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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 and Exchange Act of 1934

Date of Report (Date of earliest event reported): September 4, 2008 (September 3, 2008)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	**(I.R.S. Employer Identification Number)**

777 Old Saw Mill River Road, Tarrytown, New York	**10591-6707**
(Address of principal executive offices)	**(Zip Code)**

(914) 347-7000
(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 registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 8.01 Other Events

On September 3, 2008, Regeneron Pharmaceuticals, Inc. issued a press release announcing results of a Phase 2 study evaluating the efficacy and safety of ARCALYST® (rilonacept) versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout. A copy of this press release is attached as Exhibit 99(a) to this Form 8-K and is incorporated herein by reference.

On September 3, 2008, Regeneron's President and Chief Executive Officer, Dr. Leonard Schleifer, and other members of senior management of Regeneron hosted a webcast conference call to discuss the findings of a Phase 2 study evaluating the efficacy and safety of ARCALYST® (rilonacept) versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout. The slides for this webcast are furnished as Exhibit 99(b) to this Form 8-K.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press release dated September 3, 2008 announcing results of a Phase 2 study evaluating the efficacy and safety of ARCALYST® (rilonacept) versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout.

99(b) Slides for September 3, 2008 webcast to discuss the findings of a Phase 2 study evaluating the efficacy and safety of ARCALYST® (rilonacept) versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: September 4, 2008

By: /s/ Stuart Kolinski
Stuart Kolinski
Senior Vice President and General Counsel

Exhibit Index

Number	Description
99(a)	Press release dated September 3, 2008 announcing results of a Phase 2 study evaluating the efficacy and safety of ARCALYST® (rilonacept) versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout.
99(b)	Slides for September 3, 2008 webcast to discuss the findings of a Phase 2 study evaluating the efficacy and safety of ARCALYST® (rilonacept) versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout.

REGENERON

FOR IMMEDIATE RELEASE

Press Release

Regeneron's ARCALYST® (rilonacept) Reduced Incidence of Gout Flares by 81 Percent in a Phase 2 Study in Gout Patients Initiating Urate-lowering Therapy

Proportion of patients experiencing gout flares reduced from 45.2 percent to 14.6 percent

Tarrytown, NY (September 3, 2008) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that treatment with ARCALYST® (rilonacept), also known as IL-1 Trap, in a Phase 2 study of gout patients initiating therapy with allopurinol to lower their uric acid levels, produced a statistically significant reduction versus placebo in the incidence of gout flares. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST ($p=0.0011$), an 81 percent reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance.

In the first 12 weeks of treatment, 45.2 percent of patients treated with placebo experienced a gout flare and, of those, 47.4 percent had more than one flare. Among patients treated with ARCALYST, only 14.6 percent experienced a gout flare ($p=0.0037$ versus placebo) and none had more than one flare. No serious drug-related adverse events were reported in patients receiving ARCALYST treatment. Injection-site reaction was the most commonly reported adverse event with ARCALYST treatment. Detailed data from the study will be presented at a future scientific conference.

This Phase 2 study evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout. ARCALYST patients received an initial 320 milligram (mg) dose, followed by weekly doses of 160 mg. Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including interleukin-1 (IL-1), resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days. In this study a gout flare was defined as patient-reported acute joint pain that was deemed by the patient and/or investigator to require rescue treatment with an anti-inflammatory drug.

"These findings could be significant in the future management of patients with gout in that they address an impediment to successful long-term treatment. Allopurinol therapy is an important approach to lowering patients' high uric acid levels, which is the cause of their gout. However, the increased risk of painful gout flares over the first few months of initiation of uric acid-lowering therapy makes it difficult for patients to stick with treatment," said John Sundy, M.D.,

Ph.D., Division of Rheumatology, Department of Medicine, Duke University Medical Center. “Currently, colchicine or anti-inflammatory drugs are recommended for use to reduce the risk of gout flares in patients taking allopurinol, but these drugs may cause side effects and some patients do not tolerate them. The results from this study suggest that concomitant use of rilonacept during the first several months of allopurinol therapy may help avoid gout flares, which could, in turn, improve patient outcomes.”

“We are encouraged about the potential role of ARCALYST® (rilonacept) therapy in the treatment of gout. The results of this study, together with the findings of a previous small study of ARCALYST in patients with chronic, active gout, suggest that ARCALYST may provide utility in a number of different gout patient populations,” stated George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. “Based upon these results, we plan to initiate a Phase 3 clinical development program early next year with ARCALYST in the prevention of gout flares in patients initiating urate-lowering drug therapy. Studies in other gout settings are also planned.”

Conference Call

Regeneron will host a webcast conference call to discuss these results today, **September 3, 2008, at 8:30 a.m., Eastern Time**. The dial-in information is:

Domestic Dial-in Number: (866)314-5050
International Dial-in Number: (617)213-8051
Participant Passcode: 16355081

For those unable to participate during the call, a replay will be available from 10:30 a.m. Eastern Time on September 3, 2008 through October 3, 2008. The call can be accessed by dialing:

Domestic Dial-in Number: (888)286-8010
International Dial-in Number: (617)801-6888
Participant Passcode: 58761816

The replay will be available over the Internet and can be accessed by visiting the Regeneron website at www.regeneron.com on the Presentations page of the Investor Relations section.

About Gout

Gout is a condition that occurs when the bodily waste product, uric acid, is deposited in the joints and/or soft tissues. In the joints, these uric acid crystals cause inflammation, which leads to pain, swelling, redness, heat, and stiffness in the joints. More than three million Americans currently suffer from gout. Treatment guidelines recommend that patients with elevated uric acid levels who experience multiple gout attacks each year should receive chronic urate-lowering therapy, such as allopurinol. Allopurinol reduces the production of uric acid in the body to prevent the occurrence of gout attacks with long-term use. Approximately 750,000 gout patients initiate allopurinol therapy each year. During the first months of allopurinol therapy while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. Anti-inflammatory therapy with colchicine is sometimes

used to help prevent these flares. However, the side effects associated with prophylactic dosing with colchicine, which include diarrhea, abdominal cramps, nausea, and vomiting, can limit patients' adherence to both colchicine and allopurinol treatment.

Rationale for the Clinical Exploration of Use of ARCALYST® (rilonacept) in the Treatment of Gout

Interleukin-1 (IL-1) is a protein secreted by infection-fighting cells in the blood and tissues. In many cases, IL-1 acts as a messenger to help regulate immune and inflammatory responses by attaching to cell-surface receptors in cells that participate in the body's immune system. In excess, it can be harmful and has been shown to be a key driver of inflammation in a variety of diseases, including gout. In gout, uric acid crystals stimulate the production of IL-1, which causes an inflammatory response in the joints and surrounding tissues.

ARCALYST is an agent that inhibits IL-1. It is designed to attach to and neutralize IL-1 in the blood stream before the IL-1 can attach to cell-surface receptors and generate signals that can trigger disease activity in body tissue. Once attached to ARCALYST, IL-1 cannot bind to the cell-surface receptors and is eventually eliminated from the body.

Important Information About ARCALYST

ARCALYST is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking ARCALYST® (rilonacept). ARCALYST should be discontinued if a patient develops a serious infection. Taking ARCALYST with tumor necrosis factor inhibitors is not recommended because this may increase the risk of serious infections. Treatment with ARCALYST should not be initiated in patients with active or chronic infections. Patients should not receive a live vaccine while taking ARCALYST. It is recommended that patients receive all recommended vaccinations prior to initiation of treatment with ARCALYST. Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted. Hypersensitivity reactions associated with ARCALYST administration have been rare. Please see the full Prescribing Information for ARCALYST, available online at www.regeneron.com/ARCALYST-fpi.pdf.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

Forward Looking Statement

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and

administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2007 and Form 10-Q for the quarter ended June 30, 2008. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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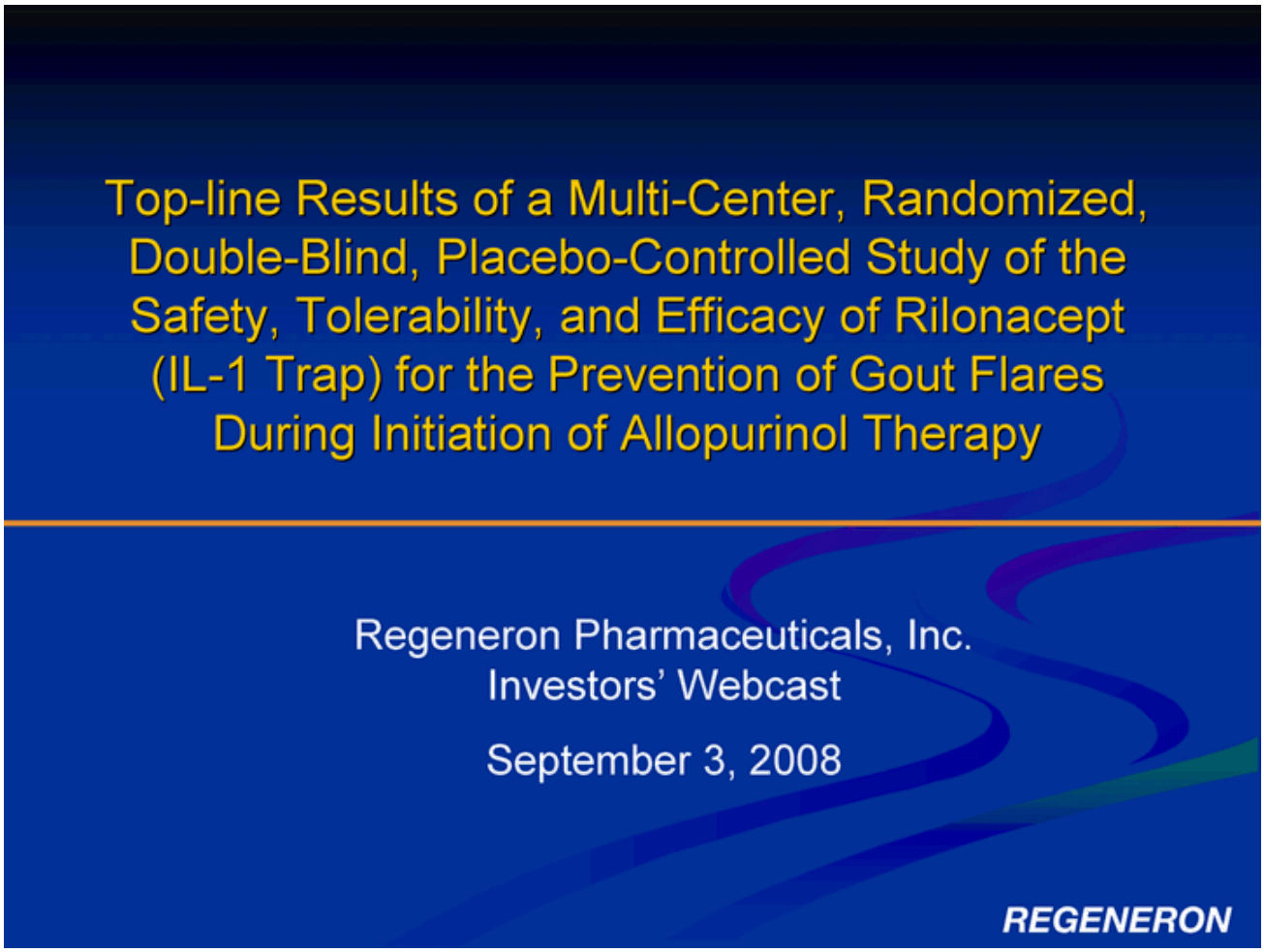
Top-line Results of a Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Efficacy of Rilonacept (IL-1 Trap) for the Prevention of Gout Flares During Initiation of Allopurinol Therapy
Regeneron Pharmaceuticals, Inc.
Investors' Webcast
September 3, 2008
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Safe Harbor Statement

Except for historical information, the matters contained in this presentation may constitute forward-looking statements that involve risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HeathCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and additional risks detailed from time to time in Regeneron's filings with the Securities and Exchange Commission (SEC). Please refer to Regeneron's recent Forms 10-K, 10-Q, and 8-K for additional information on the uncertainties and risk factors related to our business.

Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Regeneron. Regeneron is providing this information as of the original date of this presentation and expressly disclaims any duty to update any information contained in these materials.

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Gout

- Gout: a disease resulting from the deposition of monosodium urate crystals in the joints caused by excess serum uric acid (a bodily waste product normally excreted by the kidneys)
- Clinical manifestations:
  - acute and chronic pain/inflammation of joints and surrounding tissue
  - tophi development (deposits of crystallized uric acid) in the joints of the toes, ankles, knees, wrists, fingers, and elbows
- Prevalence: > 3 million in U.S.
- Treatment:
  - resolve acute attacks with anti-inflammatory therapy
  - reduce and maintain normal uric acid levels (< 6.0 mg/dL)

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Allopurinol in the Treatment of Gout

- Role: reduces the production of uric acid to help normalize serum uric acid levels with chronic use
- Usage:
  - over 1.3 million gout patients receive allopurinol treatment each year
  - over 750,000 new gout patient starts are initiated with allopurinol each year
- Major treatment impediment:
  - during first months of allopurinol therapy while uric acid blood levels are being reduced, uric acid crystal dissolution can result in stimulation of inflammatory mediators, causing acute flares of joint pain and inflammation
  - adherence to allopurinol therapy is therefore low, potentially leading to continued gout symptoms and tophi progression
- Other drawbacks of allopurinol: rash related to hypersensitivity, leukopenia, GI disturbances

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Gout: Evidence for Role of IL-1

- Gout has IL-1-associated clinical features
  - inflammation, fever, elevated acute phase response
- IL-1 is a major product of human white blood cells stimulated by monosodium urate crystals (Duff, 1983, Malawista 1985, Martinon, 2006)
- The NLRP-3 (cryopyrin) inflammasome is required for crystal-induced IL-1 production (Martinon, 2006)
  - In gout, IL-1 appears to be higher in the inflammatory cascade than other inflammatory mediators (e.g., TNF and IL-6)
- IL-1 signaling is required for crystal-induced inflammation in *in vivo* knock-out models (Chen 2006)

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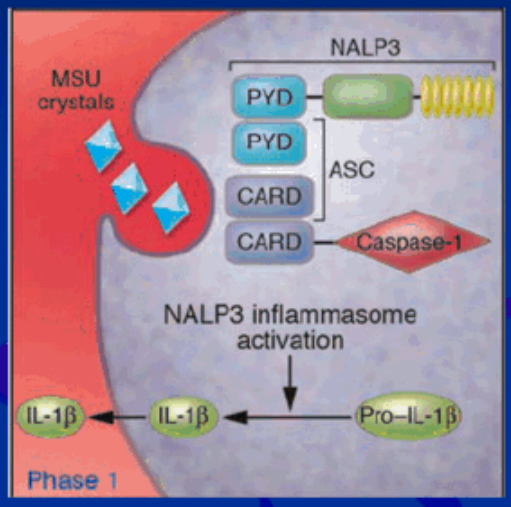
Gout: Evidence for Role of IL-1(Continued)

- Monosodium urate crystals internalized by monocytes activate the NLRP3 inflammasome which leads to the processing and release of IL-1β
- IL-1β induces the expression of adhesion molecules and chemokines which are critical for the recruitment of PMNs into the site of acute inflammation



Martinon, 2006

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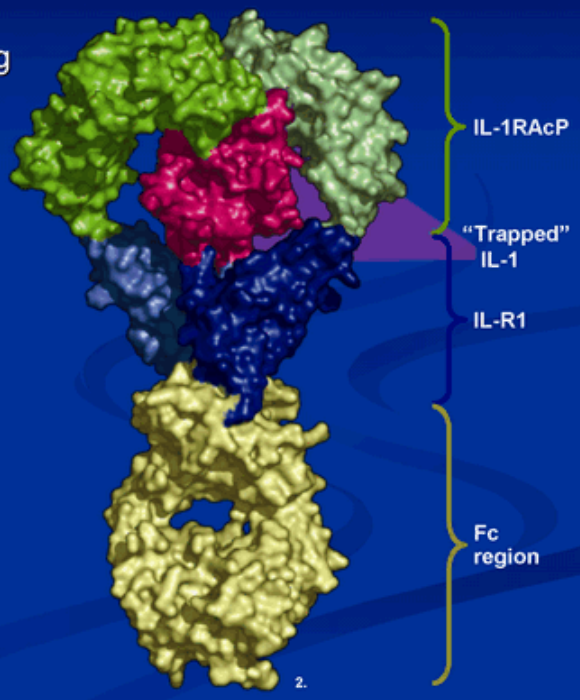
Rilonacept (ARCALYST®): Structure and Characteristics

- Rilonacept: a dimeric fusion protein
  - Specific blocker of IL-1, incorporating extracellular domains of the 2 receptor components required for IL-1 signalling
    - IL-1RI (IL-1 receptor sub-type 1)
    - IL-1RAcP (IL-1 receptor accessory protein)
  - Molecular weight ~251 kDa
  - Expressed in recombinant Chinese hamster ovary (CHO) cells
- 8.6 days circulation half-life *in vivo*, allowing for once-weekly dosing



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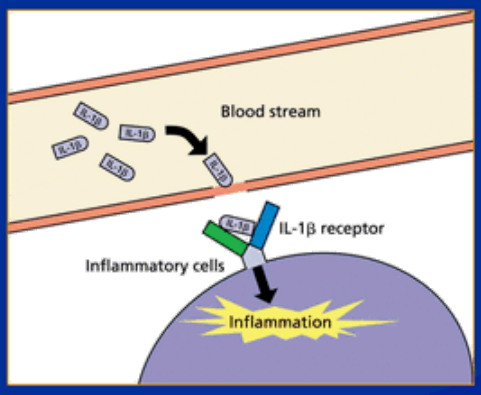
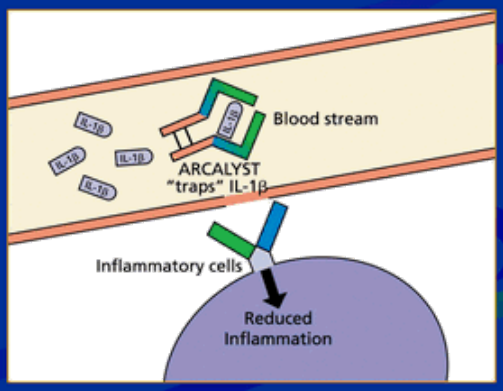
Mechanism of Action of Rilonacept

- Certain inflammatory responses arise from excessive release of activated IL-1 β
- Rilonacept blocks IL-1 signaling by acting as a soluble decoy receptor that binds IL-1 and prevents its interaction with cell surface receptors

IL-1 and inflammation



Mechanism of action of rilonacept



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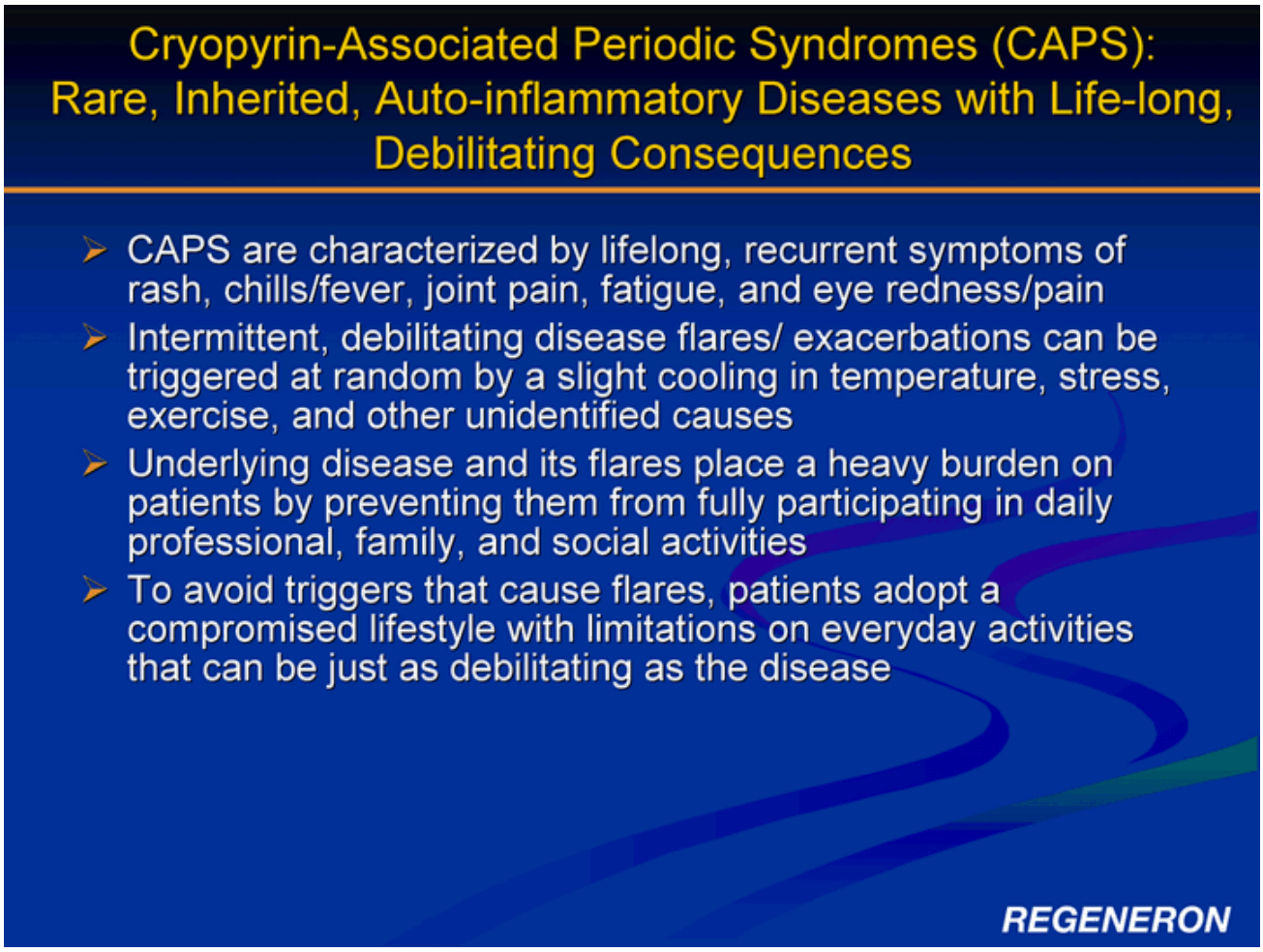
Cryopyrin-Associated Periodic Syndromes (CAPS): Rare, Inherited, Auto-inflammatory Diseases with Life-long, Debilitating Consequences
CAPS are characterized by lifelong, recurrent symptoms of rash, chills/fever, joint pain, fatigue, and eye redness/pain
Intermittent, debilitating disease flares/ exacerbations can be triggered at random by a slight cooling in temperature, stress, exercise, and other unidentified causes
Underlying disease and its flares place a heavy burden on patients by preventing them from fully participating in daily professional, family, and social activities
To avoid triggers that cause flares, patients adopt a compromised lifestyle with limitations on everyday activities that can be just as debilitating as the disease
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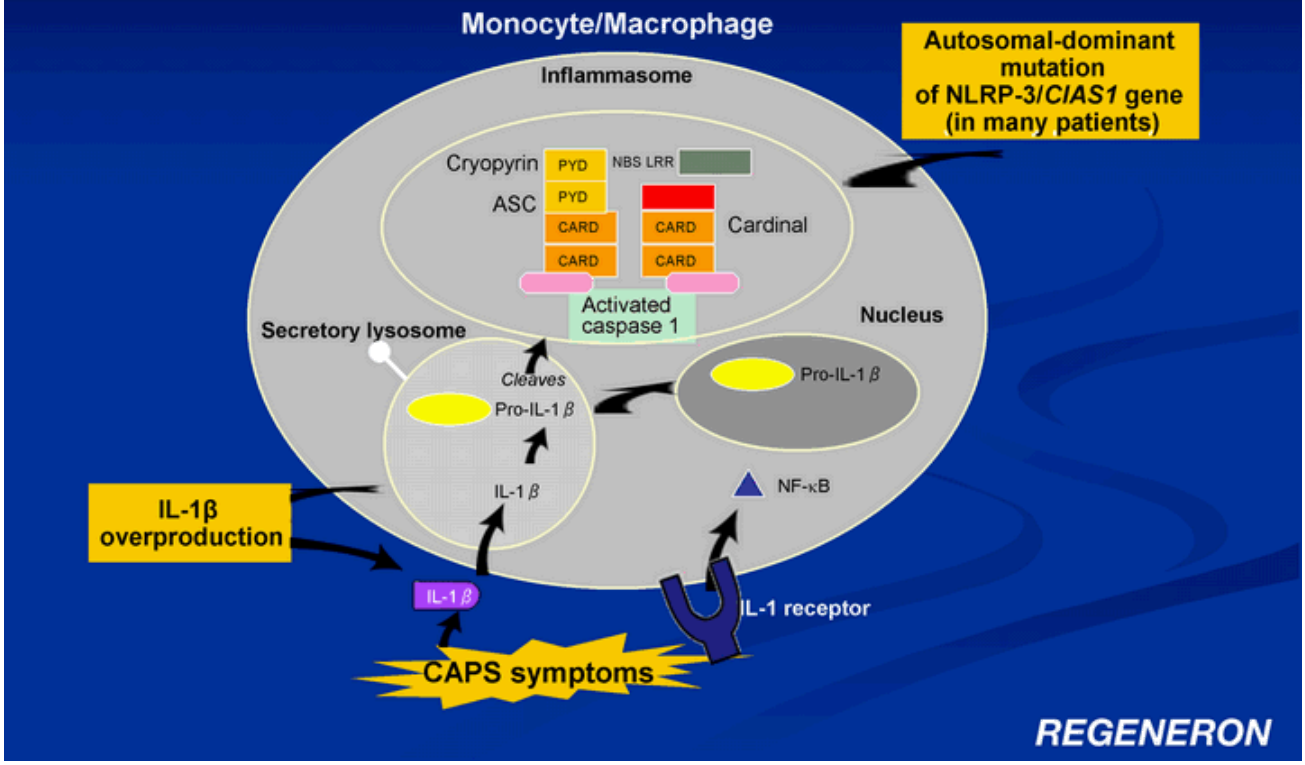
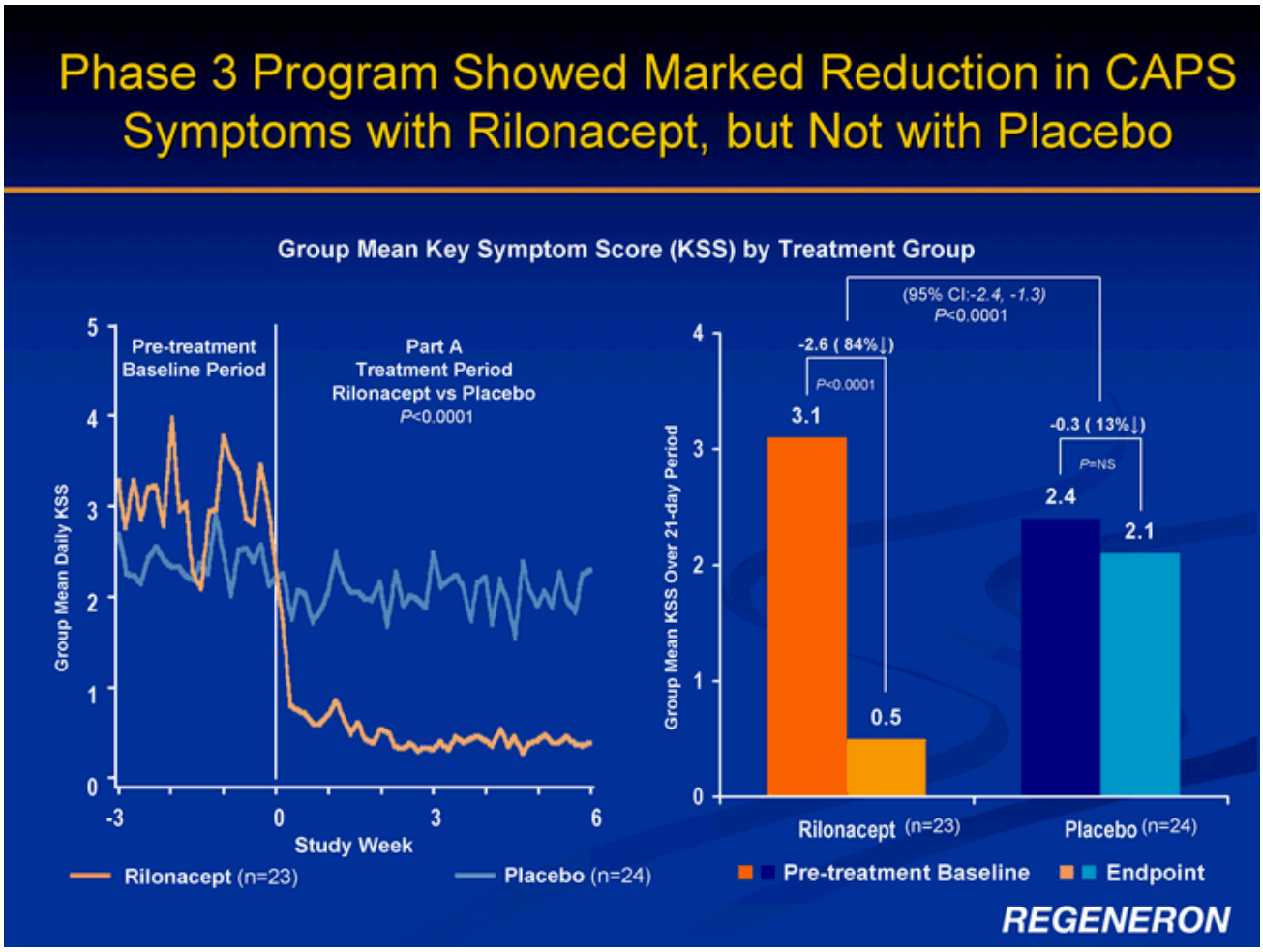
CAPS: Generally Caused by a Mutation in a Gene that Helps Regulate the Body's Innate Immune Response, Resulting in Overproduction of Interleukin-1β (IL-1β)




Phase 3 Program Showed Marked Reduction in CAPS Symptoms with Rilonacept, but Not with Placebo
Group Mean Key Symptom Score (KSS) by Treatment Group
Pre-treatment Baseline Period
Part A Treatment Period Rilonacept vs Placebo P<0.0001
Group Mean Daily KSS
Study Week
Rilonacept (n=23)
Placebo (n=24)
(95% CI:-2.4, -1.3) P<0.0001
-2.6 (84%↓)
P<0.0001
-0.3 (13%↓)
P=NS
3.1
0.5
2.4
2.1
Group Mean KSS Over 21-day Period
Rilonacept (n=23)
Placebo (n=24)
Pre-treatment Baseline
Endpoint
REGENERON

Important Information about Rilonacept

- Rilonacept is not indicated for use in gout. It is currently being studied in a Phase 2 exploratory trial in gout
- Rilonacept is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children age 12 and over
  - IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking rilonacept
    - rilonacept should be discontinued if a patient develops a serious infection
    - taking rilonacept with tumor necrosis factor inhibitors is not recommended because this may increase the risk of serious infections
    - treatment with rilonacept should not be initiated in patients with active or chronic infections
  - Patients should not receive a live vaccine while taking rilonacept. It is recommended that patients receive all recommended vaccinations prior to initiation of treatment with rilonacept
  - Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted.
  - Hypersensitivity reactions associated with rilonacept administration have been rare.
  - Please see the full Prescribing Information for rilonacept, available online at www.regeneron.com/ARCALYST-fpi.pdf

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Gout Pilot Study of Rilonacept: Single-Blind, Placebo Run-In Study in Patients with Chronic Active Gout

S = screening; D = day; W = week

- Two week placebo run-in
- Loading dose of rilonacept at Week 2 [2X 160 mg subcutaneously (SC)] followed by five weekly 160 mg SC injections of rilonacept
- Evaluations every 2 weeks, then follow-up 6 weeks after the last dose (Subject's Pain and Global Scores, Physician's Global Score , Joint assessment, and C-reactive protein)

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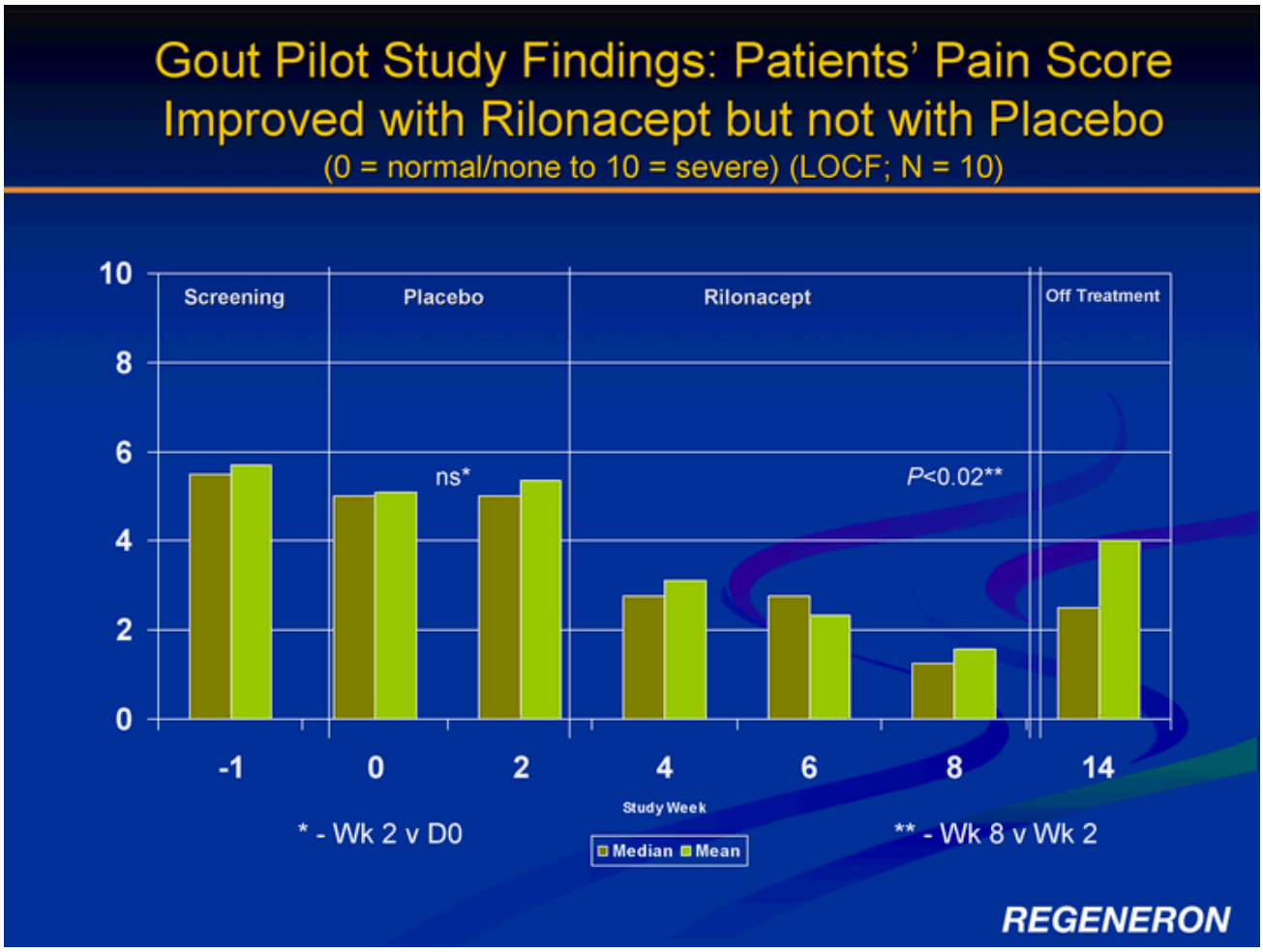
Gout Pilot Study Findings: Patients' Pain Score Improved with Rilonacept but not with Placebo
(0 = normal/none to 10 = severe) (LOCF; N = 10)
10
8
6
4
2
0
Screening
Placebo
Rilonacept
Off Treatment
ns*
P<0.02**
-1
0
2
4
6
8
14
Study Week
* - Wk 2 v D0
** - Wk 8 v Wk 2
Median
Mean
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Phase 2 Study Objectives

- Primary Objective
  - To assess the activity of rilonacept in reducing the frequency of acute gout flares in hyperuricemic patients initiating allopurinol therapy compared to placebo
- Secondary Objective
  - To assess the severity and duration of gout flares during initiation of allopurinol therapy
  - To assess the safety and tolerability of rilonacept in patients receiving concomitant allopurinol

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Phase 2 Study Design

- Multi-center, randomized double-blind, placebo-controlled trial in 83 hyperuricemic (serum uric acid ≥ 7.5 mg/dL) patients with inter-critical gout
  - Group 1- rilonacept 320mg on day 1, followed by rilonacept 160mg once a week for 16 weeks
  - Group 2- placebo
- Patients in both treatment arms started on a daily dose of 300 mg allopurinol on Day 1
  - Dose was titrated upward in 100 mg increments (maximum 800 mg) monthly in patients not achieving a target serum uric acid level < 6.0 mg/dL
  - Starting dose was adjusted downward in patients with renal impairment based upon creatinine clearance

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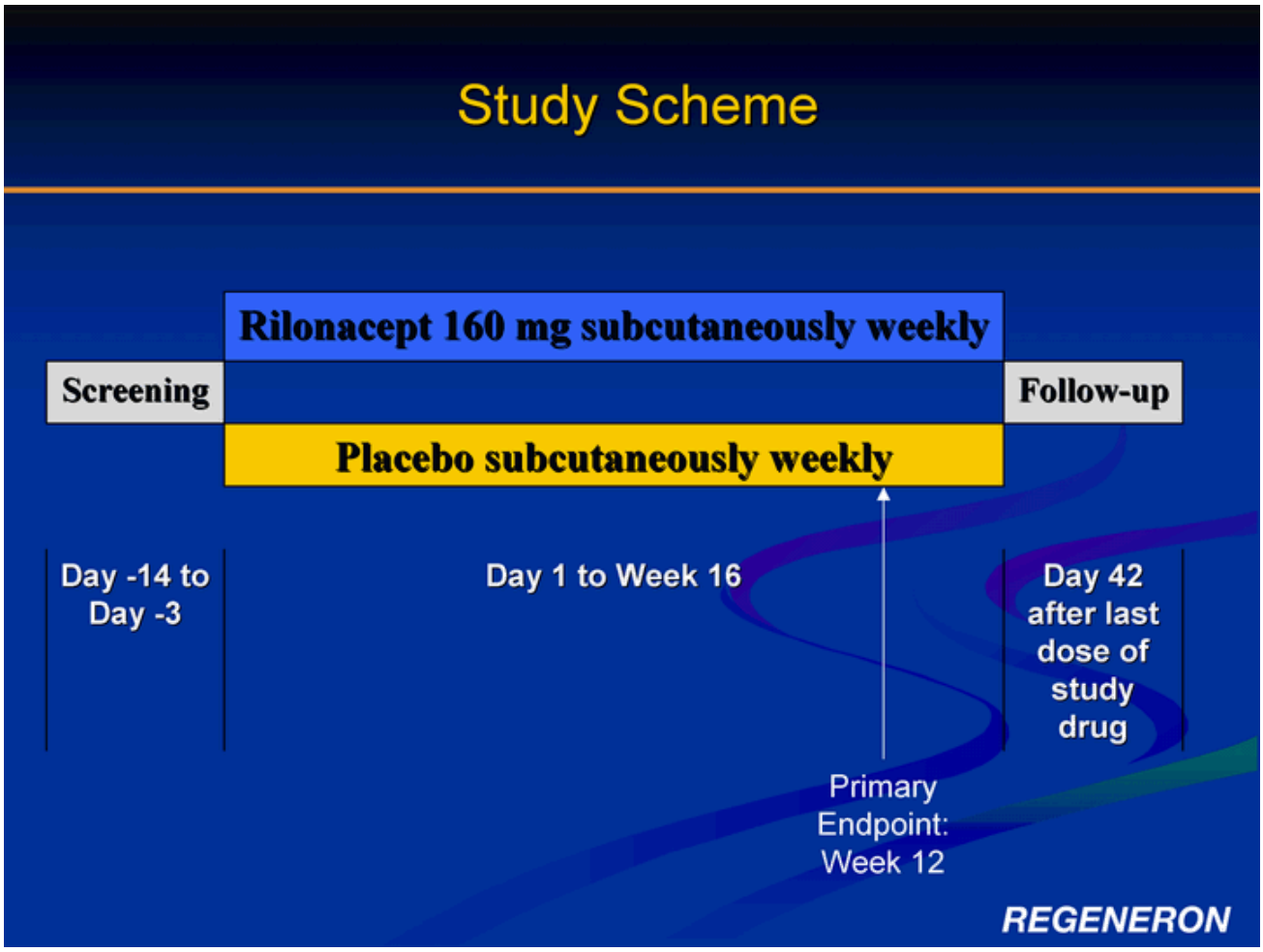
Study Scheme
Rilonacept 160 mg subcutaneously weekly
Screening
Follow-up
Placebo subcutaneously weekly
Day -14 to Day -3
Day 1 to Week 16
Day 42 after last dose of study drug
Primary Endpoint: Week 12
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Patient Population

