

# ASSESSMENT OF THE EFFICACY OF COMBINATION THERAPY BUDESONIDE/FORMOTEROL FUMARATE (BUFOMIX EASYHALER 160/4.5 µG OR 320/9.0 µG PER INHALATION) IN PATIENTS DIAGNOSED WITH ASTHMA (ORN/AST/2016/004)

**First published:** 13/12/2016

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/22949>

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### **EU PAS number**

EUPAS16451

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### **Study ID**

22949

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## **DARWIN EU® study**

No

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### **Study countries**

Poland

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### **Study description**

This is a prospective non-interventional observational study of approximately 2500 patients in Polish population receiving combination therapy bufomixeasyhaler - inhalation powder containing budesonide/formoterol fumarate - 160/4.5 µg or 320/9.0 µg per inhalation active substances for at least 14 days prior to study enrollment. All study participants will be followed-up for at least 6 months. Data on the efficacy BUFOMIX EASYHALER formulation will be recorded in a Study Questionnaire (SQ) over three consecutive visits (planned according to the routine clinical needs of the patient), within a period of 6 months from the initiation of the use of BUFOMIX EASYHALER. The efficacy will be assessed on the basis of ACT scale and the results of spirometry and compliance on the basis of the Medication Adherence Questionnaire (MAQ). The role of the study is to establish that new combination therapy budesonide/formoterol fumarate (bufomixeasyhaler 160/4.5 µg or 320/9.0 µg) is efficient and safe in treatment of patients diagnosed with asthma. Non additional diagnostic procedures or monitoring will be used, and all data will be collect during the routine use of BUFOMIX EASYHALER. Analisis of the collected data will be preformed by epidemiological methods only.

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### **Study status**

Finalised

## **Research institutions and networks**

# Institutions

## Euopharma

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Michał Pirożyński

Study contact

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### Primary lead investigator

Michał Pirożyński

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 08/03/2016

Actual: 08/06/2016

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### Study start date

Planned: 15/04/2016

Actual: 15/06/2016

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### **Data analysis start date**

Planned: 15/12/2016

Actual: 13/12/2016

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### **Date of final study report**

Planned: 31/05/2017

Actual: 26/04/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Orion Pharma Poland Sp. z o.o.

## Study protocol

[ORN-2016-AST PB.pdf](#)(809.41 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Primary data collection

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**Main study objective:**

the assessment of the efficacy of BUFOMIX EASYHALER®  
(budesonide/formoterol fumarate 160/4.5 micrograms or 320/9.0 micrograms  
dose inhalation) in the form of powder for inhalation in patients with asthma.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Non-Interventional, post-authorization efficacy study

## Population studied

## **Short description of the study population**

Adult patients of either sexes with diagnosis of asthma, treated with novel combination therapy of budesonide/formoterol fumarate (BUFOMIX EASYHALER® 160 / 4.5 micrograms or 320 / 9.0 micrograms) at least 14 days before enrollment into the study in Poland by 250 allergist and pulmonologist or doctors currently in course of obtaining these specializations.

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## **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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## **Special population of interest**

Other

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## **Special population of interest, other**

Asthma patients

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## **Estimated number of subjects**

2500

# Study design details

## **Data analysis plan**

The Study Questionnaires (SQ) will be transferred from the Study centers to the Office of the Study Organizer will be analyzed in terms of completeness, consistency, clarity and compliance with the Protocol. If data elements are missing from the SQ, the Investigator should state the reason for the missing

data or other deviations from the Protocol. The Office of the Study Organizer will communicate to the Investigator any questions regarding the processing of data and the points that have not been sufficiently explained, for the purpose of clarification or improvement. The Investigator must ensure that all requests for clarification of data are immediately addressed. The Investigator is obliged to keep copies of all data, including a record of all changes and clarifications with SQ. Epidemiological and Statistical analysis of the data will be carried out in accordance with the standards of the EU GCP/ICH.

## Documents

### Study results

[Budesonide Publication.pdf](#)(564.68 KB)

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### Study publications

[Pirożyński M, Hantulik P, Almgren-Rachtan A, Chudek J. Evaluation of the effici...](#)

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## Data management

### Data sources

#### Data sources (types)

[Other](#)

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#### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown