
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): January 13, 2014

CymaBay Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-55021
(Commission
File Number)

94-3103561
(IRS Employer
Identification No.)

3876 Bay Center Place
Hayward CA 94545
(Address of principal executive offices)

(510) 293-8800
(Registrant's telephone number, including area code)

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 Instruction 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))
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Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 to this report, and incorporated herein by reference, is a slide presentation (the “Corporate Presentation”), which will be presented by CymaBay Therapeutics, Inc. at management presentations beginning Monday, January 13, 2014, to be held in San Francisco, California.

In accordance with General Instruction B.2. of Form 8-K, the information contained above in this report (including the Corporate Presentation) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall the Corporate Presentation be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing. This report will not be deemed a determination or an admission as to the materiality of any information in the Corporate Presentation that is required to be disclosed by Regulation FD.

Item 9.01. Financial Statements and Exhibits.

Exhibit	Description
99.1	Corporate 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.

CymaBay Therapeutics, Inc.

By: /s/ Sujal Shah

Name: Sujal Shah

Title: Chief Financial Officer

Dated: January 13, 2014

EXHIBIT INDEX

Exhibit	Description
99.1	Corporate Presentation



**Corporate Presentation
January 2014**



Safe Harbor Statements

This presentation contains "forward-looking" statements that involve risks, uncertainties and assumptions. The opinions, forecasts, projections, or other statements about future events or results, are forward-looking statements. If the risks or uncertainties ever materialize or the assumptions prove incorrect, CymaBay's results may differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements include, but are not limited to: any projections of financial information; any statements about historical results that may suggest trends for CymaBay's business and results of operations; any statements concerning CymaBay's plans, strategies or objectives; any statements of expectation or belief regarding future events; any statement of projected sales forecasts, revenues or anticipated or projected markets; and any statements of assumptions underlying any of the foregoing. These statements are based on estimates and information available to CymaBay at the time of this presentation and are not guarantees of future performance. Actual results could differ materially from CymaBay's current expectations as a result of many factors, including but not limited to: CymaBay's ability to obtain additional financing to fund its operations as it currently expects; unexpected delays or results in clinical trials; uncertainties regarding obtaining regulatory approvals; uncertainties regarding the ability to protect CymaBay's intellectual property; uncertainties regarding market acceptance of any products for which CymaBay is able to obtain market acceptance; the effects of competition; and market factors and general economic conditions. You should read CymaBay's Form 10 and S-1 registration statements, which are available on the SEC web site at <http://www.sec.gov>, including the Risk Factors set forth therein, completely and with the understanding that our actual future results may be materially different from what we expect. CymaBay assumes no obligation for and does not intend to update these forward-looking statements. Nothing contained herein is, or should be relied on as, a promise or representation as to the future performance of CymaBay.

CymaBay Investment Highlights

- **Restructured company retaining the prior Metabolex pipeline and core management team**
 - Became public through Form 10 self registration route
 - \$38M financing completed to fund arhalofenate development
 - Application to FINRA to trade on the OTCBB under review
 - Application for NASDAQ listing under review
- **Arhalofenate is a potentially game changing dual-acting treatment for gout**
 - Anti-flare activity of Colcrys (URL, acquired by Takeda for \$800M)
 - Uricosuric activity of lesinurad (Ardea, acquired by AZ for \$1.3B)
 - Large (>\$500M peak sales) market opportunity
 - Highly de-risked asset with large clinical safety database
- **Other pipeline projects**
 - MBX-2982 and MBX-8025 in Phase 2

CymaBay Leadership
Averages >20 years of drug development experience

<u>Name</u>	<u>Title</u>	<u>Experience</u>
Harold Van Wart	President, CEO	Syntex, Roche
Sujal Shah	CFO	Credit Suisse, Citi
Charles McWherter	CSO	Pfizer, Sugen
Mary Jean Stempien	Interim CMO	Roche, Tularik
Robert Martin	VP Project Management	Syntex, Roche
Patrick O'Mara	VP Business Dev.	Metabolex
Diana Petty	VP Human Resources	SmithKline, 3M

CymaBay Pipeline, January 2014

Multiple partnered and unpartnered programs

Lead Optimization	Preclinical	Phase 1	Phase 2	Phase 3
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Arhalofenate

