

Title	About	Abstract Details
<b>LTE Safety and Efficacy Data Up to Five Years</b>		
Tofacitinib, an Oral Janus Kinase Inhibitor, in the Treatment of Rheumatoid Arthritis: Open Label, Long-Term Extension Safety and Efficacy Up To 5 Years	<p>Data from a pooled analysis of two open-label LTE studies (global A3921024 ORAL Sequel Study and Japan A3921041 Study) involving patients with moderately to severely active RA who had participated in randomized Phase 2 or 3 studies of XELJANZ dosed at 5 or 10 mg BID.</p> <ul style="list-style-type: none"> <li>Analysis showed a consistent safety profile and sustained efficacy for XELJANZ over time up to five years in LTE.</li> <li>Primary endpoints were adverse events and confirmed laboratory safety data.</li> </ul>	<p>Poster Abstract #: 33993 Date: October 29, 2013</p>
<b>Post-Hoc Analysis Of Risk Factors for Serious Infection Events (SIE)</b>		
Post-Hoc Analysis Of Serious Infection Events and Selected Clinical Factors In Rheumatoid Arthritis Patients Treated With Tofacitinib	<p>Data from a pooled analysis of five randomized Phase 2 studies, five randomized Phase 3 studies and two open-label LTE studies involving patients with moderately to severely active RA who had received XELJANZ dosed at 5 or 10 mg BID were analyzed to determine risk factors for SIEs.</p> <ul style="list-style-type: none"> <li>Consistent with reports from multiple RA patient databases, analysis identified age (elderly); diabetes; prednisone and corticosteroid equivalent dose <math>\geq 7.5</math> mg as independent factors associated with an increased risk of SIEs.</li> <li>Tofacitinib dose was also identified as an independent risk factor for SIEs.</li> </ul>	<p>Poster Abstract #: 34301 Date: October 27, 2013</p>

## **Integrated Safety Analysis Of Malignancies**

Tofacitinib, An Oral Janus Kinase Inhibitor: Analysis Of Malignancies Across The Rheumatoid Arthritis Clinical Program

Data from a pooled analysis of six randomized Phase 2 studies, six randomized Phase 3 studies and two open-label LTE studies involving patients with moderately to severely active RA who had received XELJANZ dosed at 5 or 10 mg BID were analyzed with regards to malignancies.

- Analysis showed that the malignancies that occurred are consistent with the type and distribution of malignancies expected for patients with moderately to severely active RA and rates are consistent with published estimates in RA patients treated with biologic and non-biologic DMARDs.

Oral presentation  
Abstract #: 34063  
Date: October 27, 2013

## **Safety and Efficacy of XELJANZ in U.S. Versus ROW Study Populations**

Efficacy and Safety Analyses Of Tofacitinib From Pooled Phase 2, Phase 3 and Long-Term Extension Rheumatoid Arthritis Studies: U.S. Compared With Non-U.S. Populations

Pooled data from DMARD-inadequate responder patients with moderately to severely active RA in six Phase 2 and five Phase 3 randomized studies and two open-label LTE studies who received XELJANZ dosed at 5 or 10 mg BID were analyzed to determine whether there were any differences in efficacy and/or safety between the U.S. and ROW populations.

- Analyses showed numerical differences with higher rates for tuberculosis, herpes zoster and lymphoma in ROW compared with the U.S. but higher rates of serious infection events, malignancies and deaths in the U.S.
- Efficacy in general was similar between populations studied.
- Conclusions are limited by the difference in population sizes.

Poster  
Abstract #: 34280  
Date: October 27, 2013

## **Additional XELJANZ Data to be Presented:**

### **Safety Data**

Tofacitinib, An Oral Janus Kinase Inhibitor: Analysis Of Gastrointestinal Adverse Events Across The Rheumatoid Arthritis Clinical Program

Integrated safety analysis of gastrointestinal adverse events

Poster  
Abstract #:34071  
Date: October 27, 2013

Cardiovascular Safety Findings In Rheumatoid Arthritis Patients Treated With Tofacitinib, A Novel, Oral Janus Kinase Inhibitor

