

Dr Tiziana Bachetti

Curriculum Vitæ

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Summary

Senior Scientist with extensive biomedical research experience. My education includes a M.Sc. in Pharmacy and post-graduate training in Pharmacology from University of Bologna, Italy. Since inception, I have been involved in various research projects first at basic and then at clinical level. My role in such projects varied from Junior to Senior Researcher, Project Coordinator, and Clinical Research Coordinator for Phase II to IV clinical trials. I have acquired international experience thanks to collaborations with overseas academies (I was a post-doc in Clinical Pharmacology at University College London, UK) and with pharmaceutical companies for contract research projects. Currently, I work as Senior Specialist Clinical Research in the Scientific Direction of the 'Istituti Clinici Scientifici Maugeri'. I have presented the results of my research studies at international biomedical conferences and I have published research articles in peer-reviewed journals (Scopus Author ID: 7004334375; Scopus Author H index: 28).

Education and training

- Post-doctoral training in Clinical Pharmacology, University College London, United Kingdom (2007-2008)
- PhD-equivalent education in Pharmacology, University of Bologna, Italy (1987-1991)
- M.Sc. in Pharmacy, University of Bologna, Italy (1987)

Professional Career

Feb 2019 – present

Istituti Clinici Scientifici Maugeri, Scientific Direction – Pavia (I)

Senior Scientist, Clinical Research

Core collaborator, responding to the Chief Scientific Officer and the Management Coordinators, with the mission to facilitate the achievement of major corporate research objectives. Facilitator of the ICS Maugeri clinical research activities and supporter of the institutional Clinical Research Centre for the organization and execution of spontaneous and sponsored phase II-III-IV clinical studies. She ensures the smooth running of clinical trials in ICS Maugeri institutes in accordance with Good Clinical Practices by detecting and solving potential critical issues; she also oversees the progress of clinical trials for the Central Scientific Directorate by maintaining relationships with the Scientific Directors of the subsidiary institutes. She also contributes to management aspects of clinical trials by performing periodic monitoring of active studies. She supports the preparation of relevant materials for research projects funded by the Italian Ministry of Health (Current Research and Finalized Research schemes) and monitors their scientific reporting. Moreover, she actively participates in the preparation of scientific reports to maintain the recognition of the scientific nature of the institutes (aka IRCCS) and supports the collection of relevant documents on behalf of the Ministerial Thematic Networks. She is also involved in the internal review of manuscripts before submission for publication to ensure that they are in keeping with the parameters required for ministerial accreditation and to the overall general and accounting activities of the Secretariat of the Central Scientific Directorate. She is personally involved in selected research activities related to her scientific background (i.e. cardiovascular science) including the dissemination of their results.

Jul 2011 – Jan 2019

Istituti Clinici Scientifici Maugeri, Clinical Trials Centre – Pavia (I)

Clinical Research Coordinator / Investigator – Study coordinator of sponsored clinical trials (Phase 2,3, and 4) in Cardiology, Nephrology, and Respiratory Sciences in accordance to GCP principles. Responsible for day-to-day activities related to clinical studies, relations with IRB/EC, data quality and data management, queries resolution, communication of serious adverse events/endpoints, relations with clinical monitors and auditors.

Jul 2008 – Jun 2011

Foundation Salvatore Maugeri, Molecular Cardiology Labs – Pavia (I)

Senior Research Scientist – Research Participant for international projects on genetically inherited cardiac arrhythmias. Principle Pharmacologist responsible to test new molecules to treat genetic cardiac arrhythmias.

Jun 2007 – Jun 2008

University College London, Centre for Clinical Pharmacology and Therapeutics – London (UK)

Postdoctoral Research Fellow – Principle Researcher responsible to accomplish the British Heart Foundation project entitled 'ADMA/DDAH pathway as a critical regulator of endothelial motility and blood vessels growth'.

Nov 1994 – May 2007

Foundation Salvatore Maugeri, Cardiovascular Pathophysiology Research Centre – Gussago (I)

Research Scientist –Project Coordinator for a range of peer-reviewed international projects on myocardial ischemia, heart failure, vascular dysfunction, and immune activation in cardiovascular diseases. Team Leader for research contracts (AstraZeneca, Pfizer, Serono International, IRIS Servier, Recordati, Sigma Tau, Valeas).

