Product	Verquvo (Vericiguat, BAY1021189)
Swissmedic approval date:	September 25, 2021
Swissmedic approval ID	68001

Bayer study ID	Study title	WS direct link
15355	Single dose, single-blind, randomized, placebo-controlled dose escalation study to investigate safety, tolerability, pharmacokinetic, and pharmacodynamic properties of BAY 1021189 after oral dosing in 10 healthy male non-smoking subjects per dose step and 10 healthy male smoking subjects in one dose step in addition	https://s3.amazonaws.com/ctr-bsp-7261/15355/19775b16-f44d-427e-bef7-72efb0e8b123/ca27b922-0a9d-476e-b5c4-2811b809d710/15355_Study_Synopsis_CTP-v2.pdf
15356	Relative bioavailability study to investigate safety, tolerability, pharmacodynamics and pharmacokinetics of 1.25 mg and 5 mg BAY 1021189 IR tablets in comparison to 5 mg oral solution, and to investigate the influence of a high fat, high calorie meal on the 5 mg IR tablet in 16 healthy male subjects in a single dose, randomized, open-label, four-fold cross-over design	https://s3.amazonaws.com/ctr-bsp-7261/15356/4a6e7ac2-df50-4ed2-ba95-8f30a41a858f/2fd89626-2502-4eeb-8a18-23fab66a2da3/15356_Study_Synopsis_CTP-v2.pdf
15357	Multiple dose escalation study to investigate safety, tolerability, pharmacokinetics and pharmacodynamics of BAY 1021189 after oral dosing of 1.25, 5, 10 mg OD and 5 mg BID over 7 days given as 1.25 mg or multiples of 1.25 mg IR-tablet in 12 healthy male subjects per dose step in a randomized, single-blind, placebo-controlled, group-comparison design	https://s3.amazonaws.com/ctr-bsp-7261/15357/24f1afb6-3c65-4d72-b68e-473f076b45a2/37f5da95-9092-4f52-b56b-44061a4e4a1f/15357_Study_Synopsis_CTP-v2.pdf
15371	A randomized parallel-group, placebo-controlled, double-blind, multi-center dose finding phase II trial exploring the pharmacodynamic effects, safety and tolerability, and pharmacokinetics of four dose regimens of the oral sGC stimulator BAY1021189 over 12 weeks in patients with worsening heart failure with reduced ejection fraction (HFrEF)	https://s3.amazonaws.com/ctr-bsp-7261/15371/ac90b9f9-c006-41b6-b63b-6e38a43e985e/c28e7b74-667e-45be-a19a-43a0e8a5e7c2/15371_Study_Synopsis_CTP-v3.pdf
15811	Interaction study to investigate the influence of a co-administration of a single dose of 10 mL Maalox® and a 4 days pre- and co-treatment with Antra® 2 x 20 mg OD,	https://s3.amazonaws.com/ctr-bsp-7261/15811/b33d8062-727a-4313-94b1-71c23dc99a22/66e28e4f-e202-4adb-9337-

	respectively, on the pharmacokinetics of a single dose of 5 mg BAY 1021189, taken as 4 x 1.25 mg IR tablets, in a threefold crossover, randomized, open label design in healthy male subjects	cc20ae13f5b2/15811_Study_Synopsis_CTP-v3.pdf
15812	An Exploratory Phase I, Randomized, Open Label Two Fold Cross-Over Study to Determine the Effect of Ketoconazole on the Pharmacokinetics of a Single Oral Dose of 1.25 mg BAY 1021189 in Healthy Male Subjects	https://s3.amazonaws.com/ctr-bsp-7261/15812/5538b16e-af08-452f-973f-23badd20aee4/bf722e21-2f19-499b-adb6-6ad487206731/15812_Study_Synopsis_CTP-v2.pdf
