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): October 1, 2019

PIERIS PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Nevada	001-37471	EIN 30-0784346
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

225 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	PIRS	The Nasdaq Capital Market

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 October 1, 2019, Pieris Pharmaceuticals, Inc. presented its phase 1 multiple ascending dose study of PRS-060 entitled*Multiple ascending dose study of the inhaled IL-4Rα antagonist, AZD1402/PRS-060, in mild asthmatics demonstrates robust FeNO reduction and a promising clinical profile for the treatment of asthma*. The presentation 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 PRS-060 Multiple Ascending Dose Study Presentation, Dated October 1, 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: October 1, 2019

/s/ Tom Bures

Tom Bures

Vice President, Finance

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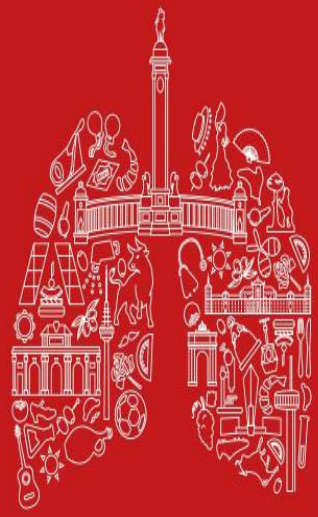


INTERNATIONAL CONGRESS 2019

MADRID Spain, 28 September – 2 October

Multiple ascending dose study of the inhaled IL-4Rα antagonist, AZD1402/PRS-060, in mild asthmatics demonstrates robust FeNO reduction and a promising clinical profile for the treatment of asthma

Bruns IB,[1] Fitzgerald MF,[1] Mensing G,[1] Tsung M,[1] Pardali K,[2] Gardiner P,[3] Keeling DJ,[2] Axelsson LT,[2] Olsson M,[4] Ghobadi C,[2] Walsh O,[5] McLendon K,[6] Farinola N,[7] Hatchuel L,[8] Close DR[2]

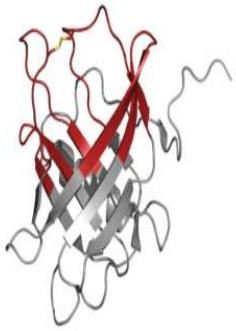
[1]Pieris Pharmaceuticals, Boston, MA, USA; [2]Early Respiratory, Inflammation and Autoimmune, BioPharmaceuticals R&D, AstraZeneca, Gothenburg, Sweden; [3]Clinical Pharmacology and Safety Sciences, Biopharmaceuticals R&D, AstraZeneca, Gothenburg, Sweden; [4] Data Science and AI, BioPharmaceuticals R&D, AstraZeneca Gothenburg, Sweden [5]Nucleus Network Limited, Melbourne, Australia; [6]Q-Pharm Pty Ltd, Herston, Australia; [7]CMAX Clinical Research Pty Ltd, Adelaide, Australia; [8]Linear Clinical Research Ltd, Nedlands, Australia

Conflict of interest disclosures

- This study was sponsored by Pieris Pharmaceuticals and funded by AstraZeneca
- IB Bruns is an employee and shareholder of Pieris Pharmaceuticals.
- MF Fitzgerald is a consultant and shareholder of Pieris Pharmaceuticals.
- G Mensing is an employee of Pieris Pharmaceuticals.
- M Tsung is an employee of Pieris Pharmaceuticals.
- K Pardali, P Gardiner, DJ Keeling, LT Axelsson, M Olsson, C Ghobadi and DR Close are employees of AstraZeneca and may own stock or stock options.
- O Walsh is an employee of Nucleus Network Limited, Melbourne, Australia.
- K McLendon is an employee of Q-Pharm Pty Ltd, Herston, Australia.
- N Farinola is an employee of CMAS Clinical Research Pty Ltd, Adelaide, Australia.
- L Hatchuel is an employee of Linear Clinical Research Ltd, Nedlands, Australia.

Rationale

- Asthma is a chronic, complex and heterogeneous respiratory disease[1]
- Interleukin (IL)-4 and IL-13, which both signal through the IL-4 receptor alpha subunit (IL-4Rα), have been identified as two key cytokines contributing to the pathogenesis of asthma[2]
- As demonstrated in clinical trials, agents that either antagonize IL-4Rα directly or its agonists reduce fractional exhaled nitric oxide (FeNO) levels[3–5]
- AZD1402/PRS-060 is a novel inhaled Anticalin® molecule that selectively antagonizes IL-4Rα and therefore inhibits the pro-inflammatory actions of IL-4 and IL-13



AZD1402/PRS-060 protein structure

Here, we describe the interim analysis of a phase 1 dose-escalation study that assessed the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple inhaled doses of AZD1402/PRS-060 in patients with mild asthma

