Report VERQUVO® Vericiguat

Product & Mechanism of action	Authorized indications Licensing status	Essential therapeutic features	NHS impact
Substance: vericiguat **Brand Name:** VERQUVO® **Originator/license:** Bayer AG **Classification:** NCE **ATC code:** C01DX22 **Orphan Status:** **Eu:** No **Us:** No **Mechanism of action:** vericiguat stimulates directly sGC, independently of and synergistically with NO, to augment the levels of intracellular cGMP. This leads to smooth muscle relaxation and vasodilation, which may improve both myocardial and vascular function [1].	**Authorized Indication:** **EMA:** vericiguat is indicated for the treatment of symptomatic chronic HF in adults with reduced ejection fraction who are stabilized after a recent decompensation event requiring IV therapy [1]. **Route of administration:** OS **Licensing status** **EU CHMP P.O. date:** 20/5/2021 **FDA M.A. date:** 19/1/2021 **EU Speed Approval Pathway:** No **FDA Speed Approval Pathway:** Yes --- **ABBREVIATIONS:** **ACE:** angiotensin-converting enzyme **AE:** adverse events **ARB:** angiotensin II receptor blocker **BNP:** B-type natriuretic peptide **CHMP:** Committee for Medicinal Products for Human Use **CV:** cardiovascular **HF:** heart failure **HFrEF:** Heart failure with reduced ejection fraction **LVEF**: Left ventricular ejection fraction **M.A.:** Marketing Authorization **MRA:** mineralocorticoid receptor antagonist **NO:** nitric oxide **NYHA:** New York Heart Association **P.O.:** Positive Opinion **pts:** patients **sGC:** soluble guanylate cyclase **vs:** versus	**Summary of clinical EFFICACY:** **VICTORIA (NCT02861534)** is a randomized parallel-group, placebo-controlled, double-blind, event-driven, multi-center pivotal phase 3 clinical trial, which enrolled 5050 adults with chronic HF (NYHA class II-IV), LVEF of <45% and plasma elevated BNP level. All pts received guideline-based medical therapy. Pts were randomly assigned to 2,5 mg vericiguat or matching placebo. Doses of vericiguat were increased to 5 mg and to 10 mg once daily. The primary endpoint was a composite of death from CV causes or first hospitalization for HF. At a median of 10,8 months, the incidence of the primary outcome was 35,5% (897/2526 pts) in the vericiguat arm vs 38,5% (972/2524 pts) in placebo group [HR, 0,90; 95% CI, 0,82 to 0,98; p=0,02][2-4] **Summary of clinical SAFETY:** Incidences of serious AE were similar in the vericiguat (32.8%) and placebo (34.8%) groups; among these anaemia occurred in 1,6% of the pts in the vericiguat group and 0,9% of the subjects in the placebo group. Non-serious AE in vericiguat group vs placebo arm were symptomatic hypotension (9.1% vs 7.9%) and syncope (4.0% vs 3.5%) [2][4]. **Ongoing studies:** • ***For the same indication:*** *Yes* • ***For other indications:*** *No* **Discontinued studies (for the same indication):** Yes [5] **References:** 1. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/verquvo 2. https://clinicaltrials.gov/ct2/show/NCT02861534 3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214377s000lbl.pdf 4. Armstrong, Paul W et al. "Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction." *The New England journal of medicine* vol. 382,20 (2020): 1883-1893. doi:10.1056/NEJMoa1915928 5. https://clinicaltrials.gov/ct2/show/NCT04464525?recrs=ghi&cond=Heart+Failure+with+reduced+Ejection+Fraction&phase=2&draw=2&rank=2 6. https://www.drugs.com/price-guide/verquvo 7. Aldo Pietro Maggioni, Federico Spandonaro. Lo scompenso cardiaco acuto in Italia, G Ital Cardiol 2014;15(2 Suppl.2):3S-4S 8. https://snlg.iss.it/wp-content/uploads/2019/10/scompenso-cardiaco-cronico.pdf 9. https://clinicaltrials.gov/ct2/show/NCT03759392?recrs=abdef&type=Intr&cond=Heart+Failure&phase=2&draw=2&rank=77	**Cost of therapy:** In US 30 tablets (10 mg) cost $618.05 [6]. **Epidemiology:** In Italy the prevalence of HF is 1-2%, with 80.000 new incident cases/year [7] --- **POSSIBLE PLACE IN THERAPY** Currently, the treatment of HF consists in: - ACE inhibitor and a beta-blocker or ARB in subjects with HFrEF and intolerable side effects with ACE-inhibitors; people - MRA in addition to an ACE inhibitor (or ARB) and beta-blockers, if pts continue to have symptoms of HF [8]. **OTHER INDICATIONS IN DEVELOPMENT:** No **SAME INDICATION IN EARLIER LINE(S) OF TREATMENT: -** **OTHER DRUGS IN DEVELOPMENT FOR THE SAME INDICATION**: Omecamtiv Mecarbil [9] [if it is..] *Service reorganization No *Possible off label use No ---

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