15813	Investigation of pharmacokinetics, safety, tolerability and pharmacodynamic effects of BAY1021189 in male and female subjects with renal impairment and in age-, gender-, and weight-matched healthy subjects following a single oral dose of 2.5 mg BAY1021189 in a single-center, non randomized, non-controlled, non-blinded, observational study with group stratification	https://s3.amazonaws.com/ctr-bsp-7261/15813/3d88c2d3-e2a5-4515-b5c5-db5b6bc0f870/392ae0a1-0eee-4fc5-9047-19189bece1cc/15813_Study_Synopsis_CTP-v5.pdf
15815	Single-center, randomized, non-blinded, non-placebo-controlled, twofold crossover study to investigate the influence of multiple doses of 10 mg OD vericiguat on pharmacokinetics, safety and tolerability of a single oral dose of 7.5 mg midazolam in comparison to a single dose of 7.5 mg midazolam alone in healthy male subjects	https://s3.amazonaws.com/ctr-bsp-7261/15815/d3537b14-ae60-4454-bd35-deb642a6d6d4/62d1e469-6279-4631-864a-aefb7dc0a013/15815_Study_Synopsis_CTP-v2.pdf
15816	Study to investigate the influence of age and gender on the pharmacokinetics of a single oral dose of 5 mg BAY 1021189 as immediate-release tablet in a randomized, double-blind, placebo-controlled, group-comparison design in healthy male and female subjects	https://s3.amazonaws.com/ctr-bsp-7261/15816/8187e174-24bf-470e-9138-218cf76b108d/375b26bb-d9a6-434e-ab0c-13083183f8fe/15816_Study_Synopsis_CTP-v2.pdf
15817	Single center, open-label, non-randomized, non-placebo-controlled study to investigate the pharmacokinetics, metabolic disposition and mass balance after single administration of 5 mg [14C]BAY 1021189 (oral solution) in healthy male subjects	https://s3.amazonaws.com/ctr-bsp-7261/15817/48eff073-5a25-4105-9aa1-1284ca285806/3ad4c820-bc12-4476-8dc4-34edf56772f0/15817_Study_Synopsis_CTP-v2.pdf

15829	A randomized parallel-group, placebo-controlled, double-blind, multi-center dose finding phase II trial exploring the pharmacodynamic effects, safety and tolerability, and pharmacokinetics of four dose regimens of the oral sGC stimulator BAY1021189 over 12 weeks in patients with worsening heart failure and preserved ejection fraction (HFpEF)	https://s3.amazonaws.com/ctr-bsp-7261/15829/5e25e2cc-8fc2-4024-879c-a72420b3d355/b3aebf09-089d-45c2-8f8c-ae3ccf566281/15829_Study_Synopsis_CTP-v3.pdf
15836	Single-center, randomized, single-blinded, placebo-controlled, group-comparison, combined single and multiple dose escalation study to investigate safety, tolerability, pharmacodynamics and pharmacokinetics of BAY 1021189 in Japanese healthy adult male subjects	https://s3.amazonaws.com/ctr-bsp-7261/15836/4bbb04e5-5bab-4ac1-9419-6b48cb1c0ab4/037c5cf2-7588-4f14-aed3-c12ba64c2c3f/15836_Study_Synopsis_CTP-v2.pdf
15837	Single-center, randomized, double-blind, placebo-controlled, single dose escalation study to investigate safety, tolerability and pharmacokinetics of BAY 1021189 in Asian (Chinese) healthy male subjects	https://s3.amazonaws.com/ctr-bsp-7261/15837/3dc6c60a-919f-46fd-9ee3-002b1e7c618c/7caecb50-ee70-470a-a3b7-908aa1c2dfe4/15837_Study_Synopsis_CTP-v2.pdf
