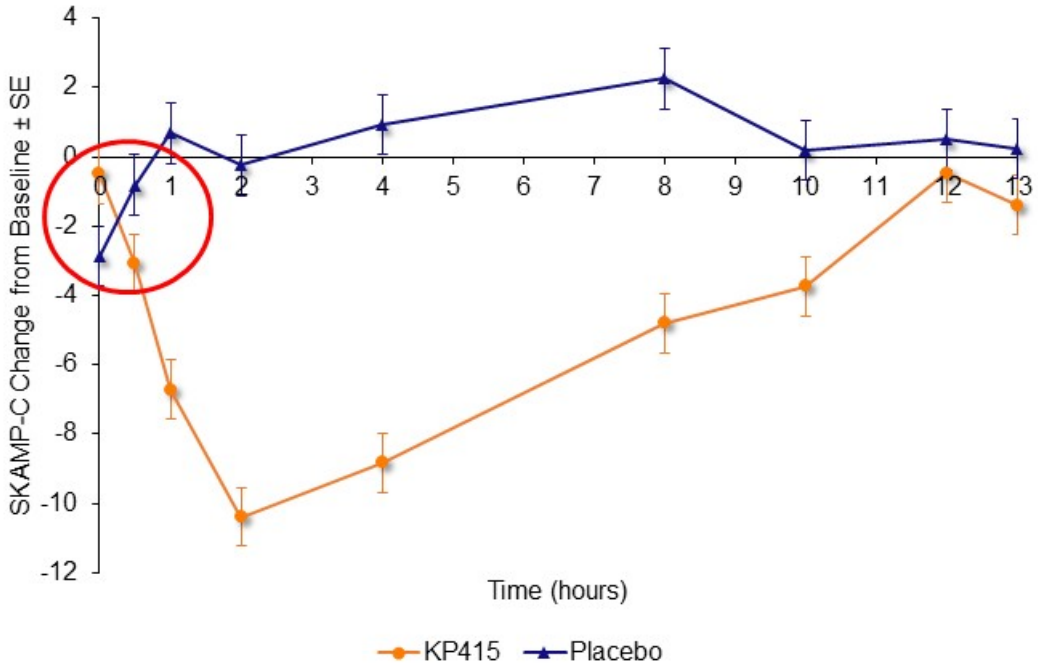
KP415.E01 Efficacy Trial : Design Schematic



Selection of Visit 5 as Pre-Dose Baseline

- The Visit 5 pre-dose SKAMP-C scores were pre-specified in the Statistical Analysis Plan (SAP) as the baseline
- Visit 5 was selected due to concerns related to a potential carryover effect related to the steady-state pharmacokinetic profile of KP415
- No KP415 carryover effect, as evidenced by pre-dose SKAMP-C and PERMP scores taken on Visit 6, was ultimately observed
- However, the Placebo group did have baseline changes from Visit 5 to Visit 6 that were not anticipated
- Using Visit 5 as pre-dose baseline did not correct for Visit 6 pre-dose differences between Active and Placebo groups

SKAMP-C Change on Visit 6 Using Visit 5 Pre-Dose Baseline



As per pre-specified SAP. LS means shown. Statistical model includes predose Visit 5 as covariate.

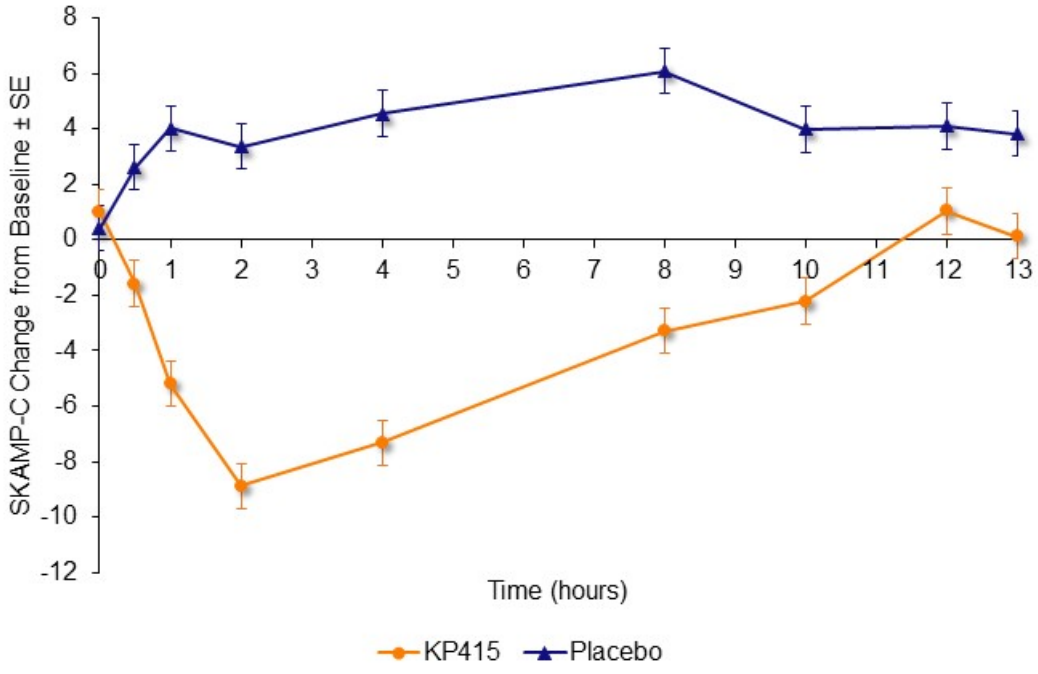
Selection of Visit 6 as Pre-Dose Baseline

