Previous and ongoing clinical trials

JAN 2001	PI	Sevelamer study (APN initiated, Genzyme REN 002-01; EU/199/123/001-004
JAN 2002-JAN 2005	PI	Basiliximab study (APN initiated, Novartis, Protokoll No: CCHI621A DE01)
JAN 2002-JAN 2004	PI	Oxalobacter studies I and II (Ixion Biotechnology Inc., CTIOx.0002 and CTIOx.0005)
JAN 2004-JAN 2006	PI	Symbiolact study (Symbiopharm, Protokoll No. SY 2003/110)
JAN 2004-OCT 2008	LKP	Alkaline Citrate Treatment to Lower the Risk of Nephrokalzinosis in Preterm Infants
JAN 2005	PI	Prospective study of diagnosis and treatment of post transplant lymphoproliferative disease after solid organ transplantation in children
JAN 2006-JAN 2007	PI	TWIST Study (Protokoll No.: FG-02-43-DE-016)
NOV 2007-SEP 2008	LKP	International Study to Evaluate the Efficacy and Safety of Oxalobact to Reduce Urinary Oxalate Excretion in Subjects with Primary Hyperoxaluria, Oxthera AB, OC01-DB
APR 2008-APR 2009	LKP	An Open Label (OL) Extension Study, Evaluating the Long Term Safety of OC, in Subjects with Primary Hyperoxaluria (PH) who participated in the Double Blind Study (DB) study
JUN 2008-JUN 2011	LKP	A Prospective Registry Study Observing the Safety and Patterns of Use of Darbepoetin Alfa in EU Pediatric Chronic Kidney Disease Patients Receiving or not Receiving Dialysis – a Post Approval Study
AUG 2008-NOV 2011	PI	An Open Label Multi-Center, multiple dose study to determine the optimum of intravenous Mircera for maintenance treatment of anemia in pediatric patients with chronic kidney disease on hemodialysis Dolphin Study (Dose Finding Trial of Pediatrics on Hemodialysis in Nephrology)
SEP 2009-SEP 2009	PI	A study to determine feasibility of procedures for 24 h urine collections and variability in urinary oxalate and creatinine excretion test results
SEP 2009-May 2010	PI	An Open Label, Multi-Center Controlled Trial Of Eculizumab in Adolescent Patients with Plasma Therapy-Resistant Atypical Hemolytic Uremic Syndrome (AHUS), Alexion
DEC 2009-2012	PI	The Cardiovascular Comorbidity in Children with Chronic Kidney Disease Study (4c)

JAN 2010-MAR 2011	PI	A Phase 2/3, Double blind, Randomized, Placebo Controlled, Multi-Center Study to evaluate the Efficacy and Safety of Oxabact to Reduce Urinary Oxalate in Subjects with Primary Hyperoxaluria. OC3-DB-01, Oxthera AB
AUG 2010-MAY 2012	PI	Randomized, multicenter cross-over study investigating the effect of bicarbonate-based solutions (Physioneal 35 vs.40) on protein metabolism in children and adolescents on chronic peritoneal dialysis
AUG 2010	PI	International registry investigating the safety of bicarbonate solutions (Physioneal 35 vs.40) in children and adolescents on chronic peritoneal dialysis
DEC 2010-JUN 2013	LKP	Pilot trial on treatment of Patients with primary Hyperoxaluria type I with pyridoxal phosphate
JAN 2011	PI	A Phase 3, Prospective, Randomized, Double-Blind, Placebo controlled Multi-Center Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Paracalcitol Capsules in Decreasing Serum Intact Parathyroid Hormone Levels in Pediatric Subjects Ages 10 to 16 years with Moderate to Severe Chronic Kidney Disease EudraCT Number: 2010-019439-37
FEB 2011	PI	Register for Lupus Nephritis
FEB 2011	PI	Register for Purpura Schoenlein Henoch Nephritis (PSNH Register)
AUG 2011	PI	Renal Insufficiency Therapy in Children: Quality Assessment and Improvement
FEB 2012-JUN 2013	PI	Tolerability of up to 200 Days of Valganciclovir oral Solution or Tablets in Pediatric Kidney Transplant Recipients EudraCT Number: 2010-022514-47
FEB 2012 - 2019	PI	A multicenter, randomized, open label study to steer immunosuppressive and antiviral therapy by measurement of virus (CMV, ADV, HSV) specific T cells in addition to determination of through levels of immunosuppressants in pediatric kidney and liver allograft recipients. An explorative study. EudraCT Number: 2009-012436-32
APR 2012-2018	PI	Early prospective therapy trial to delay renal failure in children with alport syndrome, Early Protect Study, GPN supported EudraCT Number: 2010-024300-10
APR 2012-FEB 2018	PI	Dia-Sport, Endurance orientated training program with children and adolescents on maintenance hemodialysis. HO DFG 1272/21-1
JUN 2012	PI	International Pediatric Peritoneal Biopsy Study
JUL 2013-NOV 2018	PI	International Registry for atypical haemolytic uremic syndrome
DEC 2013-2015	PI	A phase 1/2, randomized, placebo controlled, double blind, multi-centre study to evaluate the efficacy and safety of OC5 to reduce urinary oxalate excretion in subjects with primary hyperoxaluria, ELIMOX EudraCT Number: 2012-005606-22
APR 2014 - 2020	PI	A phase 2, open label, multi-centre study to evaluate the efficacy and safety of Oxabact® to reduce plasma oxalate in subjects with primary hyperoxaluria who are on dialysis EudraCT Number: 2013-004368-74
May 2015 - 2020	PI	Initial treatment of idiopathic nephrotic syndrome in children with mycophenolate mofetil *vs.* prednisone: A randomized, controlled, multicenter study (INTENT Study) EudraCT Number: 2014-001991-76

NOV 2015 – Dec 2017	PI	An observational Study of Patients with Primary Hyperoxaluria Type 1, PHYOS
MAR 2016 – OCT 2016	PI	A Phase 1 Study of DCR-PH1 in Patients with Primary Hyperoxaluria Type 1 (PH1)
AUG 2016 - 2018	PI	A Phase 1/2, Single-Blind, Placebo-Controlled, Single– and Multiple-Ascending Dose Safety, Tolerability, Pharmacokinetic and Pharmacodynamics Study of Subcutaneously Administered ALN-GO1 in Healthy Adult Subjects, and Patients with Primary Hyperoxaluria Type 1 EudraCT Number: 2015-004407-23
NOV 2016 - 2018	PI	A multicenter, open label, uncontrolled study to evaluate the nutritional suitability, acceptability, and tolerability of Renastart EudraCT Number: 2016-001737-31
APR 2017 – AUG 2018	PI	A single Arm, Phase III study to of ALXN1210 in complement inhibitor treatment naïve adult and adoslescent patients with atypical haemolytic uremic syndrome (aHUS). ALXN1210-aHUS-311 EudraCT Number: 2016-002027-29
JUN 2017 – MAR 2019	PI	A 24-week randomized, open-label, Phase III study to evaluate the safety and efficacy of Fesoterodine in subjects aged 6 to 17 years with symptoms of detrusor over-activity associated with a neurological condition (neurogenic detrusor overactivity). EudraCT Number: 2010-022475-55
AUG 2017 – NOV 2017	PI	Evaluation of potential predictors of disease progression of disease progression in patients with aHUS, including genetics, biomarkers and treatment. EudraCT Number: 2015-003135-35
SEPT 2017 – 2019	PI	A phase III double-blind, randomised study to evaluate the long-term efficacy and safety of Oxabact® in patients with primary hyperoxaluria. OC5-DB-02 EudraCT Number: 2017-000684-33
JAN 2018 – 2020	PI	A Phase 3, open-label. Multicenter study of ALXN1210 in children and adoslescents with Atypical-Hemolytic-Uremic syndrome (aHUS). ALXN1210-aHUS-312. EudraCT Number: 2016-002499-29
MAR 2018 – DEC 2018	PI	A Phase 2, Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Administration of ALN-Go1 in patients with Primary Hyperoxaluria Type 1 ALN-GO1-002 EudraCT Number: 2016-003134-24
July 2018 - 2019	PI	A Placebo-Controlled, Single-Blind, Single-Center Phase 1 Study in Normal Healthy Volunteers and Open-Label Multi-Center Study in Patients with Primary Hyperoxaluria to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Doses of DCR-PHXC Solution for Injection (subcutaneous use). DCR-PHXC-101 EudraCT Number: 2017-0035324-89
NOV 2018 - 2020	PI	Evaluate the Safety and Efficacy of ALLN-177 in Patients with Enteric Hyperoxaluria: A Phase III Randomized, Placebo-Controlled Study. ALLN-177-301 EudraCT Number: 2017-004352-33
NOV 2018 - 2020	PI	A Phase 2, Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Administration of ALN-GO1 in Patients with Primary Hyperoxaluria Type 1 ALN-GO1-002. EudraCT Number: 2016-003134-24.
OCT 2018 - 2021	PI	PHYOX: A Safety and Tolerability Study of DCR-PHXC in Primary Hyperoxaluria Types 1 and 2
MAR 2019 – 2020	PI	Alnylam Pharmaceuticals ILLUMINATE-A study: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study with and Extended Dosing Period to Evaluate the Efficacy and Safety of Lumasiran in Children and Adults with Primary Hyperoxaluria Type I. ALN-GO1-003.