15838	Aspirin interaction study to investigate the influence of Aspirin (2x 500 mg, 500 mg once daily) combined with a single dose of 15 mg Vericiguat (BAY 1021189) on bleeding time and platelet aggregation in comparison to a single dose of 15 mg Vericiguat (BAY 1021189) alone and to 2 single doses of Aspirin in healthy male subjects in randomized, non-blinded, non-placebo-controlled 3-fold cross-over design (main-part), preceded by a pilot part to investigate safety, tolerability and pharmacokinetics of 15 mg Vericiguat (BAY 1021189) tablet in healthy male subjects in a non-randomized, non-blinded, non-controlled design	https://s3.amazonaws.com/ctr-bsp-7261/15838/dd0dffef-05c0-4253-ad31-70af96ea4a92/64fc27d1-6dcd-4d8a-8359-39d5276c3e8d/15838_Study_Synopsis_CTP-v2.pdf
15839	Randomized, double-blind, placebo-controlled, 2-fold cross-over study to investigate the effects of vericiguat, administered as 10 mg IR tablets OD over 9 days, on the safety, tolerability,	https://s3.amazonaws.com/ctr-bsp-7261/15839/d7330025-f82d-4256-b7e1-fe82a0346c44/3f6a0b39-97a5-49a5-86e6-e329c5234cb9/15839_Study_Synopsis_CTP-v2.pdf

	pharmacodynamics and pharmacokinetics of warfarin in healthy subjects	
15840	Investigation of the pharmacokinetics, safety, and tolerability of vericiguat (BAY1021189) in subjects with hepatic impairment (classified as Child Pugh A or B) and in age-, weight-, and gender-matched healthy subjects following a single oral dose in a single-center, non-randomized, non-controlled, non-blinded, observational study with group stratification	https://s3.amazonaws.com/ctr-bsp-7261/15840/05a33efc-32f2-49f1-9234-3fe84090fc0f/da83729e-c20a-4ea0-ba5c-addec9d037c1/15840_Study_Synopsis_CTP-v4.pdf
15841	Randomized, non-blind, non-placebo-controlled, 2-fold cross-over study with additional 1st period with fixed treatment to investigate the pharmacokinetic interaction between vericiguat (10 mg once-daily) and digoxin (0.375 mg once-daily) and to investigate the safety and tolerability of the combined administration in healthy male subjects	https://s3.amazonaws.com/ctr-bsp-7261/15841/4860a835-3caa-436d-91e6-51948f44453d/3d76ad4e-b81a-42e1-a692-083121745f45/15841_Study_Synopsis_CTP-v2.pdf
16440	Relative bioavailability study to investigate pharmacokinetics, safety and tolerability following administration of 1.25 mg, 2.5 mg, 5 mg and 10 mg BAY 1021189 as IR tablets following a high fat, high calorie meal in 16 healthy male subjects in a randomized, open label, fourfold crossover design	https://s3.amazonaws.com/ctr-bsp-7261/16440/e44e9958-46e8-451f-8e75-406d74f95910/c0557572-f73c-482c-adfa-742775014e57/16440_Study_Synopsis_CTP-v2.pdf
16493	A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT GlObal Study in Subjects With Heart Failure With Reduced EjectIon FrAction (VICTORIA)	https://s3.amazonaws.com/ctr-bsp-7261/16493/7d88a34e-33ca-479f-9c66-c89f7d95ded9/2d67bc94-9142-46e8-9136-4b2575ad6892/16493_Study_Synopsis_CTP-v4.pdf
17114	Single-center, open-label study in healthy male subjects to evaluate the absolute bioavailability of a 10 mg oral dose of vericiguat (BAY 1021189) (as IR tablets following a high-fat, high-calorie meal) in	https://s3.amazonaws.com/ctr-bsp-7261/17114/e73951db-d9ca-44f4-8eb2-a0c0f5a08acd/8910c009-b092-4f6c-8bbe-679c231a6bcc/17114_Study_Synopsis_CTP-v2.pdf

	comparison to an intravenous, 14C-labeled micro-dose (20 microgram) of vericiguat	
17115	Evaluation of the effect of 0.2 mg sublingually administered nitroglycerin after pretreatment with 5 mg vericiguat on safety, tolerability and blood pressure in a randomized, placebocontrolled, double-blind crossover study in two cohorts of healthy male subjects aged 40 to 60 years	https://s3.amazonaws.com/ctr-bsp-7261/17115/443a9c90-75fe-4054-a6f3-b0a657f9da8c/308e9679-7fd8-432f-ab0d-1dc20b0ee5cb/17115_Study_Synopsis_CTP-v2.pdf