- Patients 18 years of age or older :
  - Meeting the criteria of the American Rheumatism Association (ARA) for the classification of the acute arthritis of primary gout
  - Serum uric acid ≥ 7.5 mg/dL
  - A self-reported history of ≥ 2 gout flares in the year prior to the Screening Visit

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Key Exclusion Criteria

- Acute gout flare within 2 weeks before Screening Visit
- Allergy to allopurinol
- Use of glucocorticoids or colchicine within 4 weeks before Screening Visit
- Use of NSAIDs within 2 weeks prior to the Screening Visit
- Use of allopurinol, probenecid, or sulfinipyrazone within 3 months prior to the Screening Visit

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Efficacy Endpoints

- Primary Endpoint:
  - The mean number of gout flares assessed from Day 1 to Week 12

  * A gout flare was defined as patient-reported acute joint pain deemed by the patient and/or investigator to require rescue anti-inflammatory therapy (NSAIDs or glucocorticoids)
- Secondary Endpoints:
  - The proportion of patients with one or more gout flares assessed from Day 1 to Week 12
  - The mean number of gout flare days assessed from Day 1 to Week 12
  - The mean number of days with the patient's pain score of 5 or more (from patient's daily diary) from Day 1 to Week 12

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Patient Disposition

	Placebo	Rilonacept 160mg/kg
Patients randomized & dosed	42	41
Patients who completed Week 12	33	40
Withdrawals before Week 12	9	1
Reasons for withdrawal before Week 12 [n(%)]		
- Lost to follow up	4 (9.5%)	0 (0%)
- Lack of efficacy	2 (4.8%)	0 (0%)
- Adverse event	2 (4.8%)	0 (0%)
- Consent withdrawn	1 (2.4%)	0 (0%)
- Other	0 (0%)	1 (2.4%)
Patients reached:		
- Week 4	37 (88.7%)	41 (100%)
- Week 8	34 (81.0%)	40 (97.6%)
- Week 12	33 (78.6%)	40 (97.6%)

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Baseline Characteristics

	Placebo	Rilonacept 160mg/kg
Patients randomized	42	41
Male (%)	95.0	98.0
Age yrs mean (median)	50 (52)	52 (50)
Prior mean number of gout flares/yr	4.4	4.7
Prior mean duration of gout flare (days)	5.4	6.0
Tophi present	6	2

