Lilly and Incyte phase 3 trials of baricitinib in moderate-to-severe rheumatoid arthritis.

**Baricitinib Phase 3 RA Program***

### Moderate-to-Severe RA Patient Population

#### RA-BEACON
- **Inadequate response or intolerance to at least one prior tumor necrosis factor (TNF) inhibitor**
- **Planned enrollment**: 525
- **Trial design**: Randomized, Double-Blind, Placebo-Controlled, Active-Controlled
- **Trial arms**:
  - Placebo
  - 2 mg Baricitinib
  - 4 mg Baricitinib
  - (Participants taking background cDMARD therapy throughout study)

#### RA-BEYOND
- **Inadequate response or intolerance to at least one conventional disease-modifying antirheumatic drug (cDMARD)**
- **Has completed a previous baricitinib rheumatoid arthritis study**
- **Has received 2 years of additional treatment with baricitinib, but may be extended to allow for continued treatment for up to 4 years**
- **Planned enrollment**: 2670
- **Trial design**: Randomized, Double-Blind, Placebo-Controlled, Active-Controlled
- **Trial arms**:
  - Placebo
  - 2 mg Baricitinib
  - 4 mg Baricitinib

#### RA-BEGIN
- **Has had limited or no treatment with cDMARD**
- **Has not received a bDMARD**
- **Planned enrollment**: 550
- **Trial design**: Randomized, Double-Blind, Placebo-Controlled, Active-Controlled
- **Trial arms**:
  - 6 mg Baricitinib
  - MTX
  - MTX

#### RA-BEAM
- **Has inadequate response to methotrexate (MTX) treatment**
- **Has not received a bDMARD**
- **Planned enrollment**: 1280
- **Trial design**: Randomized, Double-Blind, Placebo-Controlled, Active-Controlled
- **Trial arms**:
  - Placebo
  - 4 mg Baricitinib
  - 40 mg Adalimumab

#### RA-BEYOND
- **Has completed a previous baricitinib rheumatoid arthritis study**
- **Has received 2 years of additional treatment with baricitinib, but may be extended to allow for continued treatment for up to 4 years**
- **Planned enrollment**: 2670
- **Trial design**: Randomized, Double-Blind, Placebo-Controlled, Active-Controlled
- **Trial arms**:
  - Placebo
  - 2 mg Baricitinib
  - 4 mg Baricitinib

*Information from trials NCT01721044, NCT01721057, NCT01721044, NCT01885078 and NCT01710358 on ClinicalTrials.gov

**An additional baricitinib RA phase 3 study, JAGS (NCT02265705) has recently been initiated to support development in China.**

The population includes moderate-to-severe RA patients who have had an inadequate response to MTX treatment.

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*See press release 12.3.14*