Observational Study Results Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Overall data disclosed, may differ from published or presented data and are a reflection of the limited information provided here. The results from a single study need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

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1. Abstract

Acronym/Title	ROVER - Real World Outcomes of Patients Treated with Vericiguat in German Routine Care
Protocol version and date	V 1.0, 17 JUN 2026
IMPACT study number	22829
Study type / Study phase	Observational / Phase IV
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Rationale and background	Vericiguat is an oral soluble guanylate cyclase stimulator indicated for the treatment of symptomatic chronic heart failure in adults with reduced ejection fraction following a recent worsening heart failure event requiring intravenous therapy. In the Phase III VICTORIA trial, vericiguat reduced the composite endpoint of cardiovascular death or heart failure hospitalization compared with placebo. Vericiguat has been available in Germany since September 2021. However, evidence describing patient characteristics, treatment patterns, and clinical outcomes among vericiguat initiators in routine care in Germany has been limited.
Research question and objectives	This study aimed to describe mortality, hospitalization, demographic and clinical characteristics, and real-world drug use patterns among patients initiating vericiguat in Germany.

	Primary objective: To describe all-cause mortality, all-cause hospitalization, and heart failure-related hospitalization after initiation of vericiguat. **Secondary objectives:** To describe baseline sociodemographic and clinical characteristics, treatment patterns including adherence, titration, and persistence, and medication use in the 3 months before and after initiation of vericiguat. **Exploratory objective:** To describe the occurrence of hypotension after initiation of vericiguat.
Study design	This report describes a retrospective, single-arm cohort study of patients initiating vericiguat in Germany from September 2021 to June 2024.
Population	The study population comprised adults aged 18 years or older with a first observed vericiguat prescription after market availability in Germany.
Variables	Primary variables: all-cause mortality, all-cause hospitalization, and heart failure-related hospitalization. Secondary variables: baseline comorbidities, concomitant medication, and measures describing drug use patterns, including medication possession ratio, titration, and time to discontinuation. Exploratory variable: diagnoses indicating hypotension.
Data sources	The InGef database is an anonymized healthcare claims database with longitudinal data from approximately 10 million German insured members of one of more than 50 German statutory health insurance providers (SHIs) currently contributing data to the database (mainly company or guild health insurances).
Study size	No formal sample size calculation was performed because the study was descriptive. A feasibility assessment based on the InGef database suggested that approximately 550 patients with at least one vericiguat prescription between 2021 and 2023 could be identified. The final number of included patients could vary depending on the applicable inclusion criteria and required observation periods.

Data analysis	Analyses were descriptive and exploratory. Mortality and hospitalization outcomes were summarized as incidence rates and with Kaplan–Meier methods. Adherence, titration, and persistence were assessed using dispensing-based measures and prespecified operational definitions. Baseline sociodemographic and clinical characteristics, as well as medication use before and after vericiguat initiation, were described. Exploratory regression models were used to examine associations between baseline characteristics and selected outcomes.
Milestones	Table 1 presents the planned and actual study milestones relevant to conduct and reporting of the study.