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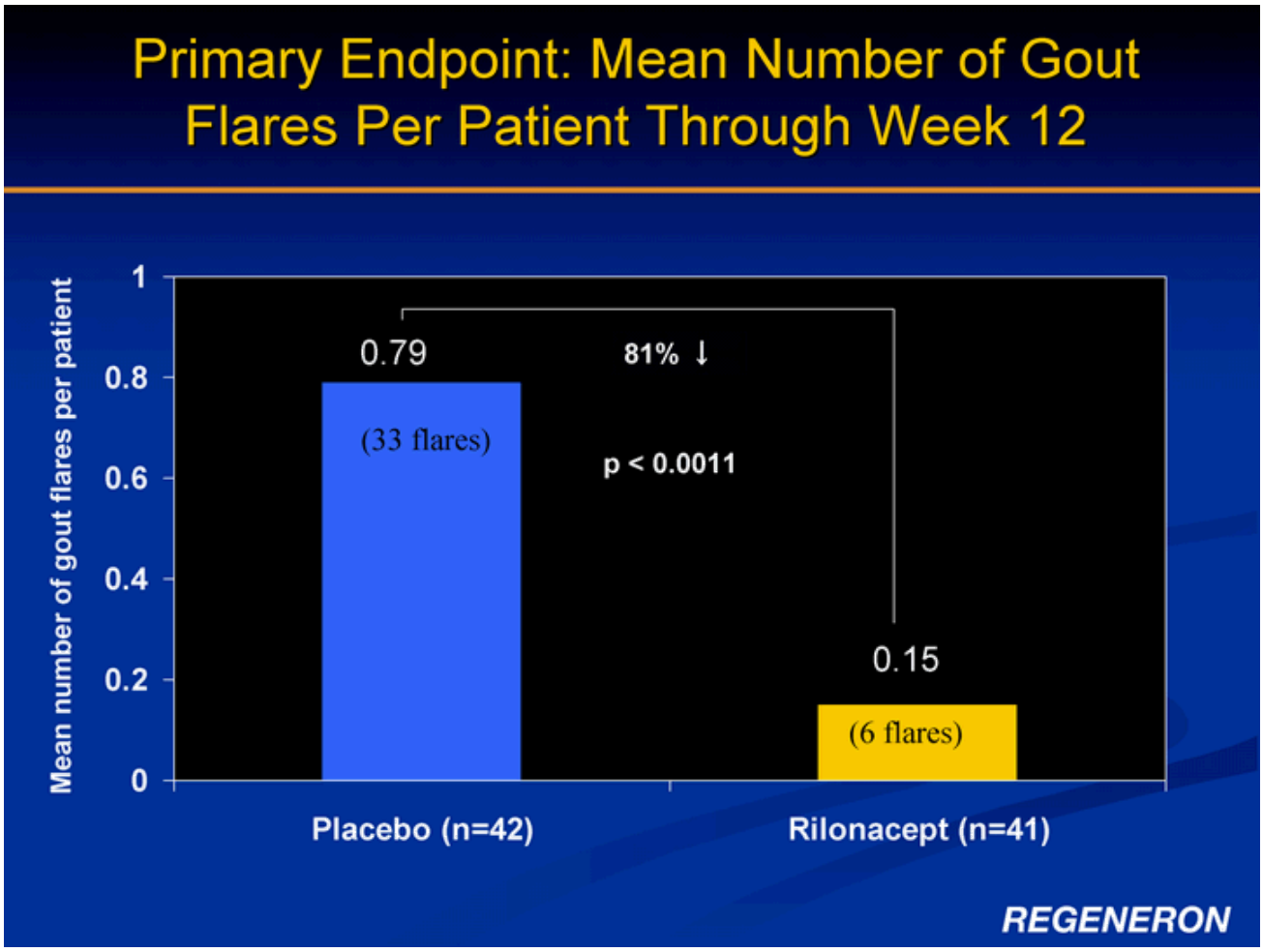
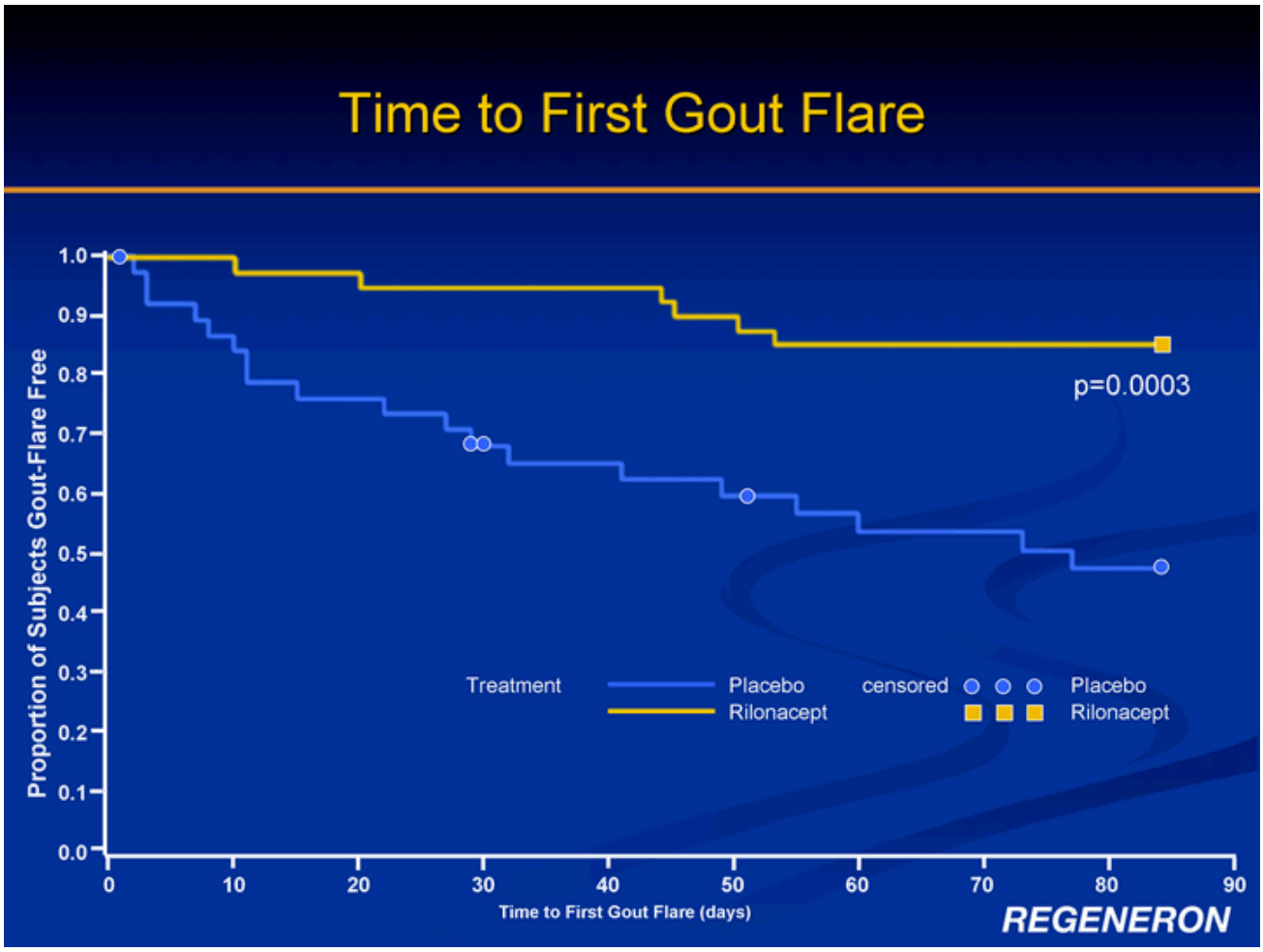
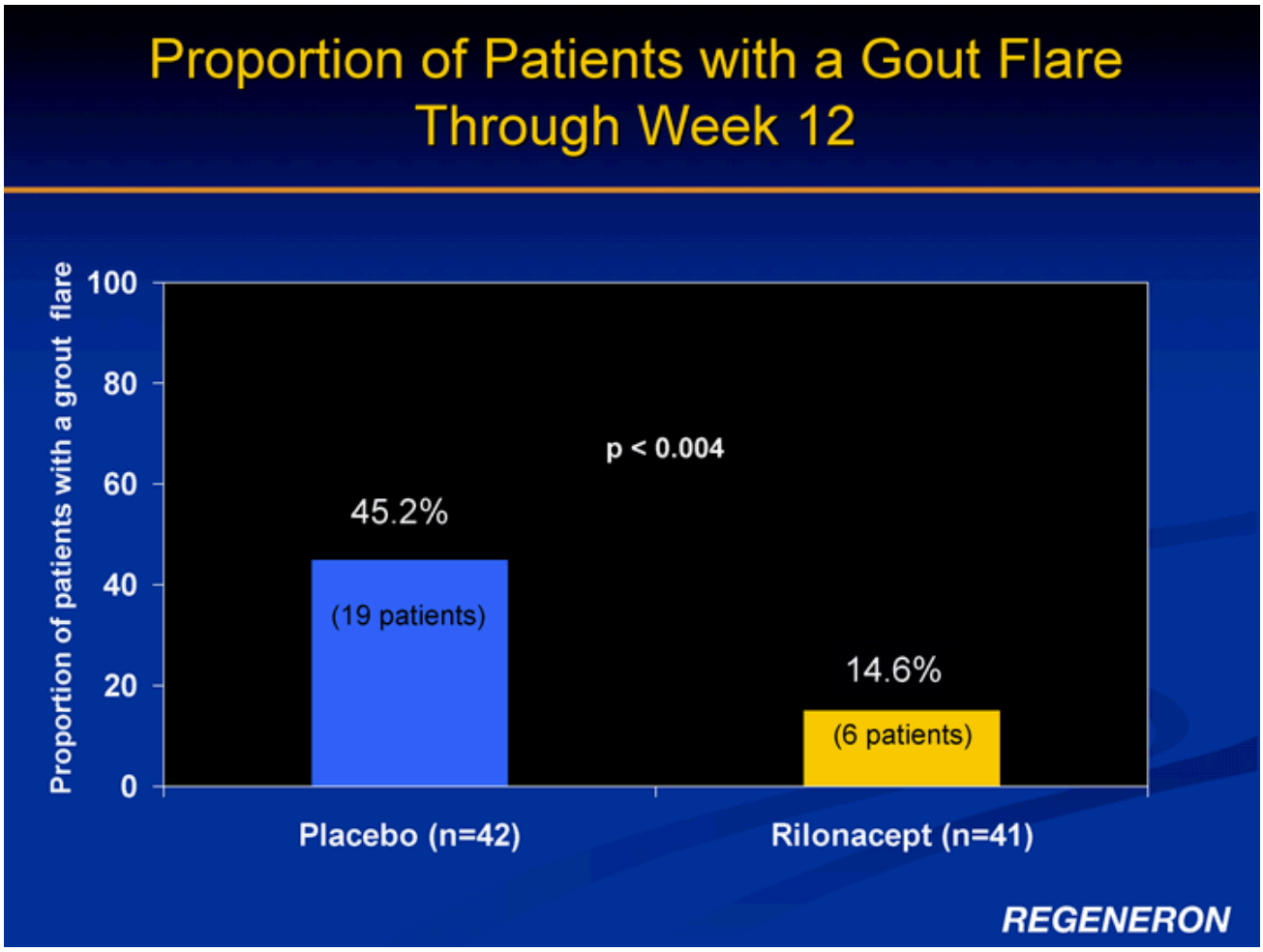
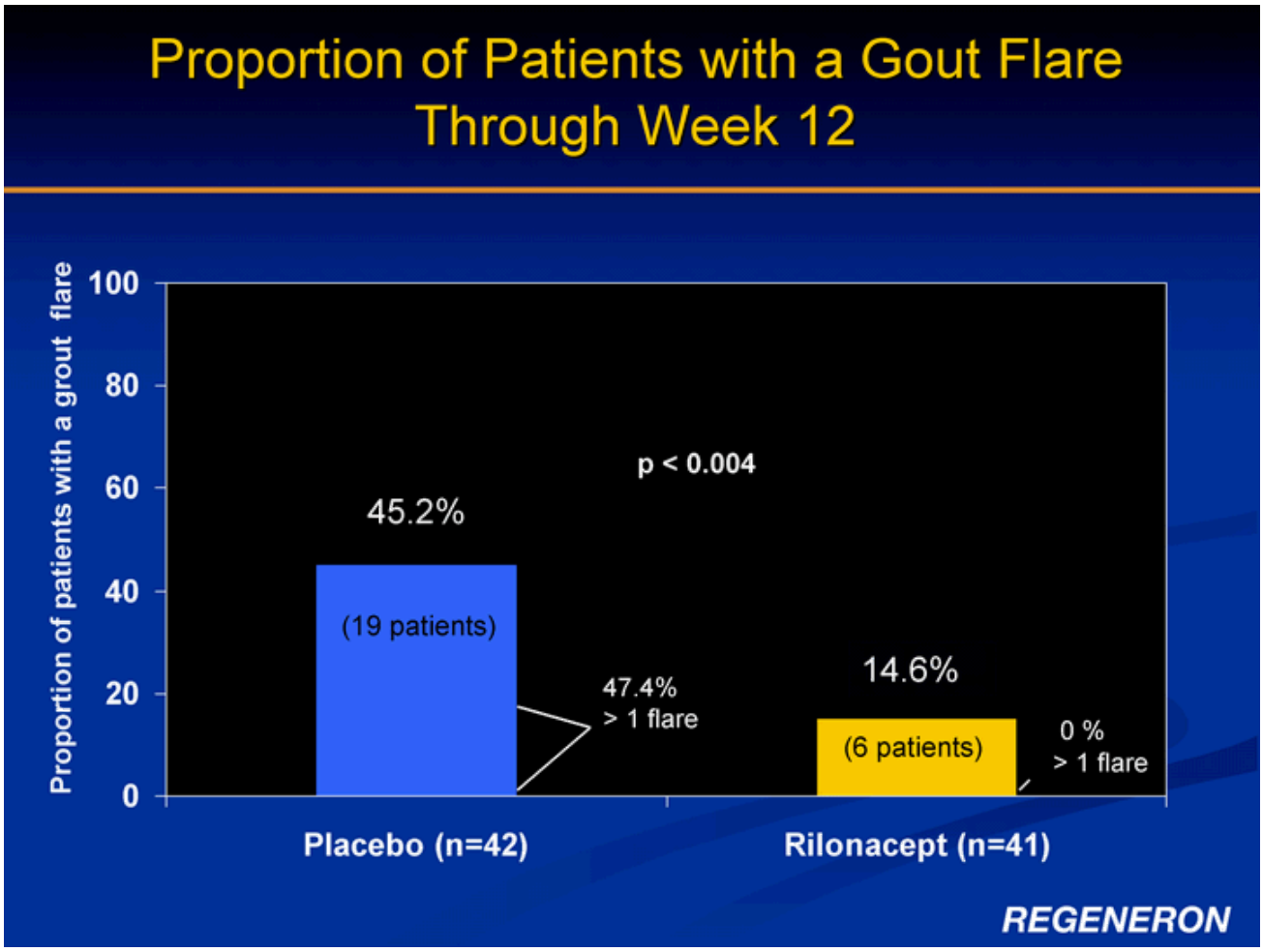
EFFICACY FINDINGS