- Using the Visit 6 pre-dose SKAMP-C scores as the baseline corrects for any pre-dose differences between the Active and Placebo groups on the efficacy assessment day

- Using Visit 6 (full classroom day) pre-dose SKAMP-C scores as the baseline has been acceptable in the past with efficacy studies conducted for other FDA approved ADHD products, the results of which appear in their respective labels

- Several precedents exist for ADHD-related trials where FDA has considered and/or requested alternative statistical analyses due to unexpected study influences that generated bias in either the Active or Placebo groups, including changes seen in Placebo and Active groups from period to period

SKAMP-C Change on Visit 6 Using Visit 6 Pre-Dose Baseline



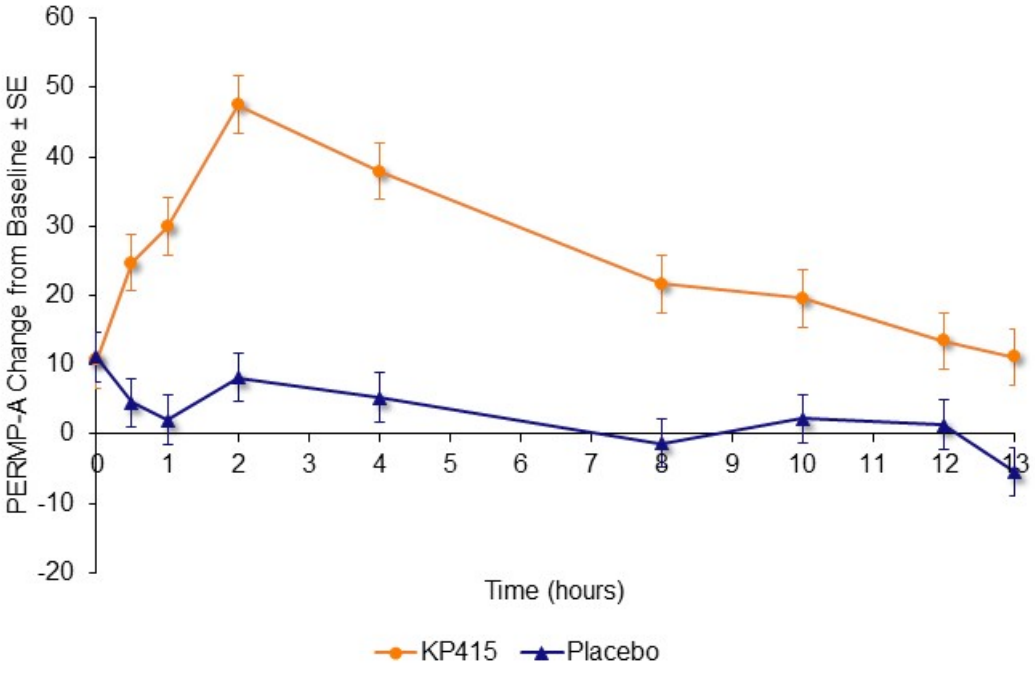
LS means shown. Statistical model also includes predose Visit 6 as covariate.