17116	Interaction study to investigate the influence of a starting dose of 500 mg followed by multiple doses of 250 mg mefenamic acid every 6 hours on the pharmacokinetics as well as safety and tolerability of a single dose of 2.5 mg vericiguat in comparison to a single dose of 2.5 mg vericiguat alone in healthy male subjects in a randomized, non-blinded, non-placebo- controlled, two-fold cross-over design	https://s3.amazonaws.com/ctr-bsp-7261/17116/e56e5896-ae24-49d3-9935-16d1ae39e207/3d5fa5b8-4e67-4f1e-b1f3-2fa406a3cdcf/17116_Study_Synopsis_CTP-v2.pdf
17743	A randomized, placebo-controlled, single-blind, group-comparison interaction study to investigate the influence of single oral doses of 25 mg, 50 mg and 100 mg sildenafil on top of 10 mg vericiguat or placebo tablets given over 16 days at steady state on safety, tolerability, pharmacodynamic effect and pharmacokinetics in healthy male subjects	https://s3.amazonaws.com/ctr-bsp-7261/17743/cc0b1a3d-ee0e-4ccc-adb3-d42558b7c5d3/8844312f-8a2e-4556-bd9e-55b9b2ca6315/17743_Study_Synopsis_CTP-v2.pdf
17745	A randomized, single-blind, placebo-controlled interaction study to investigate the influence of co-administration of 2.5 mg vericiguat once daily and Entresto® 97/103 mg (sacubitril/ valsartan) twice daily at steady state on the safety, tolerability, pharmacodynamics and pharmacokinetics in healthy male subjects	https://s3.amazonaws.com/ctr-bsp-7261/17745/bd5f6377-a9a3-4e56-96c3-9fe78afab930/d428d9a7-bc63-400f-b2f5-b8996e85091e/17745_Study_Synopsis_CTP-v2.pdf
17746	Non-randomized, non-blinded, non-placebo-controlled study with intra-individual comparison to investigate the influence of multiple doses of 600 mg rifampicin once daily on the pharmacokinetics, safety and tolerability of a single oral dose of 10 mg vericiguat (BAY 1021189; IR tablets) in	https://s3.amazonaws.com/ctr-bsp-7261/17746/4b3dbc31-1c90-485f-ae61-ccac2ec2015c/f9c21785-76a4-485f-b11f-0e0a0883ec32/17746_Study_Synopsis_CTP-v2.pdf

	comparison to a single oral dose of 10 mg vericiguat alone in healthy male subjects	
17849	Evaluation of the effect of 0.4 mg nitroglycerin spray after pretreatment with multiple once daily oral doses of 2.5 mg, 5 mg and 10 mg vericiguat (BAY 1021189) each given over 14 ± 3 days on safety, tolerability and blood pressure in a multi-center, randomized, placebo-controlled, double-blind group comparison study in stable coronary artery disease (CAD) patients aged 30 to 80 years	https://s3.amazonaws.com/ctr-bsp-7261/17849/5d865185-8861-431f-a069-d1086081ff9b/d43b459b-ca2e-4643-a69c-b0c27f111141/17849_Study_Synopsis_CTP-v3.pdf
18580	Pivotal food effect and dose proportionality study to investigate pharmacokinetics, safety and tolerability following administration of 2.5 mg, 5 mg and 10 mg vericiguat (BAY 1021189) as IR tablets following a high fat, high calorie meal and 10 mg fasted in 32 healthy male subjects in a randomized, open-label, four-fold cross-over design	https://s3.amazonaws.com/ctr-bsp-7261/18580/2d1b5e53-33be-48d2-8a2d-19cd53a14fba/035e02cc-9805-4281-a9d2-0bd73763f443/18580_Study_Synopsis_CTP-v2.pdf