Gout

MBX-8025

High Unmet Need/
Orphan Disease

MBX-2982

Diabetes



Novel Target

Diabetes



Targets

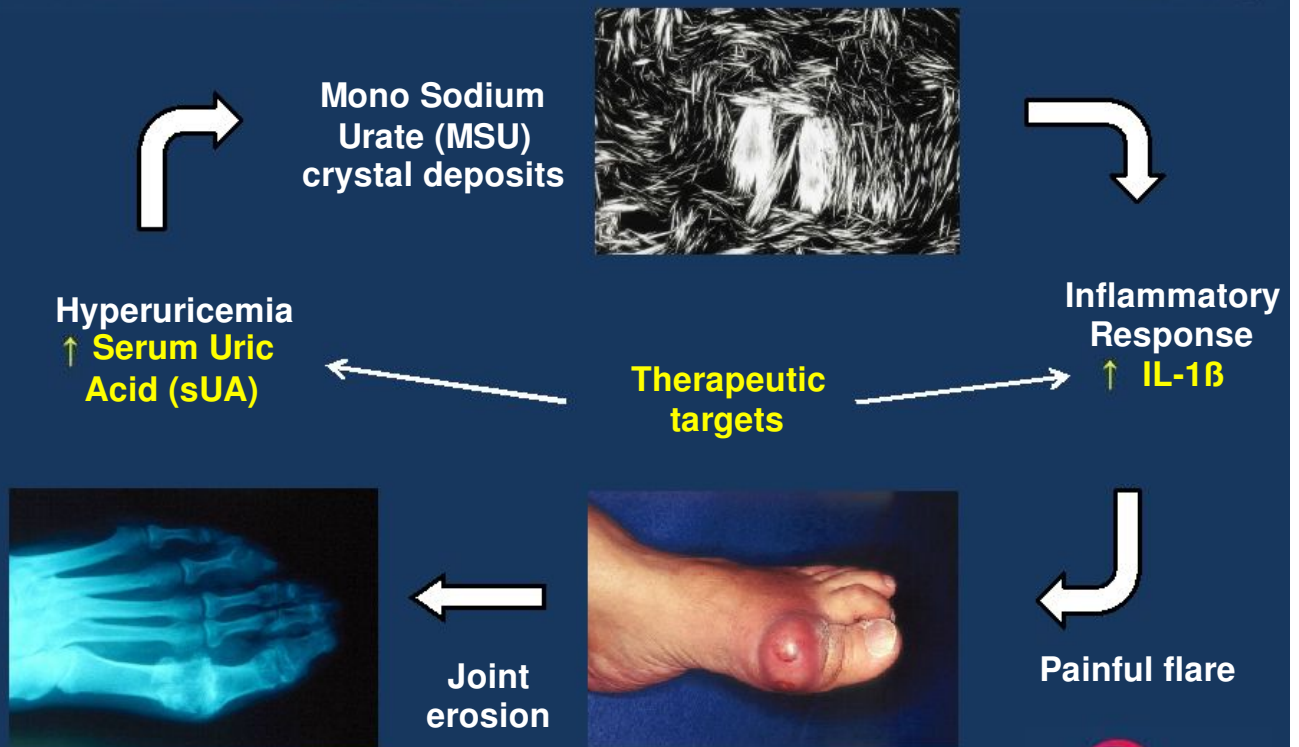
Diabetes

Target

Diabetes

Key Features of Gout

Hyperuricemia, urate crystal deposits and flares



Current Treatment of Gout

Uric acid Lowering Therapies (ULTs) and anti-inflammatories

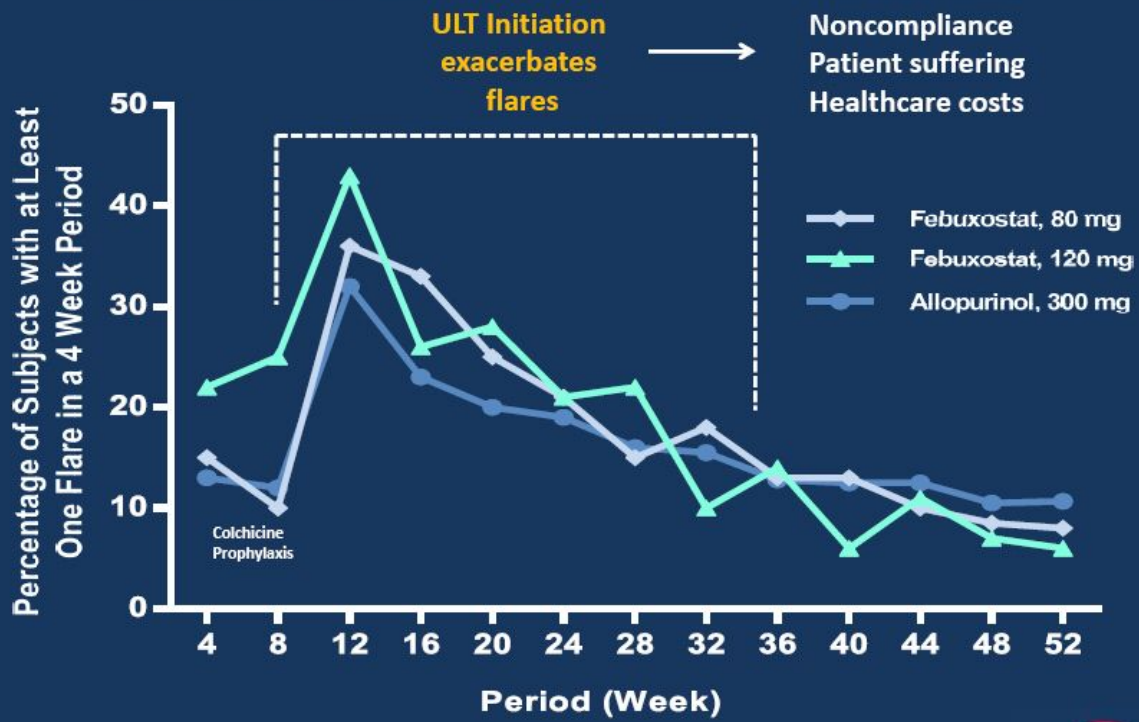
- **Treatment paradigm (ACR Guidelines)**
 - Anti-inflammatory to treat the flare
 - ULT is initiated to address the hyperuricemia with a goal of sUA < 6 mg/dL to debulk offending MSU burden
 - **Initiation of ULT increases flare risk, requiring Colcrys prophylaxis**

- **Anti-inflammatory drugs**
 - Colchicine (Colcrys)
 - NSAIDs, steroids
 - Ilaris (anti-IL-1 β biologic) approved in EU

- **ULTs**
 - Xanthine oxidase (XO) inhibitors (allopurinol, febuxostat)
 - Uricosurics (probenecid, lesinurad)
 - Pegloticase (for severe treatment failure gout)

The Big Paradox

Currently marketed ULTs increase flares



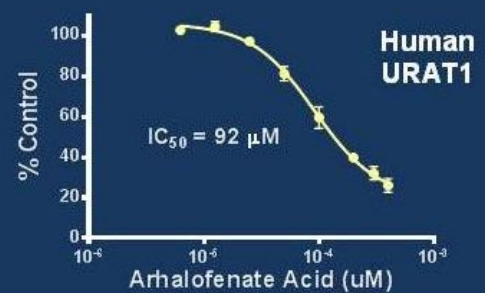
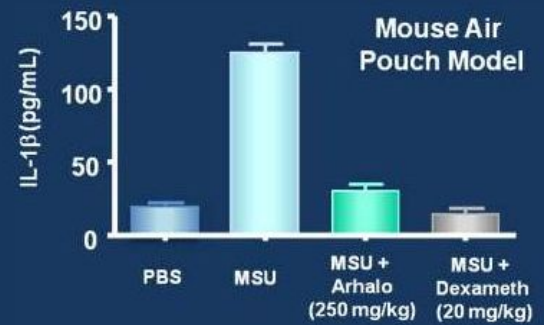
Gout Patients Are Poorly Served by Available Drugs *Need for better control of flares and sUA*

- **Patients care about the pain, suffering and medical costs due to flares**
 - Despite ULT, at least 1 million patients flare \geq 3 times/year
 - More than 50% of patients on ULT do not reach the sUA goal of < 6 mg/dL and are unable to debulk their MSU burden
 - Poor performance of available therapies leads to non-compliance
- **Current anti-inflammatory drugs have limitations for gout patients**
 - Colcrys (\$496M sales in 2012) has GI side effects, drug interactions and is difficult to use in patients with comorbidities (CKD, CVD)
 - Steroids and NSAIDs are also problematic
 - Ilaris is an expensive injectable with risk of infections
- **Unmet needs**
 - Better flare control
 - Additional sUA lowering, but not if it causes more flares

The Arhalofenate Solution

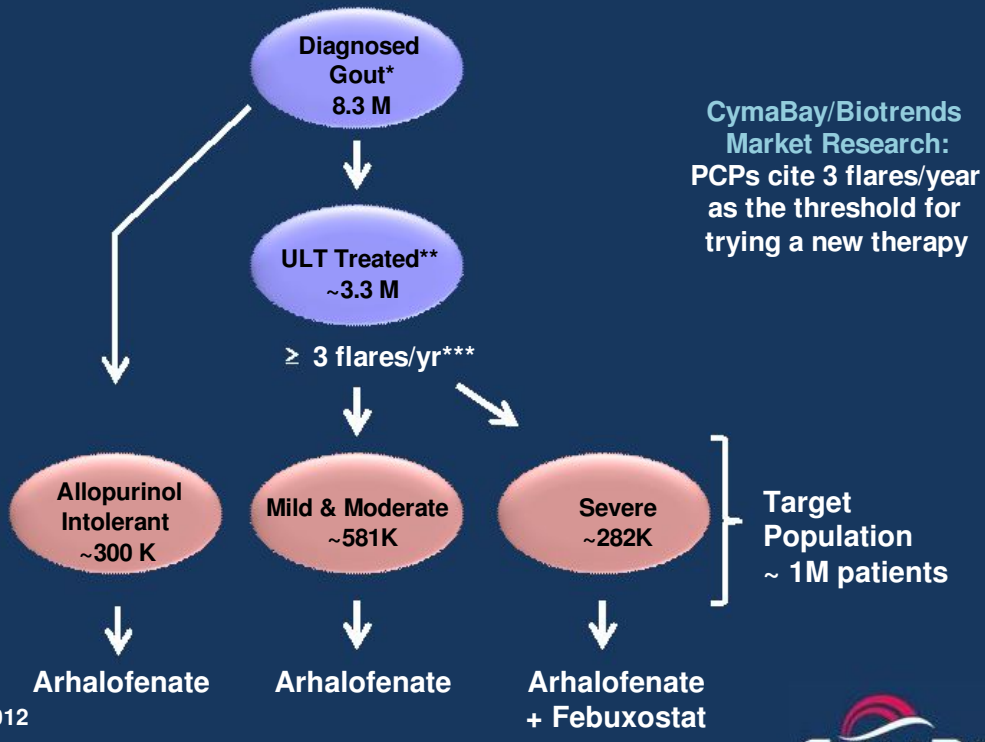
The only therapy that reduces flares while lowering sUA