Differences in SKAMP-C Change Between KP415 and Placebo on Visit 6 Using Visit 5 vs. Visit 6 Pre-Dose Values as Baseline

	SKAMP-C Change at Visit 6 from Baseline			
	Baseline = predose Visit 5 (prespecified)*		Baseline = predose Visit 6 (post hoc)*	
	Difference in LS mean (SE)		Difference in LS mean (SE)	
Time	KP415 – Placebo	p-Value	KP415 – Placebo	p-Value
Predose	2.37 (1.18)	0.044	0.599 (1.14)	0.600
0.5 hours postdose	-2.28 (1.18)	0.053	-4.19 (1.14)	<0.001
1 hours postdose	-7.40 (1.18)	<0.001	-9.22 (1.14)	<0.001
2 hours postdose	-10.14 (1.18)	<0.001	-12.25 (1.14)	<0.001
4 hours postdose	-9.76 (1.18)	<0.001	-11.88 (1.14)	<0.001
8 hours postdose	-7.05 (1.18)	<0.001	-9.37 (1.14)	<0.001
10 hours postdose	-3.91 (1.18)	<0.001	-6.20 (1.14)	<0.001
12 hours postdose	-0.96 (1.18)	0.412	-3.07 (1.14)	0.007
13 hours postdose	-1.63 (1.18)	0.167	-3.71 (1.14)	0.001

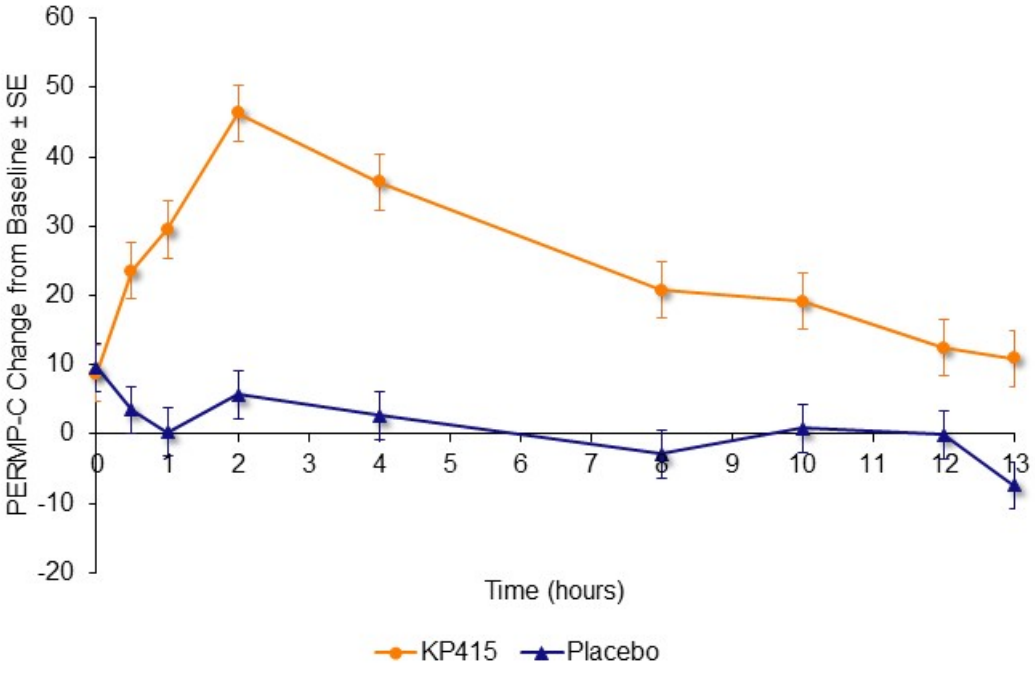
* Statistical model includes pre-dose Visit 5 or Visit 6 as covariate, respectively.

PERMP-A Change on Visit 6 Using Visit 5 Pre-Dose Baseline



LS means shown. Statistical model includes predose Visit 5 as covariate.
No meaningful difference between use of Visit 5 or Visit 6 baselines.

PERMP-C Change on Visit 6 Using Visit 5 Pre-Dose Baseline



LS means shown. Statistical model includes predose Visit 5 as covariate.
No meaningful difference between use of Visit 5 or Visit 6 baselines.

Summary and Next Steps

- KP415.E01 efficacy trial met its primary endpoint
- Trial results for onset and duration were confounded by pre-dose SKAMP-C baseline differences between Visit 5 and Visit 6 for patients randomized into the placebo arm of the trial
- Trial data using Visit 6 as the pre-dose baseline is supportive of a 30-minute onset and a 13-hour duration; secondary endpoints are similarly supportive
- Based on this and previously published trial data, we believe KP415 has an attractive safety and efficacy profile for the treatment of ADHD; NDA remains on track for submission in Q1 2019
- Strategic partnering discussions for KP415 continue based on:
  - Near-term ADHD prodrug commercial opportunity
  - KP415 IV HAP data, with more HAP data to come
  - Long patent life and potential NCE status

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