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1) **Study to Evaluate the Safety & Tolerability of MRT5005 Administered by Nebulization in Adults With Cystic Fibrosis (RESTORE-CF)**
ClinicalTrials.gov Identifier: NCT03375047 – in Vorbereitung

2) **A Multicentre, Randomised, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy and Safety of Dirocaftor/Posenacaftor/ Nesolicaftor in Subjects with Cystic Fibrosis Aged 18 Years or Older (CHOICES)**
EudraCT number: 2020-000584-24 – in Vorbereitung

3) **SMR 3372: A randomised, double-blind, dose finding study of inhaled alginate oligosaccharide (OligoG) vs placebo in patients with Cystic Fibrosis (CF)**
EudraCT number: 2018-000378-30 – in Vorbereitung

4) **VX20-445-119: A Phase 3b Open-label Study Evaluating the Long-term Safety and Efficacy of Elexacaftor/Tezacaftor/Ivacaftor Combination Therapy in Cystic Fibrosis Subjects Ages 6 Years and Older Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)**
EudraCT Number: 2020-001404-42 – März 2021 bis aktuell

5) **VX19-445-116: A Phase 3b, Randomized, Placebo-controlled Study Evaluating the Efficacy and Safety of Elexacaftor/Tezacaftor/Ivacaftor in Cystic Fibrosis Subjects 6 Through 11 Years of Age Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)**
EudraCT Number: 2019-003554-86 – September 2020 bis aktuell

6) **VX17-661-116 b: A Phase 3, Open-label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With Tezacaftor in Combination With Ivacaftor in Subjects With Cystic Fibrosis Aged 6 Years and Older, Homozygous or Heterozygous for the F508del-CFTR Mutation**
EudraCT Number: 2017-002968-40 – September 2020 bis aktuell

7) **VX19-445-115: A Phase 3b, Open-label Study Evaluating the Safety of Elexacaftor/Tezacaftor/Ivacaftor Combination Therapy in Cystic Fibrosis Subjects**
EudraCT Number: 2019-003455-11 – April 2020 bis aktuell

8) **VX18-445-113: A Phase 3, Open-label Study Evaluating the long-term Safety of VX-445 Combination Therapy in Subjects with Cystic Fibrosis**
EudraCT Number: 2018-004652-38 – Januar 2020 bis aktuell

9) **VX18-445-109: A Phase 3b, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-445/Tezacaftor/Ivacaftor in Cystic Fibrosis Subjects, Homozygous for F508del**
EudraCT Number: 2019-001735-31 – Oktober 2019 bis Oktober 2020

10) **VX17-659-105: A Phase 3, Open-label-Study Evaluating the Long-term Safety and Efficacy of VX-659 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)**
EudraCT Number: 2017-004134-29 – Oktober 2018 bis März 2021

11) **VX17-661-116: A Phase 3, Open-label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With Tezacaftor in Combination With Ivacaftor in Subjects With Cystic Fibrosis Aged 6 Years and Older, Homozygous or Heterozygous for the F508del-CFTR Mutation**
EudraCT Number: 2017-002968-40 – November 2018 bis aktuell

12) **PTI-808-01: A Phase 1 Study of Evaluate the Safety, Tolerability, and Pharmacokinetics of PTI-808 in Healthy Subjects and in Adults with Cystic Fibrosis**
EudraCT Number: 2017-003319-21 – Oktober 2018 bis Dezember 2020

13) **VX17-659-102: A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-659 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)**
EudraCT Number: 2017-004132-11 – Mai 2018 bis März 2019

14) **VX16-661-115: A Phase 3, Double-blind, Parallel-group Study to Evaluate the Efficacy and Safety of Tezacaftor in Combination with Ivacaftor in Subjects Aged 6 Through 11 Years with Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation**
EudraCT number 2016-004479-35 – September 2018 bis März 2019

15) **GLPG2737-CL-202: A Phase IIa, randomized, double-blind, placebo-controlled study to evaluate GLPG2737 in Orkambi-treated subjects with cystic fibrosis homozygous for the F508del mutation.**
EudraCT: 2017-002181-42 – Dezember 2017 bis Juni 2018

16) **QBW276X2201: A Randomized, double blind, placebo-controlled study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses of inhaled QBW276 in patients with Cystic Fibrosis**
EudraCT number 2014-004915-35 – September 2017 bis Januar 2019

17) **VX15-440-101: A Phase 2, Randomized, Double-blind, Controlled Study to Evaluate the Safety and Efficacy of VX-440 Combination Therapy in Subjects Aged 12 Years and Older With Cystic Fibrosis**
EudraCT number 2016-000454-36 – Januar 2017 bis November 2017

18) **V15-809-110: A Phase 3, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With Lumacaftor in Combination With Ivacaftor in Subjects Aged 6 Years and Older With Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation**
EudraCT number 2015-001644-11 – September 2016 bis November 2018

19) **GLPG1837: A phase IIa, open-label study of multiple doses of GLPG1837 in subjects with cystic fibrosis and the G551D mutation.**
EudraCT number 2015-003291-77 – April 2016 bis Dezember 2016

20) **VX14-661-107: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508del-CFTR Mutation and With a Second CFTR Mutation That Is Not Likely to Respond to VX-661 and/or Ivacaftor Therapy (F508del/NR)**
EudraCT number 2014-004787-37 – Januar 2016 bis November 2016

21) **VX14-809-109: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Lumacaftor in Combination With Ivacaftor in Subjects aged 6 Years Through 11 Years with Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation**
EudraCT number 2014-004787-37 – Januar 2016 bis November 2016

22) **PTC 124-GD-021e-CF A Phase 3 Extension Study of Ataluren (PTC124) in Patients with Nonsense Mutation Cystic Fibrosis**
EudraCT number 2014-005355-83 – Juli 2016 bis August 2017

23) **PTC124-GD-021-CF A Phase 3 Efficacy and safety Study of Ataluren (PTC124) in Patients with nonsense Mutation Cystic Fibrosis (phase III study)**
ClinicalTrials.gov Identifier: NCT02139306 – April 2015 bis Juli 2016

24) **SMR-2984 A double-blind, randomised, placebo-controlled cross over study of inhaled alginate oligosaccharide (OligoG) administered for 28 days in subjects with Cystic Fibriosis (phase II study)**
EudraCT number 2014-000844-13 – Februar 2015 bis März 2017

25) **CQBW251X2101 A randomized, double blind placebo-controlled study to assess the safety, tolerability, pharmacokinetics, and preliminary pharmacodynamics of single and multiple ascending doses of QBW251 in healthy subjects and multiple doses in cystic fibrosis patients (phase I/IIa study)**
EudraCT number 2011-005085-37 – August 2014 bis März 2015

26) **VX12-809-105: A Phase 3, Rollover Study to Evaluate the Safety and Efficacy of Longterm Treatment With Lumacaftor in Combination With Ivacaftor in Subjects aged 12 Years and Older with Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation**
ClinicalTrials.gov Identifier: NCT01931839 – Februar 2014 bis Februar 2016

27) **VX12-809-103: A phase 3, Randomized, Double-Blind Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Lumacaftor in Combination with Ivacaftor in Subjects aged 12 years and older with Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation**
ClinicalTrials.gov Identifier: NCT01807923 – Juli 2013 bis August 2014

28) **VX11-661-101: Study of VX-661 Alone and in Combination With VX-770 in Subjects Homozygous to the F508del-CFTR Mutation (phase II study)**

ClinicalTrials.gov Identifier: NCT01531673 – Februar 2012 bis Mai 2014

29) **PsAer-IgY-Study: Prospective randomized, placebo-controlled, double blind, multicenter study (phase III) to evaluate clinical efficacy and safety of avian polyclonal anti-Pseudomonas antibodies (IgY) in prevention of recurrence of Pseudomonas aeruginosa infection in cystic fibrosis patients (phase III study)**
ClinicalTrials.gov Identifier: NCT01455675 – November 2011 bis Januar 2018

30) **VX09-809-102: A Phase 2, Multicenter, Randomized, Double-Blinded, Placebo-Controlled, Multiple-Dose Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of VX-809 Alone and in Combination with VX-770 in Subjects with Cystic Fibrosis Homozygous for the F508del-CFTR Mutation**
ClinicalTrials.gov Identifier: NCT01225211 – Mai 2010 bis August 2014

31) **PTC124-GD-009e-CF: Extension Study of Ataluren (PTC124) in Cystic Fibrosis**
A Phase 3 Extension Study of Ataluren (PTC124) in Subjects with Nonsense-Mutation – mediated Cystic Fibrosis (phase III study)
ClinicalTrials.gov Identifier: NCT01140451 – Juli 2010 bis Oktober 2013

32) **PTC124-GD-009-CF: Study of Ataluren (PTC124™) in Cystic Fibrosis (phase III study)**
ClinicalTrials.gov Identifier: NCT00803205 – Juli 2009 bis Oktober 2010

33) **VX08-809-101: A randomized, Double-Blind, Placebo-Controlled, Multiple Dose Study of VX809 to evaluate Safety, Pharmacokinetics and Pharmacodynamics of VX 809 in Cystic Fibrosis Subjects Homozygous for the DelF508-CFTR-Gene Mutation (phase II study)**
ClinicalTrials.gov Identifier: NCT00865904 – März 2009 bis Dezember 2009

34) **VX07-809-002: A Phase 1, Open-label, Randomized, Single Dose Pharmacokinetic Study of VX-809 in Pancreatic-Insufficient Subjects with Cystic Fibrosis**
Eudra CT Number 2008-002229-35 – Oktober 2008 bis Januar 2009

