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): May 16, 2019

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	001-37471	30-0784346
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
255 State Street, 9th Floor Boston, MA		02109
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: 857-246-8998

N/A
(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:

☐ 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 May 16, 2019, Pieris Pharmaceuticals, Inc.'s abstract related to its phase 2a study of PRS-080 was released for the 24th Congress of the European Hematology Association. The abstract is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information set forth under this “Item 7.01. Regulation FD Disclosure,” including Exhibit 99.1 attached hereto, shall not be deemed “filed” for any purpose, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing. except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 Conference Abstract, Dated May 16, 2019.

SIGNATURE

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.

PIERIS PHARMACEUTICALS, INC.

Dated: May 16, 2019

/s/ Allan Reine

Allan Reine

Chief Financial Officer

A PHASE IIA STUDY TO EVALUATE THE SAFETY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF REPEATED ADMINISTRATIONS OF THE HEPCIDIN ANTAGONIST PRS-080 OVER 4 WEEKS IN ANEMIC CHRONIC KIDNEY DISEASE PATIENTS UNDERGOING HEMODIALYSIS

Author(s):
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Abstract: S1630

Type: Oral Presentation

Presentation during EHA24: Sunday, June 16, 08:45 – 09:00

Location: Hall 3B

Background
Patients suffering with chronic kidney disease (CKD) commonly present with anemia. Current treatment regimens consist of iron, erythropoietin stimulating agents (ESAs), or both, but a significant number of patients remain anemic despite these therapies. Hepcidin, a liver-derived hormone, is a central regulator of iron homeostasis, frequently elevated in CKD patients and thought to represent a root cause of the hypoferremia. Therefore, hepcidin inhibition has the potential to ameliorate functional iron deficiency anemia in CKD patients. PRS-080 is a pegylated Anticalin® hepcidin antagonist that has been shown to induce dose dependent serum iron mobilization and increased transferrin saturation (TSAT) in single ascending dose phase 1 clinical studies, both in healthy male volunteers and dialysis dependent CKD patients (PLOS-One, in press).

Aims
To determine the safety and tolerability of 5 repeated intravenous administrations of PRS-080 at doses of 4 and 8 mg/kg body weight (BW) compared to placebo, in anemic, hemodialysis dependent stage 5 CKD patients, as well as to assess pharmacokinetics, pharmacodynamics and immunogenicity.

Methods
Twelve patients were enrolled. Four patients per cohort each received PRS-080 at a dose of 4 or 8 mg/kg, with two patients per cohort receiving placebo. The study included a screening period of 4 weeks; the mean of 3 hemoglobin (Hb) values during the screening period, each obtained at least 7 days apart was required to be ≤10.5 g/dL, with a difference of ≤1.0 g/dL between the lowest and highest values. Additional inclusion criteria included Ferritin > 300 ng/mL and TSAT ≤30%. The ESA dose had to remain stable for at least 4 weeks prior to screening, as well as through the treatment period, and iron therapy had to be withdrawn 1 week before randomization. Study medication was administered by infusion over 60 minutes using an infusion pump on day 0, day 7, day 14, day 21, and day 28. Patients were observed with regard to safety up until day 112. Safety was monitored continuously by a data safety

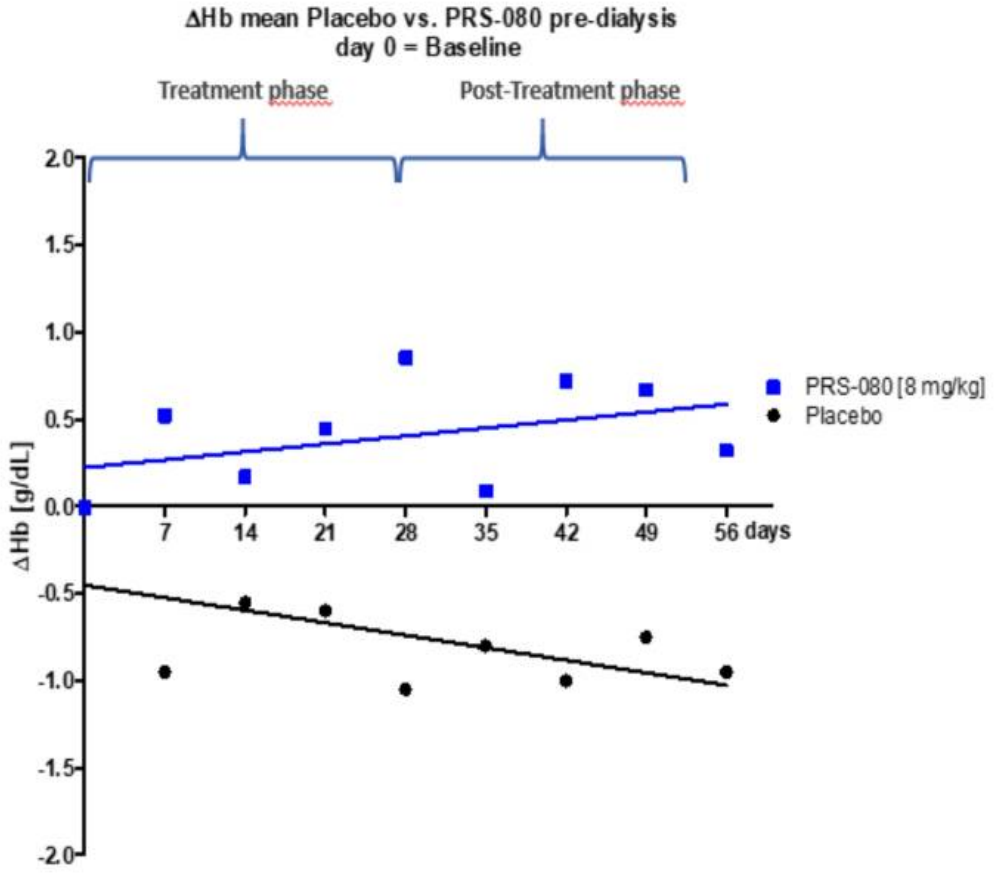
monitoring board (DSMB), including prior to dose escalation.

Results

There were no treatment related adverse events (AEs) or serious adverse events (SAEs). Robust iron mobilization with increases in both serum iron and TSAT were consistently observed following each weekly dose in both dose cohorts. Peak iron concentrations were higher in the 8mg/kg cohort than in the 4mg/kg cohort.

Whereas there was no clear difference in Hb values between placebo and PRS-080 patients in the 4mg/kg cohort over the course of treatment, evidence of a Hb response with clear separation of Hb values between placebo and PRS-080 could be shown in the 8mg/kg cohort during the treatment period, consisting of an increase of Hg in drug treated patients and a decline in placebo patients, potentially related to the withdrawal of iron treatment.

Fig 1: Hb Difference to Day 0, pre-dialysis values Day 0 to Day 56



Conclusion

PRS-080 was safe and well tolerated at both dose levels in this exploratory phase 2a multiple ascending dose clinical study in anemic dialysis-dependent CKD patients. Promising results were achieved in terms of both iron mobilization and increased TSAT, as well as initial evidence of an increase in Hb levels in the higher dose group. Further studies to determine the optimal treatment regimen with PRS-080 are warranted.

Session topic: 29 - Iron metabolism, deficiency and overload.

Keyword(s): Anemia, CKD, Hepcidin Antagonist, Anticalin

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