		EudraCT Number: 2018-001981-40.
DEC 2019-2021	PI	A Phase 2 Placebo-Controlled, Double-Blind, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of DCR-PHXC Solution for Injection (subcutaneous use) in Patients with Primary Hyperoxaluria DCR-PHXC-201. EudraCT Number: 2018-003098-91.
MAR 2022-ongoing	PI	Postnatal screening for cystinosis and primary hyperoxaluria type 1 and 3 – early treatment (B6, RNAi) versus late onset treatment in historical controls
SEP 2022 - ongoing	SI / DE	An Open-Label Roll-Over Study to Evaluate the Long-Term Safety and Efficacy of DCR PHXC Solution for Injection (subcutaneous use) in Patients with Primary Hyperoxaluria. DCR-PHXC-301. EudraCT Number: 2018-00309910
SEP 2022 - ongoing	SI / DE	A Phase 2 Open-Label Study to Evaluate the Safety and Efficacy of DCR PHXC in Patients With Primary Hyperoxaluria Type 1 or 2 and Severe Renal Impairment, With or Without Hemodialysis. DCR-PHXC-204. EudraCT Number: 2020-002826-97
SEP 2022 – NOV 2024	SI / DE	A Phase 2 Open-Label Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Nedosiran in Pediatric Patients from Birth to 11 Years of Age with Primary Hyperoxaluria and Relatively Intact Renal Function. DCR-PHXC-203. EudraCT Number: 2021-001083-16
AUG 2021 – ongoing	PI	NEOCYST Registry Study on early onset cystic kidney disease
MAR 2022 – ongoing	SI / DE	A Phase 3 Study of Etelcalcetide in Children With Secondary Hyperparathyroidism Receiving Hemodialysis. AMGEN 20170724. EudraCT Number:2018-004608-21
AUG 2022 – APR 2024	PI	AregPKD Registry Study on Autosomal Recessive Polycystic Kidney Disease
NOV 2022 – ongoing	PI	FOrMe Registry Study on Focal Glomerulosclerosis and Minimal Change Disease
FEB 2023 - ongoing	DE	A 6-month multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and PK/PD of an age-and body weight adjusted oral finerone regimen, in addition to an ACEI or ARB, for the treatment of children, 6 months to <18 years of age with chronic kidney disease and proteinuria. FIONA. EudraCT Number: 2021-002071-19
NOV 2023 - ongoing	DE	An 18-month, open-label, single-arm safety extension study of an age- and bodyweightadjusted oral finerenone regimen, in addition to an ACEI or ARB, for the treatment of children and young adults from 1 to 18 years of age with chronic kidney disease and proteinuria. FIONA-OLE. EudraCT Number: 2021-002905-89
JUN 2024 - ongoing	SI	A phase 1, open-label, uncontrolled study to evaluate activity, safety, pharmacokinetics and pharmacodynamics of Roxodustat for the treatment of anemia in pediatric patients with chronic kidney disease. 1517-CL-1003. EudraCT Number: 2022-501980-42

LKP	National Coordinating Investigator, *Leiter Klinischer Prüfung* gemäß AMG
PI	Prinicipal Investigator
DE	Deputy
SI	Subinvestigator

Bonn, _____ _____
(Prof. Dr. med. Bernd Hoppe)