35) **Pharmacokinetic Evaluation of an 8-Week Treatment With Inhaled Tobramycin (phase II study)**
ClinicalTrials.gov Identifier: NCT00634192 – Februar 2008 bis Juli 2009

36) **IGOR-Study: Randomized, Placebo-Controlled, Double-Blind Study to Investigate the Efficacy and Safety of a 24-week Inhalation Treatment with Glutathione in Cystic Fibrosis Patients (phase II study)**
ClinicalTrials.gov Identifier: NCT00506688 – Mai 2007 bis Mai 2010

37) **Safety of Tobramycin Inhalation Powder (TIP) versus Tobramycin Solution for Inhalation in Patients With Cystic Fibrosis (EAGER) (phase III study)**
ClinicalTrials.gov Identifier: NCT00388505 – Oktober 2006 bis Juni 2009

38) **DEB-EPI-206 Multicenter, 8-week, Randomised, Double-Blind, Placebo Controlled Study of Two Doses of Depelestat in Cystic Fibrosis Patients (phase IIb study)**
Januar 2005 bis Januar 2006

39) **Multicenter, randomized, parallel group study to investigate the optimal deposition site for inhaled Prolastin® in patients with Cystic Fibrosis (CF) (phase II study)**
ClinicalTrials.gov Identifier: NCT00486837 – Dezember 2003 bis Juni 2004

40) **Microbiological Efficacy and safety of two treatment regimens of Inhaled Tobramycin nebuliser Solution (TNS) for the treatment of early onset Pseudomonas aeruginosa lower respiratory tract infection in subjects with Cystic Fibrosis (phase III study)**
EU-C-Tob-03-001 – September 2003 bis September 2007

41) **Early Diagnosis of Diabetes Mellitus in Patients With Cystic Fibrosis (phase III study).**
ClinicalTrials.gov Identifier: NCT00662714 – September 2001 bis Dezember 2011

Studien vor 2005:

42) **Bronchoalveolar Lavage for the Evaluation of Anti-Inflammatory Treatment (BEAT) in Cystic Fibrosis**

43) **A Multicenter, Randomised, Double-Blind, Placebo Controlled Trial Evaluating the Metabolic and Respiratory Effects of Genotropin® in Children with Cystic Fibrosis**

44) **A Randomized, Double-Blind, Placebo Controlled Study to Investigate the Efficacy and Safety of 24 Weeks of Oral Treatment with BIIL 284BS in Adult (75 mg, 150 mg) + Pediatric 75 mg Cystic Fibrosis Patients (LTBIV)-Study (phase II study)**

45) **Pharmacokinetics of Inhaled Colistin in Patients with Cystic Fibrosis**

46) **A Randomized, Open Label Study to Compare the Efficacy and Safety of a Dry Powder Formulation of Inhaled Colistinmethate Sodium and Nebulised TNSFI (Tobramycin Nebuliser Solution for Inhalation, TOBI®) in Cystic Fibrosis Patients with Pseudomonas Aeruginosa Lung Infection.**

Investigator Initiated Trials / Investigator Initiated Projects
Studien- bzw. Projektleitung: PD Dr. Silke van Koningsbruggen-Rietschel

1) **CAR-CF: Corona-Virus Disease-19 (COVID-19) Antibody Responses in Cystic Fibrosis - global study**
ClinicalTrials.gov Identifier: NCT04863573 - Mai 2021 bis aktuell
Studienleitung Europa: PD Dr. Silke van Koningsbruggen-Rietschel und
Dr. Damian Downey, Universität Belfast, Nordirland

2) **ICAM (Identification and characterisation of antibacterial antibodies in the serum of patients with cystic fibrosis) in collaboration with PD Dr. Dr. Jan Rybniker (Internal Medicine I/Translational Research Unit – Infectious Diseases Center for Molecular Medicine Cologne (CMMC))**

ClinicalTrials.gov Identifier: NCT04700358 - November 2020 – aktuell

3) **Investigation of the mechanistic role of TGFβ1 on CFTR expression and CFTR-function for a new potential therapeutic approach in CF**
Seit 2019

4) **Establishment of the "organoid system" for evaluating new CFTR-modulating therapies**
Seit 2020

5) **DZL_DA_AA-1: The All-Age Asthma Cohort (ALLIANCE) of the German Center for Lung Research (DZL), Pediatric Arm**
ClinicalTrials.gov Identifier: NCT02496468 – Januar 2013 - aktuell

6) **The role of the Tgf-beta System on the Clinical Course of Cystic Fibrosis**
2012 -2019

7) **Whole Body Vibration - A New Therapeutic Approach to Improve Muscle Function in Cystic Fibrosis (phase II study)**
ClinicalTrials.gov Identifier: NCT0038846 – Juni 2005 bis August 2006