Mar 1993 – Aug 1994

Foundation Salvatore Maugeri, Cardiovascular Pathophysiology Research Centre – Gussago (I)

Research Fellow – Junior Researcher for the projects: 'Haemodynamic properties of REC 15/2375 on isolated and perfused rabbit heart' and 'The endothelial function: an in vitro study in human endothelial cells'.

May 1991 – Apr 1992

Glaxo Pharma – Verona (I)

Research Fellow – Junior Researcher for the project entitled 'Evaluation of the effects of a new calcium antagonist in vascular smooth muscle cells'.

Additional Information

Awards and Teaching

- Award winner 'Best short presentation', 10th Symposium on Vascular Endothelium, Imperial College London, London, UK (2007).
- Special award, 7th Meeting of the Italian Society of Cardiovascular Research, Bologna, Italy (2000).
- Research Award in Cardiology, Italian Society of Cardiology, Rome, Italy (1995).
- Teacher of Biochemistry and Cardiac Metabolism, University of Brescia, School of Medicine, Specialty of Cardiology (2001–2008).

Courses

- E-learning course: 'ICH Good Clinical Practice E6 (R2)', The Global Health Network (issued on 25/05/2022)
- MOOC: 'Fundamentals of Clinical Trials', Instructors: Professors James Ware, Elliott Antman, Julie Buring, Graham McMahon, and Robert Truog, Harvard University, USA (2013-2014)
- MOOC: 'A crash course on creativity', Instructor: Professor Tina Seeling, Stanford University, USA (2012)
- Seminar in 'Medical Writing', University of Edinburgh, Institute for Applied Language Studies, Edinburgh, UK (2000)

Skills

- Excellent project management skills: ability to design, set up, and manage research projects from study protocol to publication
- Thorough knowledge of Pharmacology and Pathophysiology, with special reference to Cardiovascular Science
- Excellent hands-on knowledge of the overall research and drug development process
- Excellent knowledge of 'Good Clinical Practice' principles
- Demonstrated team leading ability, i.e. coordination of lab research technicians, research students, and health professionals
- Ability to write and publish peer-reviewed scientific articles (80+ published articles)
- Ability to communicate science at various levels (group meetings, conferences, academia)
- Troubleshooting attitude, excellent organization, ability to prioritise work flow
- Data analysis, literature mining, and graphical skills, IT proficiency
- Responsibility, commitment to anti-discriminatory practices
- Languages: English (fluent), French (fair), Italian (mother tongue).

