# 1.0 Abstract

**Title**

Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 Months on Adalimumab Treatment

22 February 2019

[redacted]

**Keywords**

Adalimumab; hidradenitis; quality of life; real-world; effectiveness

**Rationale and Background**

Hidradenitis Suppurativa (HS) is a painful, chronic, skin disease characterized by recurrent inflamed nodules and abscesses. HS has a severely negative effect on patients' quality of life (QoL). Adalimumab is the first approved systemic treatment for HS, and national data on adalimumab treatment of HS patients in a routine clinical dermatological setting was needed.

**Research Question and Objectives**

The objective of this observational study was to assess the changes in QoL, skin pain, work productivity/activity and health related problems before and after 6 months treatment with adalimumab (Humira®) in Swedish patients with moderate to severe HS in real-life and as per routine clinical care.

**Study Design**

This was a Post Marketing Observational Study (PMOS); a non-interventional study. The patients were treated in accordance with normal routine care and adalimumab (Humira®) was prescribed in accordance with the approved labeling. The decision to prescribe adalimumab was clearly separated from and preceding the decision to include the patient in the study. The patients were assessed during routine visits at the clinic at baseline (inclusion) and at approximately 4 weeks, 12 weeks and 24 weeks after the first dose of adalimumab. Data was collected from the patient's medical records, by investigator assessment and by patient questionnaires.

**Setting**

The participating investigators were dermatologists, who routinely see HS patients. Nine clinics of varying sizes enrolled patients in this study.

**Subjects and Study Size, Including Dropouts**

Subjects eligible for enrollment in the study were patients >18 years of age with moderate to severe HS, where the treating dermatologist had made the decision to prescribe adalimumab in accordance with the current approved label.

Planned enrollment: 50 patients

Actual enrollment: 24 patients

Analyzed: 19 patients for Week 4 and 18 patients for Week 12 and 24, respectively.

Drop-outs: 5 patients

**Variables and Data Sources**

Data was collected from the patient's medical records, by investigator assessment and by patient questionnaires.

At baseline, demographic data and clinical baseline characteristics were collected.

The following assessments that were completed by the patients or physician at each timepoint were also considered source documentation:

- Dermatology Life Quality Index (DLQI)
- EuroQol -5D (EQ-5D)
- Hidradenitis Suppurativa Impact Assessment (HSIA)
- Patient's Global Assessment of Skin Pain (NRS)
- Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP)
- Hidradenitis Suppurativa Clinical Response (HiSCR)

Serious adverse events, non-serious events of malignancy in patients 30 years of age and younger, and pregnancy occurrences during the study were collected.

**Results**

Treatment with adalimumab resulted in statistically significant improvements in patient-reported QoL at all timepoints as measured by DLQI, with mean changes from baseline of -9.3 (SD 5.9; $p<0.001$) units at Week 4, -7.8 (SD 6.8; $p=0.0001$) units at Week 12 and -9.3 (SD 9.1; $p=0.0004$) units at Week 24. This was mirrored in the EQ-5D, where the mean change from baseline in the analyzed VAS item was 9.9 (SD 18.1) at week 4, 11.4 (SD 19.1) at week 12 and 8.7 (SD 25.5) at week 24.

The study patients reported significant reductions in pain, both for Skin Pain At Its Worst and Skin Pain On Average across all analysis timepoints. For the three timepoints, observed mean change from baseline were -3.2 (SD 3.2; $p=0.0005$) at

week 4, -2.9 (SD 2.8; p=0.0004) at week 12 and -2.3-2.8 (SD 2.7; p=0.0003) at week 12 for worst pain and -2.3 (SD 2.5; p=0.0006) at week 4, -2.2 (SD 2.5; p=0.002) at week 12 and -1.4 (SD 2.1; p=0.009) at week 12 for average pain.

The mean baseline of the HSIA Overall score (% of worst extreme HS impact) was 53.9. Observed change from baseline to Week 4, 12 and 24 was -26.7, -27.1 and -26.0, respectively.

At Week 4, 73.7% of the patients were HiSCR responders. At Weeks 12 and 24, 55.6% and 61.1%, had achieved HiSCR, respectively.

For Work Productivity and Activity Impairment, the observations were unevenly distributed and did not allow for reliable interpretation. Although observed values indicated an improvement in several of the WPAI components during adalimumab treatment, analysis failed to detect consistent significant changes.

No SAEs, pregnancies or non-serious malignancies in patients 30 years or younger were reported in the study.

**Discussion**

This study from Swedish routine clinical practice, although limited in actual sample size, suggests the results from adalimumab pivotal trials of adalimumab's effectiveness on improving HS patients' quality of life as well as their disease symptoms are reflected in real-life clinical practice. No findings to impact the known safety profile of the product were made.

**Marketing Authorisation Holder(s)**

AbbVie Deutschland GmbH & Co. KG

Knollstrasse

67061 Ludwigshafen

Germany

**Names and Affiliations of Principal Investigators**