Safety and Effectiveness of Capivasertib with Fulvestrant in Patients with Advanced Breast Cancer and Diabetes – a Multi-country Observational Study using Secondary Real-World Data (CAPIseid)

First published: 17/12/2025

Last updated: 17/12/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000805

Study ID

1000000805

DARWIN EU® study

No

Study countries

Denmark

France

Germany

United States

Study description

This is a non-interventional, longitudinal, capivasertib + fulvestrant new-user cohort study that will use secondary data (administrative claims, electronic medical records [EMR] and/or registries) from multiple EU member states (France, Germany, Denmark) and the United States of America (USA) to further characterize the safety and effectiveness of capivasertib + fulvestrant in patients with breast cancer and diabetes. The main objectives are to assess (i) the risk of acute complications of hyperglycaemia (including diabetic ketoacidosis) and (ii) time to first subsequent therapy (TFST) or death due to any cause in adult patients with advanced breast cancer and type 1 or type 2 diabetes receiving capivasertib + fulvestrant treatment. The study will include two distinct cohorts: a safety cohort for assessing safety outcomes and an effectiveness cohort for evaluating effectiveness outcomes.

Study status

Planned

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aetion

Spain

First published: 24/11/2022

Last updated: 16/07/2024

Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Zachary Bouck

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2025

Actual: 13/01/2025

Study start date

Planned: 01/10/2026

Data analysis start date
Planned: 01/01/2027

Date of interim report, if expected
Planned: 30/09/2027

Date of final study report
Planned: 30/09/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study is sponsored by AstraZeneca.

Study protocol

d3612r00020-csp-v2_redacted.pdf (3.17 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This non-interventional, longitudinal, capivasertib + fulvestrant new-user cohort study will use secondary data (administrative claims, electronic medical records [EMR] and/or registries) from multiple EU member states and the USA.

Main study objective:

The main objectives of this non-interventional study are to assess (i) the risk of acute complications of hyperglycaemia (including diabetic ketoacidosis) and (ii) time to first subsequent therapy (TFST) or death due to any cause in adult patients with advanced breast cancer and type 1 or type 2 diabetes receiving capivasertib + fulvestrant treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TRUQAP

Anatomical Therapeutic Chemical (ATC) code

(L01EX27) capivasertib

capivasertib

(L02BA03) fulvestrant

fulvestrant

Medical condition to be studied

Breast cancer

Population studied

Short description of the study population

The study population will consist of all adults with diabetes mellitus and breast cancer in the
selected secondary data sources who, during the accrual period, initiate treatment with
capivasertib + fulvestrant (index date)

Study design details

Outcomes

Outcomes

• Primary outcomes:

o Safety: Acute complications of hyperglycaemia (composite), including diabetic ketoacidosis

o Effectiveness: TFST

• Secondary outcomes:

o rwOS

o TTD

• Exploratory outcomes:

o rwPFS

o Time-to-acute complications of hyperglycaemia (composite), including diabetic
ketoacidosis

o Acute complications of hyperglycaemia (composite), including diabetic ketoacidosis, stratified by insulin-dependent diabetes and non-insulin-dependent
diabetes

o TFST stratified by insulin-dependent diabetes and non-insulin-dependent diabetes

o rwOS stratified by insulin-dependent diabetes and non-insulin-dependent diabetes

o Primary safety outcome (acute complications of hyperglycaemia [composite], including diabetic ketoacidosis) and effectiveness outcome (TFST) in patients with ER+/HER2- advanced breast cancer with ≥1 PIK3CA/AKT1/PTEN alteration10

o Primary safety outcome (acute complications of hyperglycaemia [composite], including diabetic ketoacidosis) in patients with a recorded baseline HbA1c level ≥ 8.0%

o Individual components of the primary safety outcome: Diabetic ketoacidosis and
hyperosmolar hyperglycaemic syndrome

o Anti-diabetic treatment patterns

Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown