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| Product | Finerenone (BAY94-8862) |
| Swissmedic approval date: | November 26, 2021 |
| Swissmedic approval ID | 68130 |

| Bayer study ID | Study title | WS direct link |
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| 13782 | Single dose, basic phase I dose escalation study in a randomized, single-blind, placebo-controlled, group-comparison design to investigate safety and tolerability of BAY 94-8862 and its pharmacodynamics and pharmacokinetics after oral dosing in 8 healthy male subjects per dose step | https://s3.amazonaws.com/ctr-bsp-7261/13782/75dc0360-6ba7-47df-b4fd-c45448a7e12d/c00d6341-9f8a-4a94-97a8-7e8f49981878/13782_Study_Synopsis_CTP_2022-01-19-v4.pdf |
| 13784 | Relative bioavailability study to investigate the pharmacokinetics, safety and tolerability of single oral doses of BAY 94-8862 given as 10 mg IR tablet in comparison to a 10 mg solution and 8 x 10 mg IR tablet in the fasting condition and to investigate the effect of a high fat, high calorie meal on the 10 mg IR tablet in healthy male subjects in a randomized, open-label, four-fold crossover design | https://s3.amazonaws.com/ctr-bsp-7261/13784/605776f7-d5d0-4bfe-8e47-16c483bf7948/b130c38c-bbbb-4998-89ab-2dd059623fc2/13784_Study_Synopsis_CTP_2022-01-20-v3.pdf |
| 13785 | Multiple dose basic phase I dose escalation study, to investigate safety, tolerability, pharmacokinetics and pharmacodynamics of BAY 94-8862 after oral dosing of 10 mg bid, 20 mg bid or 40 mg od over 10 days given as 10 mg IR-tablets in 12 healthy male subjects per dose step in a randomized, single-blind, placebo-controlled, group-comparison design | https://s3.amazonaws.com/ctr-bsp-7261/13785/89c40b81-c22c-4ad7-b074-bb0486c17e58/ea78e6b5-90a2-4239-8fb9-d4517a435bbe/13785_Study_Synopsis_CTP_2022-01-20-v3.pdf |
| 13786 | Study to investigate the effectiveness of different single oral doses of BAY 94-8862 on natriuresis after administration of 0.5 mg fludrocortisone (Astonin H®) with 50 mg eplerenone (Inspra®) as active control in healthy male subjects in a randomized, single-blind, placebo-controlled, combined 3-fold crossover, and parallel-group design | https://s3.amazonaws.com/ctr-bsp-7261/13786/bfab029e-4e13-4618-9831-f2184729b133/89e96b81-10c3-40f4-8aa7-5e5313549eb9/13786_Study_Synopsis_CTP_2022-01-20-v3.pdf |
| 14502 | Single center, open-label, non-placebo-controlled, single-dose study in healthy male subjects to compare the bioavailability of 10 mg finerenone aqueous oral solution and tablet (Part A; randomized) and to investigate the metabolism, excretion pattern and mass balance of 10 mg [$^{14}$C]finerenone oral solution (Part B; non-randomized). | https://s3.amazonaws.com/ctr-bsp-7261/14502/ee9ccd09-89dd-4816-be79-46720513d474/4b9c971e-4a98-4e2d-a40f-561e19dd6362/14502_Study_Synopsis_CTP_2021-12-06-v3.pdf |
| 14503 | Randomized, double-blind, placebo-controlled, 2-fold cross-over study to investigate the effects of | https://s3.amazonaws.com/ctr-bsp-7261/14503/189778dd-f971- |

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| | finerenone, administered as 20 mg IR tablets once-daily over 6 days, on the safety, tolerability, pharmacodynamics and pharmacokinetics of warfarin in healthy male subjects | 409b-91e8-9e44c630f437/0391dd4e-c891-4f19-87a2-90a5ee9f8877/14503_Study_synopsis_CTP_2021-12-06-v5.pdf |
| 14504 | Randomized, non-blinded, non-placebo-controlled, 2-fold cross over study to investigate the influence of multiple doses of 500 mg erythromycin tid on the safety, tolerability, pharmacodynamics, and pharmacokinetics of a single oral dose of 1.25 mg BAY 94-8862 in comparison to a single dose of 1.25 mg of BAY 94-8862 alone in healthy male subjects | https://s3.amazonaws.com/ctr-bsp-7261/14504/45f6e058-932a-49d5-8393-d300d7ed7134/78337ec3-8252-4b74-acea-2cdc25a7c8d6/14504_Study_Synopsis_CTP_2022-01-21-v3.pdf |
| 14505 | Randomized, non-blind, non-placebo-controlled, 2-fold cross-over study with additional 1st period with fixed treatment to investigate the pharmacokinetic interaction between finerenone (20 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-7261/14505/ba932fd2-8e8c-435c-b2d6-8529242e82df/faeedb63-e201-42f1-9e91-4857d0786d4a/14505_Study_Synopsis_CTP_2021-12-14-v4.pdf |
| 14506 | Interaction study to investigate the influence of a co-administration of a single dose of 10 mL Maalox® and a 4-day pre- and co-treatment with omeprazole 40 mg OD, respectively, on the pharmacokinetics of a single dose of 10 mg BAY 94-8862 IR-tablet in a threefold crossover, randomized, open-label design in healthy male subjects | https://s3.amazonaws.com/ctr-bsp-7261/14506/4479313a-bee3-49ab-9362-caa07518c786/8be90cac-aafd-4dd2-a674-28a1ff731bca/14506_Study_Synopsis_CTP_2022-01-21-v3.pdf |
| 14508 | Study to investigate the influence of age and gender on the pharmacokinetics of a single oral dose of a 10 mg BAY 94-8862 IR tablet in a randomized, single-blind, placebo-controlled, group-comparison design in healthy male and female subjects | https://s3.amazonaws.com/ctr-bsp-7261/14508/8f5cf1c1-54c3-460c-ab16-f15b9c108d74/bba69fcb-c3fd-41f6-8fe2-659e54f55ebe/14508_Study_Synopsis_CTP_2022-01-21-v3.pdf |
| 14509 | Investigation of pharmacokinetics, safety, and tolerability of BAY94-8862 in male and female subjects with renal impairment and in age and weight matched healthy subjects following a single oral dose of 10 mg BAY94-8862 IR tablet in a single center, non randomized, non controlled, non blinded, observational study with group stratification | https://s3.amazonaws.com/ctr-bsp-7261/14509/8e6a4f08-e659-4d59-aa62-0690a2a2d5fa/d0193ff0-ce42-4c68-b1ab-9f00b0a5ca90/14509_Study_Synopsis_CTP_2022-01-20-v5.pdf |

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| 14510 | Investigation of the pharmacokinetics, safety, and tolerability of finerenone (BAY94-8862) 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-7261/14510/4e25fbc2-4c3a-4681-8476-144c2a874c0a/d2e6b812-9512-49b2-aec2-8cbb7a92be67/14510_Study_Synopsis_CTP_2022-01-20-v7.pdf |
| 14563 | A randomized, double blind, multi center study to assess safety and tolerability of different oral doses of BAY 94-8862 in subjects with stable chronic heart failure with left ventricular systolic dysfunction and mild (Part A) or moderate (Part B) chronic kidney disease versus placebo (Part A) or versus placebo and spironolactone (Part B) | https://s3.amazonaws.com/ctr-bsp-7261/14563/ad98c3a1-072b-4184-a1a4-702e6b1e90e1/f90aab73-dbc4-4405-a867-1ba6e0162810/14563_Websynopsis_2021-12-24-v15.pdf |
| 14564 | A randomized, double-blind, double-dummy, multi-center study to assess safety and efficacy of BAY 94-8862 in subjects with emergency presentation at the hospital because of worsening chronic heart failure with left ventricular systolic dysfunction and either type 2 diabetes mellitus with or without chronic kidney disease or moderate chronic kidney disease alone versus eplerenone | https://s3.amazonaws.com/ctr-bsp-7261/14564/5437e479-8fd4-4642-8da1-670cb5238d84/07151039-832f-4468-96c0-2806c521521a/14564_Study_Synopsis_CTP_2021-12-24-v5.pdf |
| 15111 | Single-center, randomized, non-blinded, non-placebo-controlled, two-fold cross-over study to investigate the influence of multiple doses of 20 mg OD finerenone 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-7261/15111/1f4348ce-638d-453d-bb18-b06ebdc1cab9/03deae0f-0729-4432-8b38-f905407a3eeb/15111_Study_Synopsis_CTP_2021-12-15-v4.pdf |
| 15112 | Randomized, non-blinded, non-placebo-controlled, two-fold cross-over study to investigate the influence of multiple doses of 600 mg gemfibrozil twice-daily on the pharmacokinetics, safety and tolerability of a single oral dose of 10 mg finerenone in comparison to a single dose of 10 mg of finerenone alone in healthy male subjects | https://s3.amazonaws.com/ctr-bsp-7261/15112/a5ac0af8-34a9-4da8-a20f-31afe9be3c39/58e30228-3d8e-4490-9c2e-bb44a6203285/15112_Study_Synopsis_CTP_2021-12-15-v3.pdf |