- **Reduces flares through anti-inflammatory properties and long plasma half-life**
 - Suppresses MSU crystal-induced IL-1 β in gouty joints
 - No systemic suppression of IL-1 β and no infection risk
 - 50 hour half-life “buffers” sUA levels to minimize intraday fluctuations
- **Lowers sUA by improving uric acid excretion in the kidney**
 - Blocks urate reabsorption by URAT1
 - Same mechanism for lowering sUA as lesinurad
 - Retains uricosuric activity in CKD patients



Arhalofenate Target Population

Three or more flares a year or allopurinol intolerant



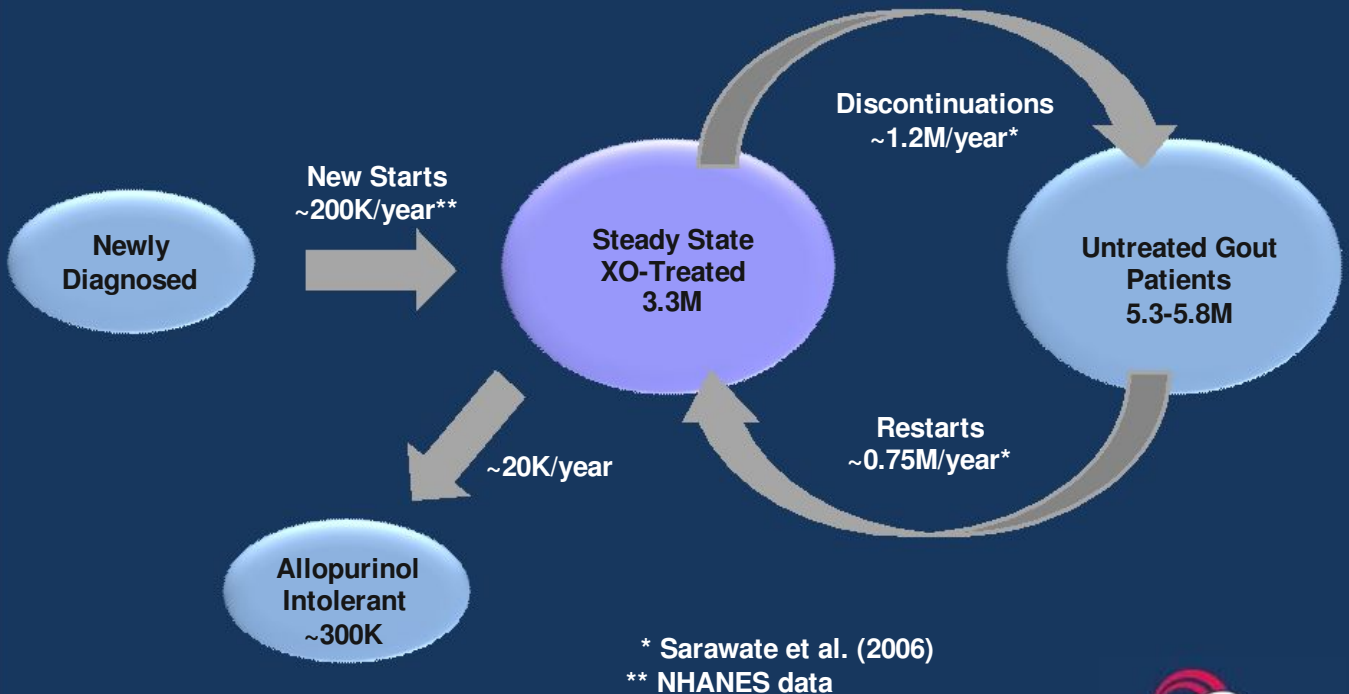
CymaBay/Biotrends
Market Research:
PCPs cite 3 flares/year
as the threshold for
trying a new therapy

* NHANES, 2008
** Source Healthcare 2012
*** BioTrends



Switch Strategy is Made Possible by Patient Presentations

Repeat visits to PCPs due to flare recurrence



Market Opportunity

Arhalofenate's unique profile creates large opportunity

- **Arhalofenate offers what patients care about – relief from flares and pain**
 - US Colcrys sales (\$496M) in 2012 validate value of flare reduction
 - Pharmacoeconomic argument for payers on reduced healthcare costs
 - 25% of patients with ≥ 3 flares/yr need an ER visit or hospitalization*
 - Hospitalizations have a mean length of stay of 4 days**
- **Arhalofenate US Sales forecast (Sage Path Partners)**
 - Peak sales >\$500M
- **Pure ULTs that lack anti-flare activity have not been commercially successful**
 - Allopurinol is an inexpensive entrenched generic (>90% market share)
 - Febuxostat sales of only ~\$216M/year is due to minimal differentiation
 - Lesinurad may face the same challenges

Discovery and History of Arhalofenate

Single enantiomer of halofenate

- **Halofenate**
 - Racemic drug studies by Merck in late 1970s
 - 1200 patient year clinical database with effective reduction in sUA and triglycerides and good overall safety (studies up to 4 years)
 - Lowered glucose in diabetics
 - Discontinued due to GI side effects associated with S-enantiomer
- **Arhalofenate**
 - *R*-enantiomer of halofenate partnered with JnJ for type 2 diabetes
 - Eight Phase 1 and four Phase 2 studies (3-6 months) completed
 - Total of 873 patients studied giving ~165 patient-years of exposure
 - Decreases in HbA1c fell short of commercial target
 - Now being repurposed for gout