FeNO, fractional exhaled nitric oxide; IL, interleukin; IL-4Rα, IL-4 receptor alpha subunit

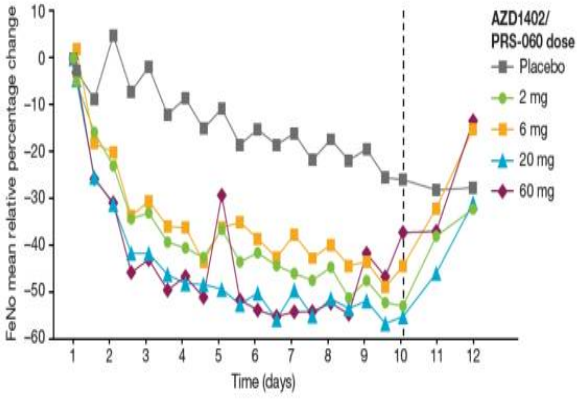
1. Reddel *et al. Eur Respir J* 2015;46:622–39; 2. Vatrella *et al. J Asthma Allergy* 2014;7:123–30; 3. Wenzel et al *New Eng J Med* 2013;368:2455–66; 4. Otulana *et al. AJRCCM* 2011;183:A6179; 5. Cai *et al. AJRCCM* 2016; 193:A1405

Results: FeNO reduction and pSTAT6

- Pulmonary target engagement was determined by reduction in FeNO levels
  - **Significant and pronounced inhibition of FeNO levels was observed at all dose levels evaluated**
- Systemic target engagement was determined ex vivo by inhibition of IL-4-stimulated phosphorylation of signal transducer and activator of transcription 6 (pSTAT6) in whole blood
  - **Inhibition of pSTAT6 ranged from minimal to near complete as a function of dose level**

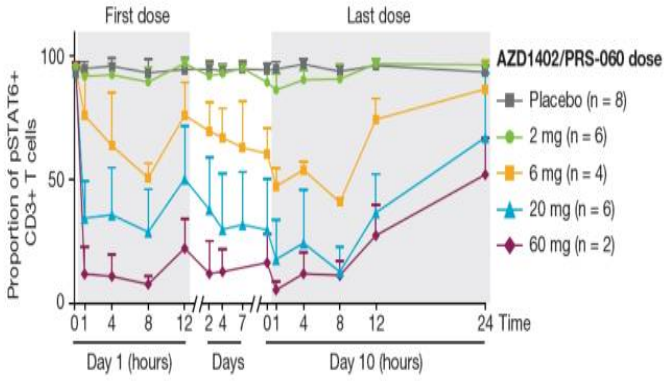
Local

Relative percentage change in FeNO[a]



Systemic

pSTAT6 levels following inhalation of AZD1402/PRS-060



[a]Relative reduction at time t is derived as 1 minus the ratio of the geometric mean at time t to the geometric mean of baseline, i.e $1-\left\{\frac{\prod FeNO}{\prod FeNO_{BL}}\right\}^{1/n}$

FeNO, fractional exhaled nitric oxide; pSTAT6, phosphorylated signal transducer and activator of transcription 6

FeNO (percentage change) and % pSTAT6+ in CD3 T-cell subpopulation: group means

Results: incidence of AEs occurring in ≥ 5% of overall patients [a]

- All doses of AZD1402/PRS-060 tested in the study were well tolerated; no treatment related serious AEs were observed

System organ class AE Preferred Terms[b]	Placebo (N = 12) n (%) m	AZD1402/PRS-060[c] (N = 30) n (%) m	Overall (N = 42) n (%) m
Gastrointestinal disorders	**4 (33.3) 4**	**13 (43.4) 14**	**17 (40.5) 18**
Dry mouth	1 (8.3) 1	2 (6.7) 2	3 (7.1) 3
Nausea	1 (8.3) 1	3 (10.0) 3	4 (9.5) 4
Infections and infestations	**1 (8.3) 1**	**7 (23.3) 8**	**8 (19.0) 9**
Upper respiratory tract infection	1 (8.3) 1	3 (10.0) 4	4 (9.5) 5
Nervous system disorders	**5 (41.7) 9**	**13 (43.4) 18**	**18 (42.9) 27**
Headache	3 (25.0) 6	5 (16.7) 7	8 (19.0) 13
Presyncope	0	4 (13.3) 6	4 (9.5) 6
Respiratory, thoracic and mediastinal disorders	**6 (50.0) 6**	**14 (46.7) 15**	**20 (47.6) 21**
Cough	1 (8.3) 1	4 (13.3) 4	5 (11.9) 5
Rhinorrhoea	2 (16.7) 2	1 (3.3) 1	3 (7.1) 3
Wheezing	2 (16.7) 2	4 (13.3) 5	6 (14.3) 7

