

## **1.0 Abstract**

### **Title**

A Post-Marketing Observational Study to Evaluate the Effectiveness of Adalimumab in Patients with Moderately to Severely Active Rheumatoid Arthritis (RA) in China

### **Keywords**

adalimumab, rheumatoid arthritis, observational study, China, effectiveness

### **Rationale and Background**

Adalimumab has demonstrated efficacy/effectiveness and safety in patients with RA in a number of randomized controlled trials and overseas post-marketing studies. In China, the efficacy and safety of adalimumab in RA have been confirmed in the registrational trial, Study M04-705, but this study had limitations regarding number of patients and had some restrictions in relation to the study population, including certain comorbid situations. Study P13-194 was intended to describe the effectiveness of adalimumab in a wider RA patient population in China.

### **Research Question and Objectives**

The objective of this observational study was to explore and describe the effectiveness of adalimumab, as prescribed according to the local product label, in patients with moderately to severely active RA in China.

### **Study Design**

Study P13-194 was an open-label, multicenter, uncontrolled, observational study in China, designed to explore and describe the effectiveness of adalimumab in RA patients, as prescribed according to the local product label. Adalimumab effectiveness was to be assessed based on data collected from clinic visits beginning at the Baseline visit and at Weeks 4, 8, 12, 26, 38, and 52.

---

## **Setting**

It was expected that approximately 30 physicians would participate in this study. Only 3 investigators enrolled patients and the study was terminated early because of low enrollment over approximately 10 months and high drop-out rate. Therefore the maximum expected observation period for each patient, approximately 52 weeks, was not met.

## **Patients and Study Size, Including Dropouts**

Enrollment of approximately 500 patients was expected; however, only 26 patients were enrolled. All patients were adults, naïve to adalimumab, and had a diagnosis of RA. Most (80.8%) were female, all were Chinese, and mean age was 45 years. Mean patient exposure to commercial adalimumab was 88.8 days, with a minimum exposure of 14 days and a maximum exposure of 221 days (median = 81 days). Four patients had adalimumab exposure > 135 days. Approximately half of the patients discontinued by Week 12.

## **Variables and Data Sources**

The primary effectiveness variable was percentage of patients with at least a moderate European League Against Rheumatism (EULAR) response at Week 12 compared to Baseline. Secondary effectiveness variables included Change in Disease Activity Score – 28 (erythrocyte sedimentation rate [ESR]), 28-swollen joint count, 28-tender joint count, C-reactive protein, ESR, Patient's global assessment of RA disease activity, Patient's assessment of pain, Physician's global assessment of RA disease activity, and Health Assessment Questionnaire-Disability Index, at all time points compared to Baseline.

Pre-specified safety variables included serious adverse events (SAEs), adverse events leading to discontinuation, vital signs, and pregnancy outcomes.

---

## Results

The primary effectiveness variable, an at least moderate EULAR response at Week 12, was achieved by 69.2% (9/13) of patients; 38.5% (5/13) had a good response and 30.8% (4/13) had a moderate response only. All secondary effectiveness variables showed improvement from Baseline at all weeks. No deaths, SAEs, or pregnancies were reported. One nonserious adverse event of respiratory tract infection that didn't lead to discontinuation was spontaneously reported and no new safety signals were observed. Mean changes in vital signs compared to Baseline were not clinically meaningful for any vital sign variable at any time point.

## Discussion

Although this study was limited by low patient numbers and was ultimately discontinued early, the primary effectiveness variable, an at least a moderate EULAR response at Week 12, was achieved by 69.2% of patients. All other effectiveness variables that were analyzed for change from Baseline showed improvement from Baseline at all weeks.

In this study, adalimumab was generally safe and well tolerated; the safety profile observed throughout the study was consistent with previous randomized controlled trials and overseas post-marketing studies for adalimumab.

## Marketing Authorisation Holder

AbbVie Ltd.

## Names and Affiliations of Principal Investigators

[Redacted]

Redacted information 09May2014

---

[REDACTED]

Redacted information 09May2014