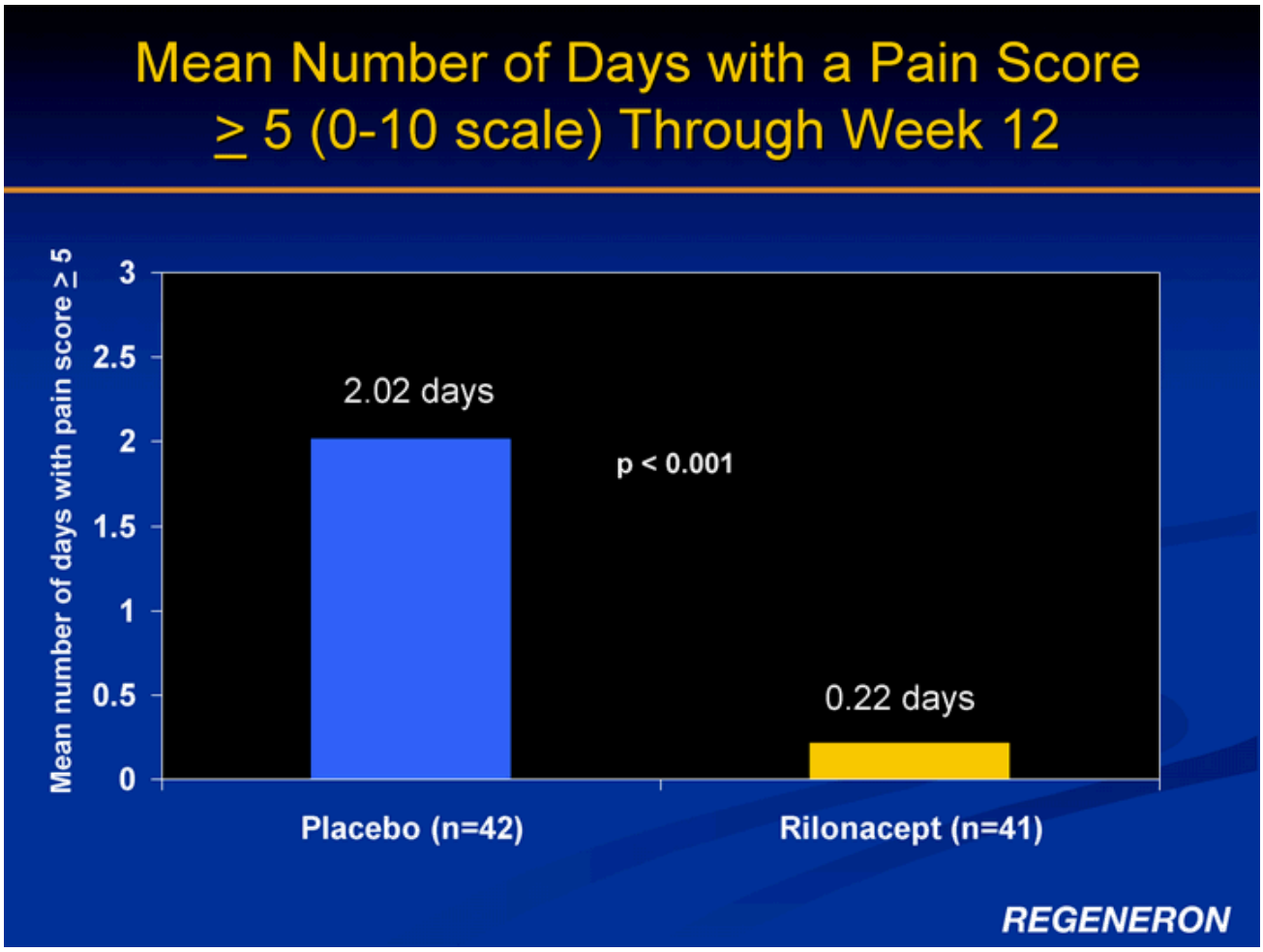
REGENERON


Primary Endpoint: Mean Number of Gout Flares Per Patient Through Week 12
Mean number of gout flares per patient
1
0.8
0.6
0.4
0.2
0
0.79
(33 flares)
81% ↓
p < 0.0011
0.15
(6 flares)
Placebo (n=42)
Rilonacept (n=41)
REGENERON


Time to First Gout Flare
Proportion of Subjects Gout-Flare Free
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
10
20
30
40
50
60
70
80
90
Time to First Gout Flare (days)
p=0.0003
Treatment
Placebo
Rilonacept
censored
Placebo
Rilonacept
REGENERON


Proportion of Patients with a Gout Flare Through Week 12
Proportion of patients with a grout flare
100
80
60
40
20
0
p < 0.004
45.2%
(19 patients)
14.6%
(6 patients)
Placebo (n=42)
Rilonacept (n=41)
REGENERON


Proportion of Patients with a Gout Flare Through Week 12
Proportion of patients with a grout flare
100
80
60
40
20
0
p < 0.004
45.2%
(19 patients)
47.4%
> 1 flare
14.6%
(6 patients)
0 %
> 1 flare
Placebo (n=42)
Rilonacept (n=41)
REGENERON


Mean Number of Days with a Pain Score ≥ 5 (0-10 scale) Through Week 12
Mean number of days with pain score ≥ 5
3
2.5
2
1.5
1
0.5
0
2.02 days
p < 0.001
0.22 days
Placebo (n=42)
Rilonacept (n=41)
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SAFETY FINDINGS
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Safety Summary

- No serious drug-related adverse events were reported with rilonacept
- Injection-site reaction was the most commonly reported adverse event reported with rilonacept treatment

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Adverse Events Through Week 12

	Placebo (n=42)	Rilonacept (n=41)
Any Adverse Event [n(%)]	23 (55%)	17 (42%)
Number of patients who discontinued due to an AE [n (%)]	3 (7.1%)	1 (2.4%)
Serious AEs [n (%)]	2 (4.8%)	1 (2.4%)

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Number of Patients with ≥ 1 Treatment-Emergent Adverse Event Through Week 12 (reported in at least 5% of patients in either group treated)

High-level Term AE Category	Placebo (n=42)	Rilonacept (n=41)
Injection/infusion site reaction	1 (2.4%)	4 (9.8%)
Upper respiratory tract infections	4 (9.5%)	1 (2.4%)
Joint-related signs/symptoms	4 (9.5%)	1 (2.4%)
Liver function enzyme elevations	0 (0%)	3 (7.3%)
Purine metabolism disorders NEC	3 (7.1%)	1 (2.4%)

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Infections

- 10% of rilonacept-treated patients and 19% of placebo-treated patients reported 1 infection or more
  - 1 rilonacept-treated patient reported pyleonephritis
  - 2 placebo-treated patients reported bronchitis
  - 1 rilonacept-treated patient and 4 placebo-treated patients reported upper respiratory tract infections
- No serious infections were reported
- No tuberculosis or other opportunistic infections were reported

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Conclusions

- In a Phase 2 study of gout patients initiating therapy with allopurinol to lower their uric acid levels
  - Rilonacept produced an 81% statistically significant reduction in the mean incidence of gout flares per patient versus placebo over the first 12 weeks of therapy
  - 45.2% of patients treated with placebo experienced a gout flare (of those, 47.4% had $\geq$ 1 flare) versus 14.6% of those treated with rilonacept (none had $\geq$ 1 flare)
  - No serious drug-related adverse events were reported in patients receiving rilonacept treatment
  - Injection-site reaction was the most commonly reported adverse event with rilonacept treatment
- Based upon these results, the Phase 3 program in drug-induced gout flare prophylaxis is scheduled to begin in early 2009 and additional uses of rilonacept in the treatment of gout are being explored

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