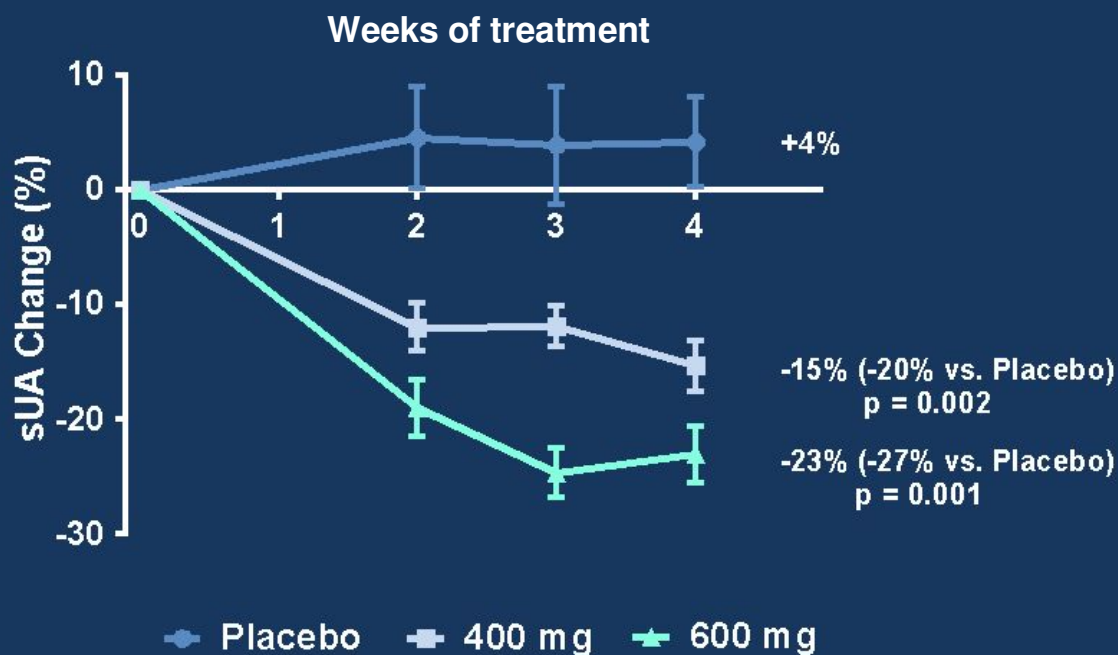
Phase 2 Gout Studies Conducted with Arhalofenate

Strong support for monotherapy and febuxostat combination

- **Monotherapy study (64 patients, 4-week treatment)**
 - Arhalofenate (400 or 600 mg) or placebo
 - Reductions in sUA lowering and flare parameters
- **Febuxostat combination study (11 patients; up-titration over 5 weeks)**
 - 80 mg febuxostat plus arhalofenate (400 or 600 mg)
 - Percentage of patients that reach sUA goals (< 6, < 5, < 4 and < 3 mg/dL) and decrease in flare parameters
- **Allopurinol combination study (95 patients, 4 weeks of treatment)**
 - Patients on allopurinol (300 mg) not reaching sUA < 6 mg/dL received arhalofenate (400 or 600 mg) or placebo
 - Reductions in flare parameters
 - Effect on sUA partially offset by drug interaction with oxypurinol

