Study Report Synopsis

Study Code	D2287R00101
Version	1.0
Date	19th Octorber 2017

ACQUIRE-2

Asthma Control, Quality of Life and Emotional Feelings in a Real Life Setting

- A Cross-sectional Study of Adult Asthma Patients in Japan

Study Report Synopsis

Sponsor: AstraZeneca

Non-Interventional Study Report

1. TITLE PAGE

Study title	Asthma Control, Quality of Life and Emotional Feelings in a Real Life Setting – A Cross-sectional Study of Adult Asthma Patients in Japan
Name of test drug	This was a non-interventional observational study, and no test drug was used.
Indication studied	Adult asthma patients receiving continued treatment by physicians in Japan
Design	Non-interventional, cross-sectional study
Name of sponsor	Study sponsor: Evidence & Observational Research, Medical Division, AstraZeneca K.K.
Protocol identification code	D2287R00101
Development phase of study	Not applicable because this was a non-interventional observational study.
Study initiation date	December 17, 2015 (date of enrollment of the first survey patient)
Study completion date	June 27, 2016 (date of completion of examination and observation of the last survey patient)
Compliance statement	This study was conducted in accordance with "Ethical Guidelines for Medical and Health Research Involving Human Subjects" (Notice No. 3, 2014 by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour, and Welfare) and in compliance with the ethical principles consistent with the Declaration of Helsinki and the International Conference on Harmonisation- Good Clinical Practice (ICH-GCP).
Date of preparing this report	December 26, 2016 (Ver 1.0)
Date of revising this report	July 14, 2017 (Ver 1.1) [revison point]:The CSR were updated based on revised SAP, with alteration.

2. SYNOPSIS

Name of Sponsor

Evidence & Observational Research, Medical Division, AstraZeneca K.K.

Study Title

ACQUIRE-2

Asthma Control, Quality of Life and Emotional Feelings in a Real Life Setting

– A Cross-sectional Study of Adult Asthma Patients in Japan

National Coordinating Investigator of the Non-Interventional Study

No one was designated as a National Coordinating Investigator in this study.

Planned and Actual Numbers of Study Sites in the Study

Planned: 60 institutions

Actual: 58 institutions

Planned and Actual Numbers of Subjects in the Study

Planned: 1,100 subjects

Actual: 1,250 subjects (enrolled)

Study Period	Planned	Actual
Date of enrollment of the first survey patient	December 2015	December 9, 2015
Date of enrollment of the last survey patient	June 2016	June 17, 2016

Medicinal Product (Type, Dose and Mode of Administration) and Concomitant Medications

Not applicable, because this was a non-interventional study.

Rationale for this Non-Interventional Study

According to the Japanese Asthma Prevention and Management Guideline 2015 (JGL2015), the goal in the management and treatment of asthma is to "enable patients to lead a daily life like healthy individuals." In order to achieve this therapeutic goal, the achievement of "well-controlled" state based on the asthma control status is considered to be a clinical goal. However, there are few studies in which

the asthma control status is accurately surveyed in a real life setting in adult asthma patients receiving continued treatment from physicians in Japan and the actual situation is unknown. By understanding the status of asthma control in asthma patients in a real life setting, the clinical issues could be clarified. Therefore, such information would contribute to appropriate treatment of asthma.
Thus, we planned this study to evaluate the asthma control status, asthma symptoms (severity, frequency, and limitations on activities, etc.), quality of life (QOL), and use of drugs for asthma attack in the study population in a real life setting by recruiting patients through medical institutions providing continued care for asthma patients.

Study Objectives

Primary objective

To assess the proportion of adult asthma patients receiving continued treatment from physicians in Japan in each status of asthma control defined by JGL2015 (“poorly- controlled,” “insufficiently-controlled,” and “well-controlled”)

Secondary objectives

To evaluate asthma symptoms (intensity, frequency, and limitations on activities, etc.), QOL, use of drugs for asthma attack, and emotional feelings in the study population; and to investigate the effects of demographic characteristics and pathologic properties of each patient on the status of asthma control, asthma symptoms, QOL, use of drugs for asthma attack, and emotional feelings.

Study Design

This was a non-interventional, cross-sectional study in 1100 adult asthma patients receiving continued treatment by physicians in Japan.

Study Population

Adult asthma patients receiving continued treatment by physicians in Japan

Study Endpoints and Variables

Primary endpoint

The primary endpoint of the study is status of asthma control in each population

Secondary endpoints

1. Asthma symptoms (intensity, frequency, and limitations on activities, etc.)
2. Use of drugs for the treatment of asthma
3. Asthma control during the past 1 week
4. Asthma control status during the past 1 month
5. QOL
6. Use of drugs for asthma attack and emotional feelings

Description of datasets to be analyzed

Before database lock, definitions of the datasets to be analyzed for evaluation of the primary and secondary endpoints together with appropriate justification will be included in the comprehensive statistical analysis plan.

Statistical methods

For the primary endpoint, the proportion of subjects in each asthma-control-status category defined by the JGL2015 and Global Initiative for Asthma (GINA) guidelines was calculated. A comprehensive statistical analysis plan describing detailed statistical methods was prepared before the database lock.

Results

A total of 1,175 patients were included in the efficacy analysis population (62.9% of them were women; mean age, 59.7 years; and mean duration of illness, 16.9 years). The proportions of patients in a "well-controlled," "insufficiently-controlled," and "poorly- controlled" state, as defined in JGL2015, were 24.4%, 69.2%, and 6.5%, respectively, and patients in a well-controlled state accounted for only about one-fourth of all patients. The proportions of patients in a well-controlled state at Treatment Steps 1, 2, 3, and 4 were 55.2%, 34.1%, 20.0%, and 10.9%, respectively, and the proportion of patients in a well-controlled state tended to decrease with escalation of treatment intensity (to higher Steps). We reviewed the patient diaries to assess "asthma symptoms" and determined the incidence of daytime and nighttime symptoms with respect to 3 items – "wheezing/ whistling," "chest tightness," and "intensity of cough." As a result, we found that 44.9% of the patients experienced nighttime symptoms. On the other hand, the proportion of patients who reported nocturnal sleep disorder was 10.8%, which was lower than that of patients who complained of nighttime symptoms. The mean Mini AQLQ score was 5.8 on a 7-point scale. As a secondary endpoint, asthma control status was also assessed using the GINA definition or ACQ-5 responses. The proportions of patients with controlled, partly controlled, and uncontrolled asthma, as defined by GINA guidelines were 35.1%, 49.8%, and 15.1%, respectively. The ACQ score was 0.75 or

less in 700 subjects (60.5%), more than 0.75 to less than 1.5 in 276 subjects (23.9%), and 1.5 or more in 181 subjects (15.6%).