MedDRA v21.0 coding applied

[a]Percentage is based on Preferred Term i.e, the incidence of AEs which occurred in ≥5% of overall patients by preferred term

[b]AEs are from cohorts 1–4, which occurred in ≥ 5% of overall patients

[c]Delivered doses of AZD1402/PRS-060 were 2 mg, 6 mg, 20 mg and 60 mg

One pregnancy leading to a serious AE of miscarriage was observed. This was considered to be due to the patient's age, and not related to the study drug by the investigator

AE, adverse event; m, number of events; n, number of patients reported with specific AEs; N, total number of patients in each treatment group

Conclusions

- The FeNO-reduction potential of AZD1402/PRS-060 is unparalleled with other inhaled therapies
- Pharmacological versatility, given low-dose FeNO reduction with no observed systemic activity (pSTAT6) versus high-dose FeNO reduction with systemic activity
- AZD1402/PRS-060 was very well tolerated and safe; there were no related SAEs, and AEs were evenly distributed between treatment and placebo groups
- The overall profile of AZD1402/PRS-060 demonstrates its suitability for continued development as an inhaled therapy for asthma

Please see poster **PA3709** for more details: 08:30–10.30, 1 October 2019 in RETIRO

The study is sponsored by Pieris Pharmaceuticals and funded by AstraZeneca. Medical writing support, funded by AstraZeneca, was provided by Sinéad Flannery, PhD, of PharmaGenesis London, London. UK. The authors would also like to acknowledge Kayti Aviano, Pieris Pharmaceuticals for her contribution to the analysis and interpretation of the data for this study.

AE, adverse event; FeNO, fractional exhaled nitric oxide; signal transducer and activator of transcription 6

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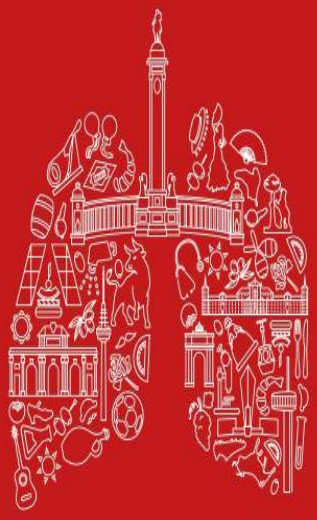

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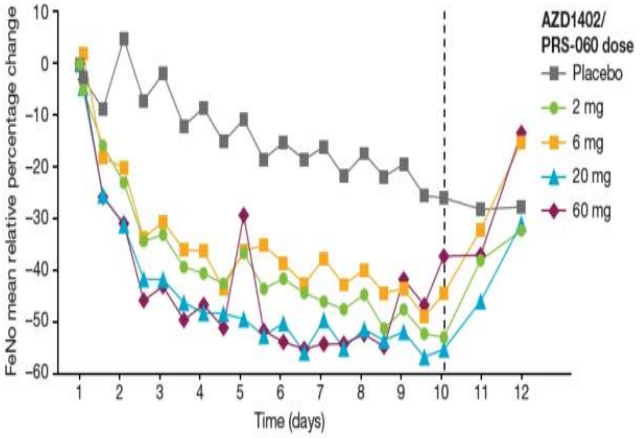
Phase 1b Interim Results: Robust FeNO Reduction

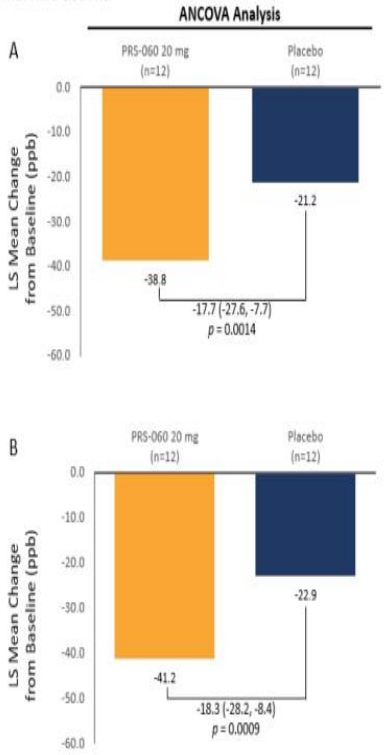
PRS-060 Relative FeNO Reduction (Emax Analysis)



PRS-060, mg (delivered)	n	Reduction vs. placebo, % (95% CI)	p-value
2	6	24.0 (1.8–41)	0.04
6	6	24.3 (2.7–41)	0.03
20	12	36.4 (22–48)	<0.0001
60	6	30.5 (10–46)	0.005
Placebo	12		

PRS-060 Relative FeNO Reduction (ANCOVA Analysis)

Mean change from baseline in FeNO levels at 0.5h (A) and 2h (B) post-dose on Day 10 in participants with mild asthma



80% relative FeNO reduction in powered cohort (20mg)

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