Integrated safety analysis of cardiovascular adverse events

Poster  
Abstract #:34076  
Date: October 27, 2013

Relationship Between Lymphocyte Count and Risk Of Infection In Rheumatoid Arthritis Patients Treated With Tofacitinib

Relationship between lymphocytes and rates of infection

Poster  
Abstract #:34133  
Date: October 29, 2013

Association Of Mean Changes In Laboratory Safety Parameters With C-Reactive Protein At Baseline and Week 12 In Rheumatoid Arthritis Patients Treated With Tofacitinib

Relationship between laboratory safety parameters and disease activity

Poster  
Abstract #:34294  
Date: October 29, 2013

Reversibility Of Pharmacodynamic Effects After Short- and Long-Term Treatment With Tofacitinib In Patients With Rheumatoid Arthritis

Reversibility of the pharmacodynamic effects

Poster  
Abstract #:34285  
Date: October 27, 2013

Tolerability and Non-Serious Adverse Events In Rheumatoid Arthritis Patients Treated With Tofacitinib As Monotherapy Or In Combination Therapy Tolerability

Poster  
Abstract #:34275  
Date: October 27, 2013

Tofacitinib, An Oral Janus Kinase Inhibitor: Safety Comparison In Patients With Rheumatoid Arthritis and An Inadequate Response To Nonbiologic Or Biologic Disease-Modifying Anti-Rheumatic Drugs

Comparison of tofacitinib safety between nonbiologic DMARD-IR and biologic DMARD-IR populations

Poster  
Abstract #:34132  
Date: October 27, 2013

## Mechanism of Action

The Jak Inhibitor Tofacitinib Suppresses Synovial Jak-Stat Signaling In Rheumatoid Arthritis

Synovial biopsy study and inflammatory biomarkers

Oral presentation  
Abstract #: 35154  
Date: October 28, 2013

## Health Economics and Outcomes Research

Effects Of The Oral JAK Inhibitor Tofacitinib In Combination With Methotrexate On Patient Reported Outcomes In a 24-Month Phase 3 Trial Of Active Rheumatoid Arthritis

Patient-reported outcomes at two years in A3921044 ORAL Scan Study

Poster  
Abstract #:34297  
Date: October 29, 2013

Effects Of Tofacitinib, An Oral Janus Kinase Inhibitor, On Work Limitations In Patients With Rheumatoid Arthritis	Work productivity	Poster Abstract #:35376 Date: October 29, 2013
Improvements In Physical Function Correlate With Improvements In Health Related Quality Of Life: Reported Outcomes In Rheumatoid Arthritis Patients Treated With Tofacitinib: Results From 3 Randomized Phase 3 Trials	Correlation between physical function and improvements in health-related quality of life	Poster Abstract #:34053 Date: October 29, 2013
<b>Sub-population Studies</b>		
Effects Of Smoking Status On Response To Treatment With Tofacitinib In Patients With Rheumatoid Arthritis	Smokers versus non-smokers	Poster Abstract #:34276 Date: October 28, 2013
Assessment of Lipid Changes and Infection Risk In Diabetic and Nondiabetic Patients With Rheumatoid Arthritis Treated With Tofacitinib	Diabetic versus nondiabetic patients	Poster Abstract #:34273 Date: October 29, 2013
Efficacy and Safety Of Tofacitinib In Older and Younger Patients With Rheumatoid Arthritis	Elderly versus non-elderly	Poster Abstract #:34271 Date: October 29, 2013
<b>Post-hoc Analysis</b>		
Remission At 3 Or 6 Months and Radiographic Non-Progression At 12 Months In Methotrexate-Naïve Rheumatoid Arthritis Patients Treated With Tofacitinib Or Methotrexate: A Post-Hoc Analysis Of The ORAL Start Trial	Prediction of response	Poster Abstract #:34274 Date: October 29, 2013
Tofacitinib, An Oral Janus Kinase Inhibitor, In A Rheumatoid Arthritis Open-Label Extension Study Following Adalimumab Therapy In A Phase 3 Randomized Clinical Trial	Switch from adalimumab to tofacitinib	Poster Abstract #:34048 Date: October 27, 2013