| 15113 | A randomized, double-blinded, double-dummy, 4 way crossover, placebo- and active-controlled Phase I study to investigate the influence of single doses (20 mg and 80 mg) of finerenone on the QTc interval in healthy male and female subjects | https://s3.amazonaws.com/ctr-bsp-7261/15113/fd30d365-17cd-4b79-83b8-308045a9f3e9/87d94671-70a4-4085-b6dc-13a2bd8ed0d3/15113_Study_Synopsis_2021-12-15-v3.pdf |

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| 15171 | Single center, randomized, open-label, 5-fold crossover study in healthy male subjects to investigate the pharmacokinetic dose proportionality of BAY 94 8862 given as 5 different single oral IR tablet doses (1.25, 2.5, 5.0, 7.5 and 10 mg) | https://s3.amazonaws.com/ctr-bsp-7261/15171/6edd0c46-394f-4c06-9970-f1da8368f440/95c0d050-937f-4b32-a57e-523ecb98fe73/15171_Study_Synopsis_2021-12-15-v3.pdf |
| 15481 | Single center, randomized, open-label, 5-fold crossover study in healthy male subjects to investigate the pharmacokinetic dose proportionality of BAY 94 8862 given as 5 different single oral IR tablet doses (1.25, 2.5, 5.0, 7.5 and 10 mg) | https://s3.amazonaws.com/ctr-bsp-7261/15481/66ef4b22-8203-4591-8a7e-bc0182f162b0/a58107a4-1971-4114-a2e1-069819a03733/15481_Study_Synopsis_2021-12-24-v3.pdf |
| 15526 | Relative bioavailability study to investigate the pharmacokinetics, safety and tolerability of single oral doses of BAY 94-8862 given as 1.25 mg IR tablet in comparison to a 10 mg IR tablet and 4 x 1.25 mg IR tablet in healthy male subjects in a randomized, open-label, three-fold crossover design. | https://s3.amazonaws.com/ctr-bsp-7261/15526/2b1188bc-49cd-4d91-a7c8-8203da6f3aea/d9d5e6c7-b739-4dba-b243-7524a4e85067/15526_Study_Synopsis_CTP_2022-01-20-v3.pdf |
| 15528 | Single-center, randomized, double-blind, placebo-controlled, group-comparison, single dose escalation study to investigate safety, tolerability, and pharmacokinetics of BAY 94-8862 in Asian (Chinese) healthy adult male subjects | https://s3.amazonaws.com/ctr-bsp-7261/15528/d2718e80-0c0c-45ce-89b5-e6f1f9719285/67d99390-5bfb-47d3-a313-c8ea65194b51/15528_Study_Synopsis_CTP_2021-12-07-v3.pdf |
| 16243 | A randomized, double-blind, placebo-controlled, multi-center study to assess the safety and efficacy of different oral doses of BAY 94-8862 in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic nephropathy | https://s3.amazonaws.com/ctr-bsp-7261/16243/bb8a7451-768d-4678-a866-682a739335fb/9b1d3595-8113-4c4a-b83c-9194d8f921f6/16243_Study_Synopsis_2021-12-24-v5.pdf |
| 16244 | A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease | https://s3.amazonaws.com/ctr-bsp-7261/16244/c83a4088-cc0b-45d7-b26e-b809dbed3b0b/4b17e44c-09a3-4ed5-9f28-01bb4b7f8a17/16244_Study_Synopsis_CTP_2022-01-28-v4.pdf |

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| 16535 | Study in healthy male subjects to assess the safety, tolerability and pharmacokinetics of an intravenous solution of finerenone (dose escalation and group comparison, part 1) and to investigate the absolute bioavailability of an oral dose of 5 mg finerenone (BAY 94-8862) in comparison to an intravenous solution of finerenone (planned dose 1 mg) administered over 1 hour (randomized, non-blinded, non-placebo-controlled, 2-way crossover design, part 2) | https://s3.amazonaws.com/ctr-bsp-7261/16535/c8dbf14e-6864-437f-b492-9580c6feb0b4/4c3fc4ba-fe53-4957-b791-33e6a7da894f/16535_Study_Synopsis_CTP_2021-12-15-v3.pdf |
| 16536 | Relative bioavailability study to investigate the pharmacokinetic dose proportionality, safety and tolerability of single oral doses of finerenone 10 mg tablet in comparison to 20 mg tablet in the fasting condition and to investigate the effect of a high fat, high calorie meal on the 20 mg tablet in healthy male subjects in a randomized, open-label, three-fold crossover design | https://s3.amazonaws.com/ctr-bsp-7261/16536/cf2268d1-6bdc-40a5-a4d8-5ab19302e96e/a5589aad-d919-4546-89af-3d94ebb1975c/16536_Study_Synopsis_CTP_2021-12-15-v3.pdf |
| 16541 | Randomized, open-label, non-placebo-controlled, threefold cross over study to investigate the effect of a single dose of 20 mg finerenone given concomitantly or 3 hours before repaglinide on the pharmacokinetics, safety and tolerability of a single oral dose of 0.5 mg repaglinide in comparison to 0.5 mg repaglinide alone in healthy male subjects | https://s3.amazonaws.com/ctr-bsp-7261/16541/422d5fdd-4bdb-4d7f-b5bf-ff22b0b69353/b6ac0c0a-f5eb-4c80-9920-a78eaeda6e36/16541_Study_Synopsis_CTP_2021-12-16-v4.pdf |
| 16537 | A single-center, randomized, placebo-controlled, single-blind study to investigate the pharmacokinetics, safety and tolerability of single and multiple oral doses of finerenone in Chinese healthy adult male subjects | https://s3.amazonaws.com/ctr-bsp-7261/16537/608433a7-3b68-4880-b590-877fc96f17ef/3803ab41-d249-4e50-a7af-31333d9dcecc/16537_Study_Synopsis_CTP_2021-12-15-v3.pdf |
| 16538 | Relative bioavailability study to investigate the pharmacokinetics, safety and tolerability of a single oral dose of finerenone 20 mg as suspension (pediatric formulation), intact tablet and crushed tablet (adult formulation) in the fasting condition, and to investigate the effect of a high fat, high calorie meal on the suspension in healthy male subjects in a randomized, open-label, four-fold crossover design | https://s3.amazonaws.com/ctr-bsp-7261/16538/14ed4d5a-fb86-4c7e-992a-c018bc87a8d1/adee7efd-1532-4a2d-96d1-78166fcba1c6/16538_Study_Synopsis_2021-12-27-v3.pdf |
| 16910 | Non-blind, non-placebo-controlled study with 2 treatments in fixed sequence to investigate the effect of verapamil (240 mg controlled-release tablet) on the pharmacokinetics of a single dose of | https://s3.amazonaws.com/ctr-bsp-7261/16910/85d4e535-d37b-4a33-b15b-f2704724eec9/110ed7a0-6bb9- |

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| | finerenone (5 mg) and to investigate the safety and tolerability of the combined administration in healthy male subjects | 4c4b-b525-4ae959fe92e0/16910_Study_Synopsis_CTP_2021-12-15-v3.pdf |
| 16815 | A randomized, double-blind, double-dummy, multi-center study to assess safety and efficacy of BAY 94-8862 in Japanese subjects with emergency presentation at the hospital because of worsening chronic heart failure with left ventricular systolic dysfunction and either type 2 diabetes mellitus with or without chronic kidney disease or moderate chronic kidney disease alone versus eplerenone | https://s3.amazonaws.com/ctr-bsp-7261/16815/86dc60f8-f6b6-46ee-8179-bc9d45f3b4c3/fd140b78-0322-4231-b338-c6b55461ec74/16815_Study_Synopsis_CTP_2021-12-28-v5.pdf |
| 16816 | A randomized, double-blind, placebo-controlled, multi-center study to assess the safety and efficacy of different oral doses of BAY94-8862 in Japanese subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic nephropathy | https://s3.amazonaws.com/ctr-bsp-7261/16816/da00b7b8-52db-4f7a-85e2-b901f5dba6f4/80f2bd62-622b-4db8-b248-95613cb64e65/16816_Study_Synopsis_CTP_2021-12-29-v4.pdf |
| 19092 | Single dose, open-label, randomized, two-fold crossover study in healthy male subjects to investigate the bioavailability of 20 mg finerenone immediate-release tablets manufactured in a continuous process (ConsiGma) in comparison to tablets manufactured in a batch process (current Phase 3 formulation) | https://s3.amazonaws.com/ctr-bsp-7261/19092/060960c0-d85a-4d27-a2a1-e2aece49c995/825ceb7b-3911-449d-9192-2aa935ff82e9/19092_Study_Synopsis_CTP_2021-12-15-v3.pdf |
| 17530 | A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease in addition to standard of care | https://s3.amazonaws.com/ctr-bsp-7261/17530/9f2f9b73-65f0-47a6-80cf-ccc077b43e18/fc49baec-fc75-4628-b655-54fa1e84cb36/17530_Study_Synopsis_CTP_2022-01-28-v4.pdf |
| 18290 | Relative bioavailability study to investigate the pharmacokinetics, safety and tolerability of single oral doses of finerenone 1.25 mg and 5 x 0.25 mg oro-dispersible tablet (pediatric formulation) in comparison to 10 mg tablet (adult formulation) in the fasting condition and to investigate the effect of a high fat, high calorie meal on 1.25 mg oro-dispersible tablet in healthy male subjects in a randomized, open-label, four-fold crossover design | https://s3.amazonaws.com/ctr-bsp-7261/18290/9dc2513a-8ae2-434d-81d7-28bb5af334ee/2a55f8dd-5269-4945-b343-80c1441adc6a/18290_Study_Synopsis_2021-12-27-v3.pdf |