

# Rheumatoid Arthritis

# Juvenile Arthritis

# Osteoarthritis

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JAK inhibitors - Baricitinib (S11112)  
 Pfizer (PFI) closed the implementation of an OIG panel for its anti-JAK inhibitor to be used, and the use could be considered in the case of drug development under FDCTA. Pfizer's claims, covered by the other agency's review, had not been approved if Pfizer's potential biosimilar (Biosimilar) for development is not.

Wilegros, DE based Pfizer has been developing the first JAK inhibitor in partnership with drug giant Eli Lilly (E.L.I.). And the results came from a milestone that dates as the drug is used as a JAK inhibitor, and a drug that is used as the JAK inhibitor. Pfizer's JAK inhibitor, according to the FDA, is used as a JAK inhibitor, according to the FDA, is used as a JAK inhibitor.

### Kinase Inhibitors-Jaks and Syk

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# Lupus

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# Gout

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## Spondylarthritis

Information on the symptoms and signs of spondylarthritis is available in the following table. The table is intended to provide a general overview of the condition and is not intended to be used as a diagnostic tool. For more information, please contact your doctor.

Symptom	Sign
Stiffness in the morning	Stiffness in the morning
Swelling in the joints	Swelling in the joints
Back pain	Back pain
Eye inflammation	Eye inflammation
Intestinal inflammation	Intestinal inflammation
Urethritis	Urethritis
Psoriasis	Psoriasis
Arthritis	Arthritis

From a paper about using immuno-targeting biologics like the ones in RA, for Uveitis -> so a lot of crossover from ophthalmology to rheum.

Drug	Indication	Mechanism of Action	Side Effects
Adalimumab	Uveitis	Tumor necrosis factor inhibitor	Headache, injection site reactions
Infliximab	Uveitis	Tumor necrosis factor inhibitor	Headache, injection site reactions
Etanercept	Uveitis	Tumor necrosis factor inhibitor	Headache, injection site reactions
Abatacept	Uveitis	CD28/CTLA-4 inhibitor	Headache, injection site reactions
Belimumab	Uveitis	B-lymphocyte stimulator inhibitor	Headache, injection site reactions

# Orphan Disorders in the Space

CAPS - Analogue is approved for this an II-1 disorder

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Actin?

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Making Healthcare Accessible to the  
Bottom of the Pyramid**

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JAK inhibitors--FierceBio-5/11/12

Pfizer (\$PFE) scored the endorsement of an FDA panel for its arthritis pill tofacitinib this week, and the win could put some wind in the sails of drug developer Incyte (\$INCY). Incyte's shares jumped this week after agency advisers backed approval of Pfizer's potential blockbuster JAK inhibitor for rheumatoid arthritis.

Wilmington, DE-based Incyte has been developing a rival JAK inhibitor in partnership with drug giant Eli Lilly (\$LLY). And the interim data from a mid-stage trial data on the drug, known as LY3009104, are due out next month at the European League Against Rheumatism's Annual European Congress of Rheumatology, according to Incyte. the pipeline, Incyte fits the profile to be gobbled up by a larger company.

## Kinase Inhibitors-Jaks and Syk

Incyte-JAK 1 and 2 Inhibitors--being tried for RA  
Jakafti (ruxolitinib) approved for MF--  
myelofibrosis  
-->this one gets JAK2 and 1?

Rigel's Syk-Fostamatinib

Galapagos (GLPG0634 ) with ABBOTT  
-->furthest behind but claims to be JAK1 specific

Tofa-Pfizer- AdCom May2012,  
PDUFA--August 2012

Vertex-VX-509--JAK3 specific?

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02.05.2012

Belimumab for lupus erythematosus: added benefit not proven

Drug manufacturer presents no relevant studies for the benefit assessment

Belimumab (trade name Benlysta ®) has been approved since July 2011 as an add-on therapy for adult patients with the autoimmune disease systemic lupus erythematosus (SLE). This monoclonal antibody is only considered as treatment when the disease is still active in spite of standard therapy

Anthera's Blisibimod for lupus  
Currently ph2b

same MOI as benlysta?

us

ACthar?

- DMPM--Dermatomyositis and polymyositis?--  
ACTHAR gel?

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CAPS---Arcalyst is approved for this--an IL-1 disorder

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- CAPS--from wiki--Cryopyrin-associated periodic syndrome (CAPS) is a spectrum of autoinflammatory syndromes including familial cold autoinflammatory syndrome (FCAS, formerly termed familial cold-induced urticaria), the Muckle-Wells syndrome (MWS), and neonatal-onset multisystem inflammatory disease (NOMID, also called chronic infantile neurologic cutaneous and articular syndrome or CINCA). They share many clinical features.
- These syndromes are associated with mutations in NLRP3, the gene encoding cryopyrin. This is a component of the interleukin 1 inflammasome, and mutations lead to unregulated production of interleukin 1 $\beta$ . Monoclonal antibodies against interleukin 1 $\beta$  (such as canakinumab), other interleukin 1 binding proteins (such as rilonacept), or interleukin 1 receptor antagonist (for example anakinra) can be used to treat these disorders.

## RA-REMS

patients with rheumatoid arthritis have twice the risk for cardiovascular mortality as the larger population

### RA registries

- CORRONA
- there's a British Registry
- others?

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## RA-Diagnostics

Crescendo Biosciences

- test-Vectra DA

- 12 biomarkers

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**The**



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## IL-17 Inhibitors

from Amgen--brodalumab (formerly AMG 827)  
an IL-17 inhibitor

- Ph2 -NEJM article
- from press release-The majority of subjects treated with brodalumab 210 mg every other week achieved total clearance of their skin disease (PASI 100 of 62 percent)--so first biologic to show total clearance

from Ely Lilly--Ixekizumab (formerly LY42439821)

- ph2 NEJM article

BOTH of these articles came out in NEJM on March 29, 2012...will have to see if these are really going head to head, which is better, etc

AND where is Novartis' secukinumab (AIN457)...Ph2, -press release- touting good ph2, oct 2011

what's this 3-way race look like? timing vs efficacy/safety?

## JAK inhibitors

-Pfizer's Tofacitinib

- which is a JAK3 inhibitor

-Incytes-INCB28050 (LY3009104)

- a jak1/2 inhibitor

-Vertex's-VX-509

- Jak3

All about the specificity, trying to be more specific to Inflammatory tissue, thus more efficacy and lessen the safety profile

Rigel's Fostamatinib- Syk inhibitor