18581	Relative bioavailability and food effect study with vericiguat to characterize the pediatric formulation in adult healthy subjects	https://s3.amazonaws.com/ctr-bsp-7261/18581/ede5fe61-9f75-46c9-aec4-803a4d95ab2c/f37c3864-e617-44d8-8aed-946fdec23116/18581_Study_Synopsis_CTP-v5.pdf
18582	Multi-center, randomized, placebo-controlled, double-blind group comparison study to investigate safety, tolerability and blood pressure of 2.5 mg, 5.0 mg and 10 mg vericiguat each given over 14 ± 3 days together with isosorbite mononitrate (ISMN) 60 mg extended release formulation after a pretreatment phase (ISMN-starting dose: 30 mg) in stable coronary artery disease (CAD) patients with or without heart failure aged 30 to 80 years - Vericiguat ISOsoRbite mononitrate interaction (VISOR) study	https://s3.amazonaws.com/ctr-bsp-7261/18582/790c8bd7-bdcc-4a35-b1e3-5372879e23ef/0e301c57-ff39-4732-b755-5004f6191fbb/18582_Study_Synopsis_CTP-v6.pdf
18979	Study to clinically evaluate the QT/QTc interval prolongation potential of vericiguat in patients with stable coronary artery disease in a 2-arm, placebo-controlled,	https://s3.amazonaws.com/ctr-bsp-7261/18979/b7fbc331-b02a-4637-b4fd-ba72505dfcd4/917000b3-290f-4d27-8558-

	randomized, double-blind, double-dummy design including a vericiguat multiple-dose part with fixed up titration periods and moxifloxacin as positive control (for assay sensitivity testing, nested into the placebo treatment)	c75e46425566/18979_Study_Synopsis_CTP-v5.pdf
19334	A randomized parallel-group, placebo-controlled, double-blind, multi-center trial to evaluate the efficacy and safety of the oral sGC stImulator vericiguat to improve physical functioning in activities of daily living in patients with heart failure and preserved ejection fraction (VITALITY-HFpEF)	https://s3.amazonaws.com/ctr-bsp-7261/19334/9be363fd-5949-4bec-bb3c-6bd19e2214bc/7d2ae615-6878-4754-bd6e-6e691f2297e6/19334_Study_Synopsis_CTP-v6.pdf
19699	Pivotal relative bioavailability study to investigate the pharmacokinetics, food effect (high fat, high calorie meal/ fasted), safety and tolerability of single oral doses of vericiguat given as 15 mg round high drug load tablet, 15 mg oblong low drug load tablet in comparison to the loose combination of 10 mg and 5 mg immediate release (IR) tablets in healthy male participants in a randomized, open-label, 5-fold crossover design (main part), preceded by a pilot part to investigate safety, tolerability and pharmacokinetics of 15 mg vericiguat (given as loose combination of 10 mg and 5 mg IR tablets) under fed conditions in healthy male participants in an open-label, non-controlled design	https://s3.amazonaws.com/ctr-bsp-7261/19699/3dd8d137-b15b-40e8-a5fa-257c66c74064/c0f727f3-5fd3-4b79-80bc-86825bd4f7cf/19699_Study_Synopsis_CTP-v2.pdf
16964	Single-center, randomized, double-blind, placebo-controlled, single-dose and multiple-dose, parallel-group study to investigate pharmacokinetics, pharmacodynamics, safety and tolerability of BAY 1021189 in Chinese healthy male subjects under fed condition	https://s3.amazonaws.com/ctr-bsp-7261/16964/32b7d2ca-4172-4d19-b7c5-ec077c7fc162/f6e2041a-38c7-42f8-919d-bd2f8c0cb76c/16964_Study_Synopsis_CTP-v3.pdf