Arhalofenate Phase 2 Monotherapy Study

Gradual dose-dependent reductions in sUA



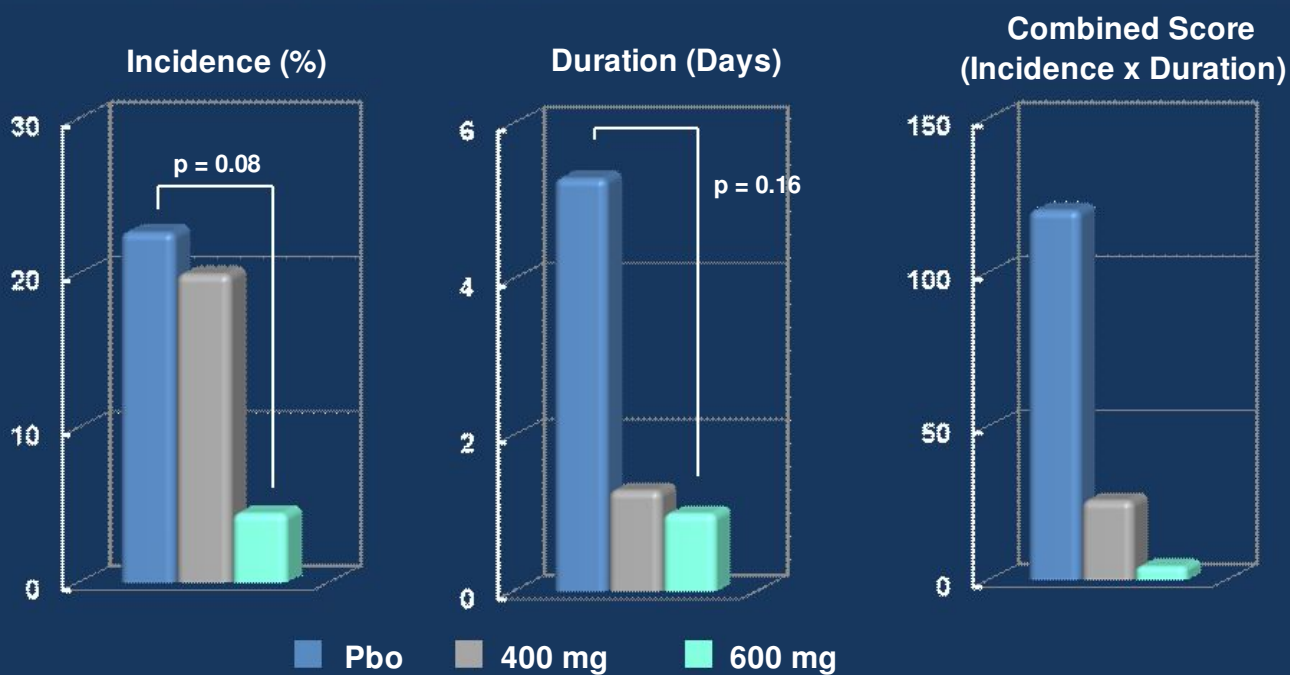
Baseline sUA	9.7	9.4	9.8
No. of patients	22	20	22

16



Arhalofenate Phase 2 Monotherapy Study

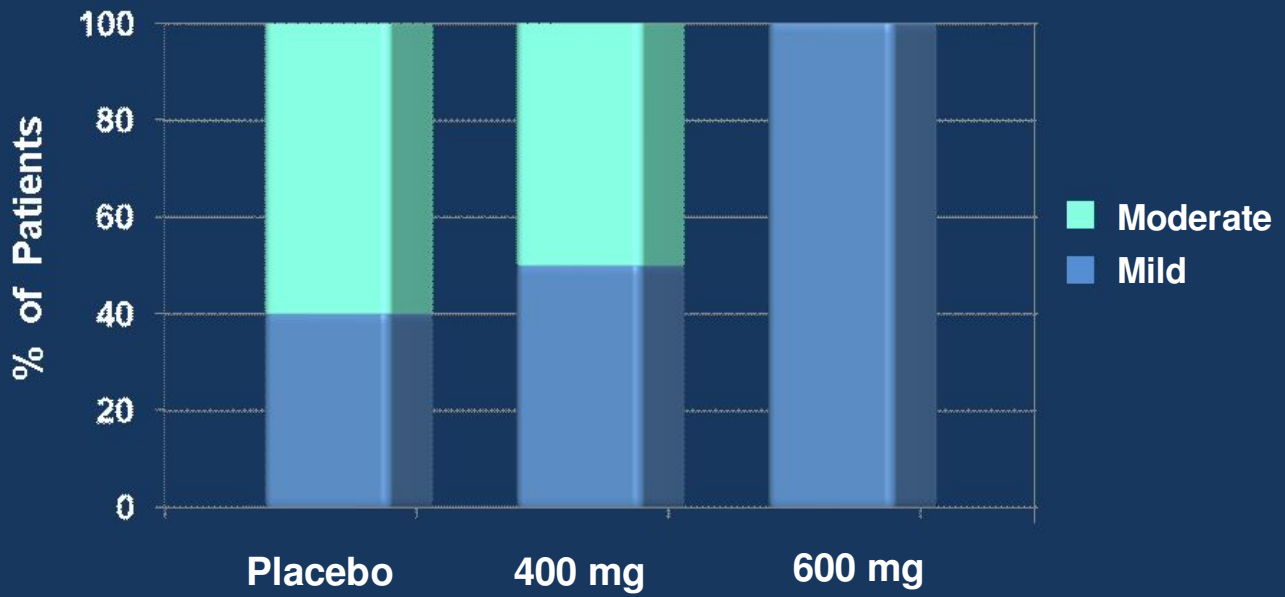
Decrease in flare incidence, duration and combined score



All patients received Colcrys for flare prophylaxis

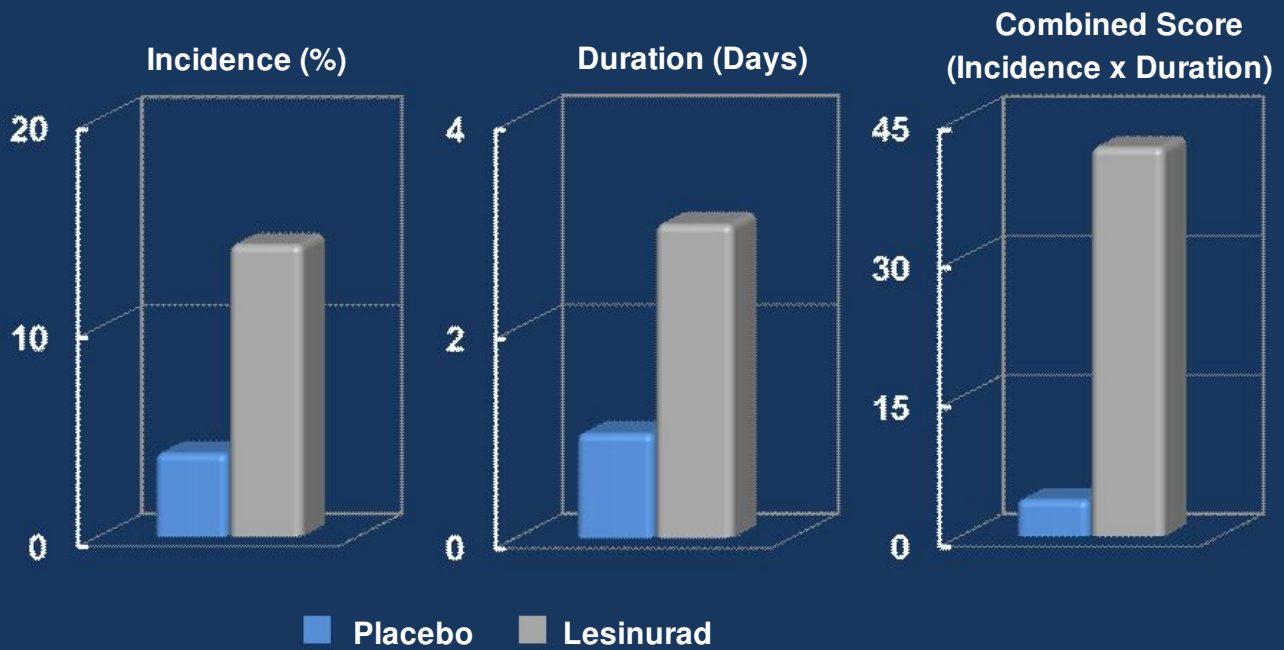
Arhalofenate Phase 2 Monotherapy Study

Decreases in flare severity



Lesinurad Phase 2 Monotherapy Study (Ardea*)

Increases in flare incidence, duration and combined score

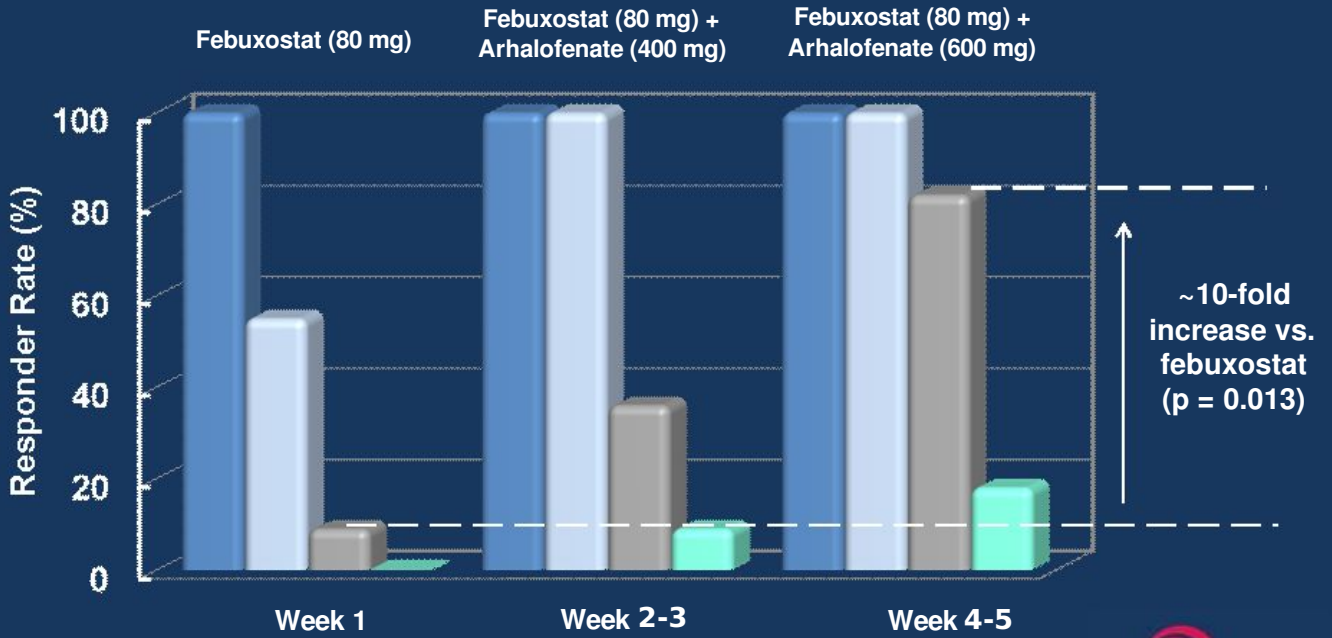


* 28-day study up-titration of lesinurad from 200 to 400 to 600 mg
All patients received Colcrys for flare prophylaxis

