1.0 Abstract

Title

Post-marketing surveillance study of adalimumab (Humira®) for hidradenitis suppurativa and pediatric chronic severe plaque psoriasis patients according to the standard for "Re-examination of New Drugs"

Keywords

hidradenitis suppurativa, pediatric chronic severe plaque psoriasis, adalimumab (Humira®)

Rationale and Background

These post-marketing surveillance studies were conducted in accordance with the Korean "Standard for Re-examination of New Drugs".

Research Question and Objectives

The real-world safety and effectiveness of adalimumab (Humira®) were evaluated in Korean hidradenitis suppurativa (HS) and pediatric chronic severe plaque psoriasis (ped PsO) patients under routine treatment practice. The safety information of both studies was described and evaluated in consistency with the label.

Study Design

Prospective, non-interventional (observational), single-country, post-marketing surveillance

Study Setting

Study Population

Hidradenitis suppurativa and pediatric chronic severe plaque psoriasis patients who have been prescribed with adalimumab (Humira®) according to clinical judgment of the physician as per Korean label

Inclusion Criteria

HS

1. Subject must be an adult ≥18 years
2. Subject who are eligible to be treated with adalimumab for hidradenitis suppurativa in accordance with the approved Korean label
3. Subject must provide written authorization form to use their personal health data prior to the participating in the study

Ped PsO

1. Children and adolescents, from 4 to 17 years at baseline, who are diagnosed with pediatric chronic severe plaque psoriasis
2. Prior to participating in the study, adalimumab (Humira®) treatment was determined according to clinical judgment of the physician
3. Patients (or legal representative) who voluntarily agreed to participate in this study and signed informed consent

Exclusion Criteria (HS and ped PsO study)

Patient with any of the following was not registered in both studies:

1. Patients with contraindication to adalimumab (Humira®) as listed in the approved local label
2. Patients who is participating on other clinical trials

3. Patients with prior treatment with adalimumab (Humira®)

Selection Criteria for Study Sites/Investigators

1. An investigator is a qualified Dermatologist who works at a clinic or a hospital, and sees a reasonable number of patients in routine clinical practice that are suitable for the respective study
2. An investigator who can conduct the study in accordance with the protocol
3. An investigator who agrees to devote adequate time for conducting of the study including subject enrollment, subject following up, filling out the case report forms, and so forth
4. An investigator who is capable of reporting all serious adverse events to AbbVie in accordance with the study protocol

Study Duration

Within 4 years from both HS and ped PsO approval (14 Dec 2015)

Study Size

In accordance with the Korean Standard for Re-examination of New Drugs requirement, at least 600 subjects should have been recruited. However, according to the data reported to Health Insurance Review & Assessment Service (HIRA), the number of HS and ped PsO patients is expected to be small in Korea and among them, only a limited number of patients can be prescribed adalimumab (Humira®) considering national health insurance benefits criteria. Due to above reasons, minimum number of patients to be enrolled was adjusted after Ministry of Food and Drug Safety (MFDS) approval and 19 subjects (17 HS subjects and 2 ped PsO subjects) were enrolled.

Data Sources

Case report form (CRF)

Results

Safety Evaluation

In these post-marketing studies, all adverse events were reported in subjects with HS, and none of subjects with ped PsO developed adverse events. Adverse events were developed in 8 of 19 subjects (42.11%, 12 cases) included in the safety set. Among those, adverse drug reactions were reported in 6 subjects (31.58%, 10 cases). Unexpected adverse events occurred in 4 subjects (21.05%, 6 cases), all of which were adverse drug reactions. No serious adverse events were reported. The severity of adverse events was reported as 'mild' in 7 subjects (36.84%, 11 cases) and 'moderate' in 1 subject (5.26%, 1 case), all of which were 'no action taken'. The results were reported as 'resolved' in 7 subjects (36.84%, 11 cases) and 'not resolved' in 1 subject (5.26%, 1 case). When classified adverse events by PT, 'Hidradenitis' was most frequently reported in 15.79% of subjects (3/19 subjects, 4 cases), all of them having a causality of 'reasonable possibility'. Except this, no adverse events were reported in 2 or more subjects. 'Chest pain' in 1 subject (5.26%, 1 case) was 'moderate' in severity, having a causality of 'no reasonable possibility'.

Effectiveness Evaluation

When evaluated the effectiveness in 17 subjects in HS study, subjects who showed HiSCR were 94.12% (16/17 subjects) at week 12 and 100.00% (13/13 subjects) at Week 24. Also, the changes in DLQI scores at weeks 12 and 24 from baseline were –8.41 ± 8.02 and –7.85 ± 10.15, respectively.

Discussion

There were no specific findings in these post-marketing studies with a adalimumab for HS and ped PsO. In conclusion, no new safety signal or unexpected trend is identified for Humira. Safety profile is consistent with the known safety profile of Humira for the treated patient population. However, safety information will be updated and managed by the continuous collection of adverse events and adverse event-related details through further studies, local and intemational self-reports, and so forth. Only two pediatric patients enrolled, which limits interpretation of the data for a pediatric population. The benefit-risk of adalimumab is unchanged.

Marketing Authorisation Holder(s)

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