Publications

1. Palmira Bernocchi , Giacomo Crotti , Elvira Beato , Francesco Bonometti , Vittorio Giudici , Patrizia Bertolaia, Elisa Perger , Andrea Remuzzi , **Tiziana Bachetti** , Maria Teresa La Rovere , Laura Adelaide Dalla Vecchia, Fabio Angeli, Gianfranco Parati, Gabriella Borghi, Michele Vitacca and Simonetta Scalvini on behalf of the MIRATO study group. COVID-19 teleassistance and teleconsultation: a matched case-control study (MIRATO project, Lombardy, Italy). *Front. Cardiovasc. Med.*, 14 August 2023, Sec. Cardiovascular Imaging, Volume 10 - 2023 | <https://doi.org/10.3389/fcvm.2023.1062232>.
2. Baldassarre D, Iacoviello L, Baetta R, Roncaglioni MC, Condorelli G, Remuzzi G, Gensini G, Frati L, Ricciardi W, Conaldi PG, Uccelli A, Blandini F, Bosari S, Scambia G, Fini M, Di Malta A, Amato M, Veglia F, Bonomi A, Klersy C, Colazzo F, Pengo M, Gorini F, Auteri L, Ferrante G, Baviera M, Ambrosio G, Catapano A, Gialluisi A, Malavazos AE, Castelvechio S, Corsi-Romanelli MM, Cardani R, Rovere MT, Agnese V, Pane B, Prati D, Spinardi L, Liuzzo G, Arbustini E, Volterrani M, Visconti M, Werba JP, Genovese S, Bilo G, Invitti C, Di Blasio A, Lombardi C, Faini A, Rosa D, Ojeda-Fernández L, Foresta A, De Curtis A, Di Castelnuovo A, Scalvini S, Pierobon A, Gorini A, Valenti L, Luzi L, Racca A, Bandi M, Tremoli E, Menicanti L, Parati G, Pompilio G; **CV-PREVITAL Study Group**. Rationale and design of the CV-PREVITAL study: an Italian multiple cohort randomised controlled trial investigating innovative digital strategies in primary cardiovascular prevention. *BMJ Open*. 2023 Jul 14;13(7):e072040. doi: 10.1136/bmjopen-2023-072040. PMID: 37451717.
3. Bergantini L, Baldassarri M, d'Alessandro M, Brunelli G, Fabbri G, Zguro K, Degl'Innocenti A; **GEN-COVID Multicenter study**; Fallerini C, Bargagli E, Renieri A. Ultra-rare RTEL1 gene variants associate with acute severity of COVID-19 and evolution to pulmonary fibrosis as a specific long COVID disorder. *Respir Res*. 2023 Jun 16;24(1):158. doi: 10.1186/s12931-023-02458-7. PMID: 37328761; PMCID: PMC10276396.
4. Mongelli, A., Panunzi, S., Nesta, M. et al. Distinguishable DNA methylation defines a cardiac-specific epigenetic clock. *Clin Epigenet* 15, 53 (2023). <https://doi.org/10.1186/s13148-023-01467-z>
5. Baldassarri M, Zguro K, Tomati V, Pastorino C, Fava F, Croci S, Bruttini M, Picchiotti N, Furini S, **GEN-COVID Multicenter Study**, Pedemonte N, Gabbi C, Renieri A, Fallerini C. Gain- and Loss-of-Function *CFTR* Alleles Are Associated with COVID-19 Clinical Outcomes. *Cells*. 2022; 11(24):4096.
6. Onoja A, Picchiotti N, Fallerini C, Baldassarri M, Fava F; **GEN-COVID Multicenter Study**, Colombo F, Chiaromonte F, Renieri A, Furini S, Raimondi F. An explainable model of host genetic interactions linked to COVID-19 severity. *Commun Biol*. 2022 Oct 26;5(1):1133.

7. **COVID-19 Host Genetics Initiative.** A first update on mapping the human genetic architecture of COVID-19. *Nature*. 2022 Aug;608(7921):E1-E10.
8. Kousathanas A, Pairo-Castineira E, Rawlik K, Stuckey A, Odhams CA, Walker S, Russell CD, Malinauskas T, Wu Y, Millar J, Shen X, Elliott KS, Griffiths F, Oosthuyzen W, Morrice K, Keating S, Wang B, Rhodes D, Klaric L, Zechner M, Parkinson N, Siddiq A, Goddard P, Donovan S, Maslove D, Nichol A, Semple MG, Zainy T, Maleady-Crowe F, Todd L, Salehi S, Knight J, Elgar G, Chan G, Arumugam P, Patch C, Rendon A, Bentley D, Kingsley C, Kosmicki JA, Horowitz JE, Baras A, Abecasis GR, Ferreira MAR, Justice A, Mirshahi T, Oetjens M, Rader DJ, Ritchie MD, Verma A, Fowler TA, Shankar-Hari M, Summers C, Hinds C, Horby P, Ling L, McAuley D, Montgomery H, Openshaw PJM, Elliott P, Walsh T, Tenesa A; GenOMICC investigators; 23andMe investigators; COVID-19 Human Genetics Initiative, Fawkes A, Murphy L, Rowan K, Ponting CP, Vitart V, Wilson JF, Yang J, Bretherick AD, Scott RH, Hendry SC, Moutsianas L, Law A, Caulfield MJ, Baillie JK, **Collaborators**. Whole-genome sequencing reveals host factors underlying critical COVID-19. *Nature*. 2022 Mar 7.
9. Zguro, K.; Baldassarri, M.; Fava, F.; Beligni, G.; Daga, S.; Leoncini, R.; Galasso, L.; Cirianni, M.; Rusconi, S.; Siano, M.; Francisci, D.; Schiaroli, E.; Luchi, S.; Morelli, G.; Martinelli, E.; Girardis, M.; Busani, S.; Parisi, S.G.; Panese, S.; Piscopo, C.; Capasso, M.; Tacconi, D.; Spertilli Raffaelli, C.; Giliberti, A.; Gori, G.; Katsikis, P.D.; Lorubbio, M.; Calzoni, P.; Ognibene, A.; Bocchia, M.; Tozzi, M.; Bucalossi, A.; Marotta, G.; Furini, S.; **GEN-COVID Multicenter Study**; Renieri, A.; Fallerini, C. Carriers of *ADAMTS13* Rare Variants Are at High Risk of Life-Threatening COVID-19. *Viruses* 2022, 14, 1185.
10. Ambrosino, P*; **Bachetti, T.***; D'Anna, S.E.; Galloway, B.; Bianco, A.; D'Agnano, V.; Papa, A.; Motta, A.; Perrotta, F.; Maniscalco, M. Mechanisms and Clinical Implications of Endothelial Dysfunction in Arterial Hypertension. *J. Cardiovasc. Dev. Dis.* 2022, 9, 136. (*joint first authorship)
11. Ambrosino, P.; Calcaterra, I.L.; Mosella, M.; Formisano, R.; D'Anna, S.E.; **Bachetti, T.**; Marcuccio, G.; Galloway, B.; Mancini, F.P.; Papa, A.; Motta, A.; Minno, M.N.D.D.; Maniscalco, M. Endothelial Dysfunction in COVID-19: A Unifying Mechanism and a Potential Therapeutic Target. *Biomedicines* 2022, 10, 812.
12. Angeli F, Verdecchia P, Balestrino A, Bruschi C, Ceriana P, Chiovato L, Dalla Vecchia LA, Fanfulla F, La Rovere MT, Perego F, Scalvini S, Spanevello A, Traversi E, Visca D, Vitacca M, **Bachetti T.** Renin Angiotensin System Blockers and Risk of Mortality in Hypertensive Patients Hospitalized for COVID-19: An Italian Registry. *J Cardiovasc Dev Dis.* 2022 Jan 6;9(1):15.
13. Fallerini C, Picchiotti N, Baldassarri M, Zguro K, Daga S, Fava F, Benetti E, Amitrano S, Bruttini M, Palmieri M, Croci S, Lista M, Beligni G, Valentino F, Meloni I, Tanfoni M, Minnai F, Colombo F, Cabri E, Fratelli M, Gabbi C, Mantovani S, Frullanti E, Gori M, Crawley FP, Butler-Laporte G, Richards B, Zeberg H, Lipcsey M, Hultström M, Ludwig KU, Schulte EC, Pairo-Castineira E, Baillie JK, Schmidt A, Frithiof R; WES/WGS Working Group Within the HGI; GenOMICC Consortium; **GEN-COVID Multicenter Study**, Mari F, Renieri A, Furini S. Common, low-frequency, rare, and ultra-rare coding variants contribute to COVID-19 severity. *Hum Genet.* 2022 Jan;141(1):147-173.
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19. **COVID-19 Host Genetics Initiative**. Mapping the human genetic architecture of COVID-19. *Nature*, 2021 Dec;600(7889):472-477.
20. Baldassarri M, Fava F, Fallerini C, Daga S, Benetti E, Zguro K, Amitrano S, Valentino F, Doddato G, Giliberti A, Di Sarno L, Palmieri M, Carriero ML, Alaverdian D, Beligni G, Iuso N, Castelli F, Quiros-Roldan E, Mondelli MU, Miceli R, Frullanti E, Furini S, Mari F, Renieri A, Gabbi C, On Behalf Of The **Gen-Covid Multicenter Study**. Severe COVID-19 in Hospitalized Carriers of Single CFTR Pathogenic Variants. *J Pers Med.* 2021 Jun 15;11(6):558.
21. Zanella I, Zacchi E, Piva S, Filosto M, Beligni G, Alaverdian D, Amitrano S, Fava F, Baldassarri M, Frullanti E, Meloni I, Renieri A; **GEN-COVID Multicenter Study**; GEVACOBA Study Group, Castelli F, Quiros-Roldan E. C9orf72 Intermediate Repeats Confer Genetic Risk for Severe COVID-19 Pneumonia Independently of Age. *International Journal of Molecular Sciences* 2021 Jun 29;22(13):6991.
22. Monticelli M, Hay Mele B, Benetti E, Fallerini C, Baldassarri M, Furini S, Frullanti E, Mari F, Andreotti G, Cubellis MV, Renieri A; **Gen-Covid Multicenter Study**. Protective Role of a TMPRSS2 Variant on Severe COVID-19 Outcome in Young Males and Elderly Women. *Genes (Basel).* 2021 Apr 19;12(4):596
23. Fallerini C, Daga S, Mantovani S, Benetti E, Picchiotti N, Francisci D, Paciosi F, Schiaroli E, Baldassarri M, Fava F, Palmieri M, Ludovisi S, Castelli F, Quiros-Roldan E, Vaghi M, Rusconi S, Siano M, Bandini M, Spiga O, Capitani K, Furini S, Mari F; **GEN-COVID Multicenter Study**, Renieri A, Mondelli MU, Frullanti E. Association of Toll-like receptor 7 variants with life-threatening COVID-19 disease in males: findings from a nested case-control study. *Elife.* 2021 Mar 2;10:e67569.
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26. A. Mongelli, S. Atlante, **T. Bachetti**, F. Martelli, A. Farsetti and C. Gaetano. Epigenetic Signalling and RNA Regulation in Cardiovascular Diseases. *International Journal of Molecular Sciences*, 2020, Jan 13;21(2):509.
27. A. Corti, F. Marcucci, **T. Bachetti**. Circulating chromogranin A and its fragments as diagnostic and prognostic disease markers. *Pflügers Archiv - European Journal of Physiology*, 2018; 470(1): 199-210.
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29. Ambrosetti M, Temporelli PL, Faggiano P, Febo O, Diaco T, Favretto G, Calisi P, Gabriele M, Greco C, Tavazzi L; THINKPAD investigators. Collaborators: Diaco T, Rotiroli G, Zaniboni D, Febo O, La Rovere MT, Bardile AF, Aloï T, Priori S, Zambelli M, **Bachetti T**, et al. Lower extremities peripheral arterial disease among patients admitted to cardiac rehabilitation: the THINKPAD registry. *International Journal of Cardiology*, 2014; 171(2):192-8.
30. **T. Bachetti**. Adherence junction proteins in angiogenesis: modulation by aspirin and salicylic acid. *Journal of Cardiovascular Medicine*, 2013, 14:395-396 (Letter to the Editor).
31. N. Liu, Y. Ruan, M. Denegri, **T. Bachetti**, Y. Li, B. Colombi, C. Napolitano, W.A. Coetzee, S.G. Priori. Calmodulin kinase II inhibition prevents arrhythmias in Ryr2R4496C+/- mice with catecholaminergic polymorphic ventricular tachycardia. *Journal of Molecular and Cellular Cardiology*, 2011; 50(1):214-22.
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Research Coordinator for the following Clinical Trials

- a. 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, Merck) [Phase-3]
- b. 'A phase-3 single-blind study to evaluate the effect of GS-6615 on shortening of the QT interval, safety, and tolerability in subjects with long QT-3 syndrome' (Gilead) [Phase-3]
- c. A randomized, parallel-group, placebo-controlled, double-blind, multi-center dose finding phase II trial exploring the pharmacodynamics 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 reduced ejection fraction (HFrEF) – SOLuble guanylate Cyclase stimulator in heart failure patientS with reduced EF (SOCRATES-REDUCED, Bayer) [Phase-2]

- d. A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP (CANTOS, *Novartis*) [Phase-3]
- e. Randomized Evaluation of the Effects of Anacetrapib Through Lipid-modification (REVEAL, *University of Oxford*) [Phase-3]
- f. A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction (PARADIGM, *Novartis*) [Phase-3]
- g. A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of both aliskiren monotherapy and aliskiren/enalapril combination therapy compared to enalapril monotherapy, on morbidity and mortality in patients with chronic heart failure (NYHA Class II-IV) (ATMOSPHERE, *Novartis*) [Phase-3]
- h. 8-week Randomized, Open-label Study to Evaluate Food Effect on Efficacy and Safety of Oral Aliskiren 300 mg in Patients With Hypertension (*Novartis*) [Phase-3]
- i. A Study to Evaluate the Effectiveness and Safety of TAK-491 (Azilsartan Medoxomil) and Chlorthalidone Combined in One Tablet (40/12.5 and 40/25 mg) in Patients With High Blood Pressure Who do Not Achieve Target Blood Pressure on Treatment With TAK-491 40 mg Alone (*Takeda*) [Phase-3]
- j. ATHerosclerosis of the lower extremities as a liNKed comorbidity in Patients Admitted for carDiac rehabilitation (ThinkPAD! *Italian association for Cardiovascular Prevention and Rehabilitation*) [Phase-4]
- k. Multi-center, open-label, extension study to evaluate the long-term efficacy and safety of oral tolvaptan tablet regimens in subjects with autosomal dominant polycystic kidney disease (ADPKD) (TEMPO 4/4, *Otsuka*) [Phase-3]
- l. Multi-level evaluation of anaemia treatment, outcomes, and determinants in chronic kidney disease stage 5 (Monitor-CKD5, *Sandoz*) [Phase-4]
- m. A multicenter, open label, randomised, controlled, two arm study to assess compliance with daily tablet intake of women on treatment with the oral contraceptive SHT00186D/BAY 86-5300 (0,02 mg ethinyl estradiol as betadex clathrate and 3 mg drospirenone) in a flexible extended regimen supported by a dispenser (CADDY) with a reminder function over 12 months (*Bayer*) [Phase-3]
- n. A 52-week Treatment, Multi-center, Randomized, Double-blind, Double Dummy, Parallel-group, Active Controlled Study to Compare the Effect of QVA149 (Indacaterol Maleate / Glycopyrronium Bromide) With Salmeterol/Futicasone on the Rate of Exacerbations in Subjects With Moderate to Very Severe COPD (FLAME, *Novartis*) [Phase-3]
- o. A randomized, placebo-controlled, double-blind, parallel group, multicenter study to investigate the efficacy and safety of 5 fixed doses of BAY 85-3934 administered orally in the correction of anemia in erythropoiesis-stimulating agent naïve, pre-dialysis subjects with chronic kidney disease in Europe and Asia Pacific (DIALOGUE 15141, *Bayer*) [Phase-2]
- p. A randomized, parallel group, open-label, multicenter study to investigate the efficacy and safety of oral BAY 85-3934 and active comparator (darbepoetin alfa) in the maintenance treatment of anemia in pre-dialysis subjects with chronic kidney disease on darbepoetin treatment in Europe and Asia Pacific (DIALOGUE 15261, *Bayer*) [Phase-2]
- q. A controlled, parallel group, open-label, multicenter extension study to investigate efficacy and safety of oral BAY 85-3934 and darbepoetin alfa comparator in the long-term treatment of anemia in pre-dialysis subjects with chronic kidney disease in Europe and Asia Pacific (DIALOGUE 15653, *Bayer*) [Phase-2]
- r. A Phase 3b, Multi-center, Open-label Trial to Evaluate the Long Term Safety of Titrated Immediate-release Tolvaptan (OPC 41061, 30 mg to 120 mg/day, Split dose) in Subjects with Autosomal Dominant Polycystic Kidney Disease (156-13-211, *Otsuka*) [Phase-3b]
- s. A 52-Week, Double Blind, Double Dummy, Randomized, Multinational, Multicentre, 2-Arm Parallel Group, Active Controlled Clinical Trial Of Fixed Combination Of Beclomethasone Dipropionate Plus Formoterol Fumarate Plus

Glycopyrronium Bromide Administered Via Pmdt (Chf 5993) Versus Indacaterol/Glycopyrronium (Ultibro®) Via Dpi In Patients With Chronic Obstructive Pulmonary Disease (TRIBUTE, *Chiesi*) [Phase 3]

- t. A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents. (ASCEND-D, *GlaxoSmithKline*) [Phase 3A]
- u. A Phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa. (ASCEND-ND, *GlaxoSmithKline*) [Phase 3A]
- v. A 52-week open-label (sponsor-blind), randomized, active-controlled, parallel-group, multi-center study to evaluate the efficacy and safety of daprodustat compared to recombinant human erythropoietin in subjects with anemia associated with chronic kidney disease who are initiating dialysis (ASCEND-ID, *GlaxoSmithKline*) [Phase 3]