Arhalofenate Phase 2 Febuxostat Combination Study

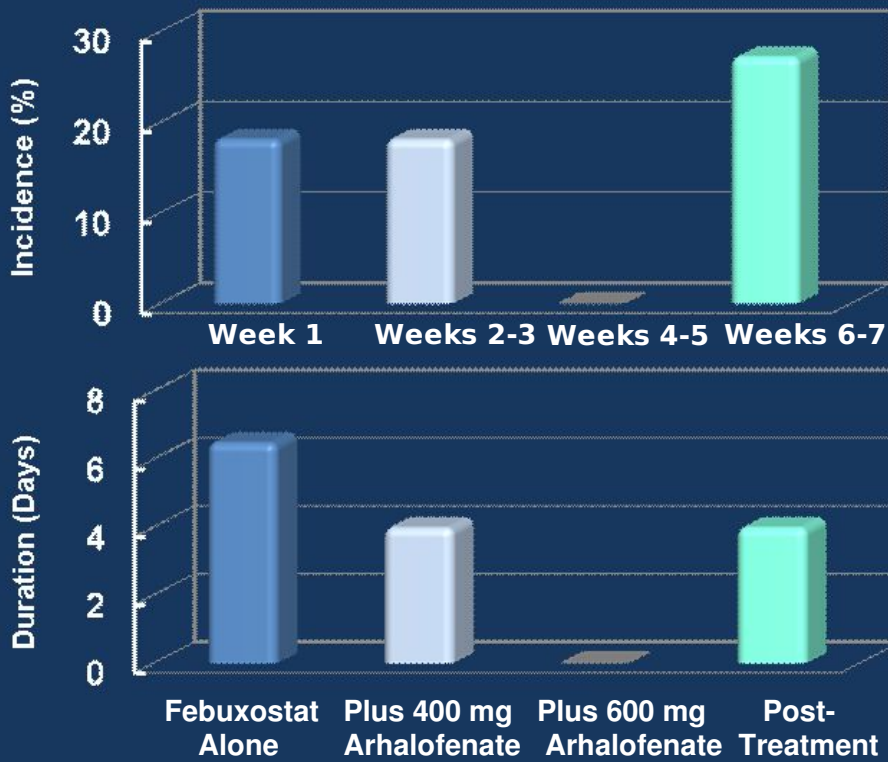
Best-in-class sUA responder rate

■ ≤ 6.0 mg/dL ■ ≤ 5.0 mg/dL ■ ≤ 4.0 mg/dL ■ ≤ 3.0 mg/dL



Arhalofenate Phase 2 Febuxostat Combination Study

Decrease in flare incidence and duration



All patients received Colcrys for flare prophylaxis through post-treatment phase

Arhalofenate Clinical Studies

Efficacy summary

- **Consistent reductions in flare parameters in all three studies**
 - Incidence, severity and duration
 - Effects comparable to the anti-IL- β biologics
 - Effects achieved without need for dose titration
- **Consistent reductions in sUA**
 - Up to 27% with monotherapy
 - Up to 60% in combination with febuxostat
 - Subset analyses show that sUA reductions are retained in:
 - Patients with Stage 2 and 3 CKD
 - Patients taking diuretics and aspirin
- **Favorable effects on metabolic comorbidities**
 - Lowers triglycerides and reverses insulin resistance

Arhalofenate Clinical Studies

Safety summary

- **Completed 15 clinical studies**
 - Nearly 1000 subjects exposed to arhalofenate for up to 6 months
- **General safety**
 - Adverse events similar to placebo and balanced across dose groups
 - Low incidence of asymptomatic liver transaminase elevations
 - No increase in infections, no changes in neutrophils
- **Renal safety**
 - No kidney stones, decrease in urine pH or effect on eGFR
 - No creatinine signal (no grade 3 or 4 elevations)
- **No dose-limiting toxicity has been identified**

Arhalofenate Clinical Studies

Development status

- **Drug materials**
 - Economical, proprietary synthesis
 - 200 kg of drug substance in hand
 - Commercial tablet formulation developed
 - 200, 300, 400 and 600 mg strengths
- **Completed preclinical safety package**
 - Sub-chronic and chronic toxicology in rat and monkey
 - Safety pharmacology and reproductive toxicology
 - Two-year carcinogenicity studies in rodents
 - Carcinogenicity and CV safety review by FDA completed
 - All studies satisfactorily completed and support further development
- **Additional Phase 2/3 study to refine product profile**



Arhalofenate Phase 2/3 Study

- **12-week study in gout patients experiencing 3 flares in the prior year**
- **Goals for arhalofenate**
 - Prevent flares without colchicine prophylaxis
 - 800 mg lowers sUA comparable to allopurinol (300 mg)
 - Generate safety data with 800 mg dose
- **Primary endpoint**
 - Mean flares/patient for arhalofenate (800 mg) vs. allopurinol (300 mg)
 - >80% power to detect a 50% decrease in flares
- **Secondary endpoint**
 - sUA responder rate (<6 mg/dL) for arhalofenate (800 mg) vs. placebo
 - >90% power to detect a responder rate of 40%

Replace
allopurinol -
Colcrys

Arhalofenate Phase 2/3 Study Design



CymaBay Milestones for Arhalofenate

- Dose first patient in Phase 2/3 study 1H 2014
- Phase 2/3 headline data 1H 2015
- End-of-phase 2 meeting 2H 2015
- Start Phase 3 1H 2016