Trials

Study-summary

Ongoing and planned studies

NB: all detailed protocol information can be found at :
Protocolnet of the Erasmus MC, www.hovon.nl or by the research hematology (010-7034546) at the Erasmus MC.

ALL			
Hovon 117 *Dr. A. Rijneveld*	*≥ 60 (ALL)*	*An observational study for older adults with Acute Lymphoblastic Leukaemia*	*On hold*
Hovon 146 *Dr. A Rijnveld*	*18-70*	*Blinatumomab added to prephase and consolidation therapy in precursor B-acute lymphoblastic leukemia in adults. A phase II trial*	*open*
AML			
AMGEN AMG330-20120252 *Dr. M. Jongen-Lavrencic*	*≥ 18 years*	*A Phase 1 First-in-human Study Evaluating the Safety, Tolerability,Pharmacokinetics, Pharmacodynamics and Efficacy of AMG 330 Administered as Continuous Intravenous Infusion in Subjects With elapsed/Refractory Acute Myeloid Leukemia*	*open*
Agios AG120-221-C-001 ***Prof. B. Lowenberg***	*≥ 18 years*	*A Phase 1, Multicenter, Open-Label, Safety Study of AG-120 or AG-221 in Combination with Induction Therapy and Consolidation Therapy in Patients with Newly Diagnosed Acute Myeloid Leukemia with an IDH1 and/or IDH2 Mutation*	*open*
Celgene AG-221-AML-005 ***Dr. M. Jongen***	*≥ 18 years*	*A Phase 1b/2 Open-Label, Randomized Study of 2 Combinations of Isocitrate Dehydrogenase (IDH) Mutant Targeted Therapies Plus Azacitidine: Oral AG-120 Plus Subcutaneous Azacitidine and Oral AG-221 Plus SC Azacitidine in Subjects With Newly Diagnosed Acute Myeloid Leukemia Harboring an IDH1 or an IDH2 Mutation, Respectively, Who Are Not Candidates to Receive Intensive Induction Chemotherapy*	*open*
Macrogenics CP-MGD006-01 ***Prof. B. Lowenberg***	*≥ 18 years*	*A Phase 1, First-in-Human, Dose Escalation Study of MGD006, a CD123 x CD3 Dual Affinity Re-Targeting (DART) Bi-Specific Antibody-Based Molecule, in Patients with Relapsed or Refractory Acute Myeloid Leukemia or Intermediate- 2/High Risk Myelodysplastic Syndrome*	*planned*
Merus MCLA-117-CL01 *Dr. M. Jongen-Lavrencic*	*≥ 18 years*	*A Phase 1, Multinational Study of MCLA-117 in Acute Myelogenous Leukemia*	*open*

Novartis CIDH305X2101 *Dr. M. Jongen-Lavrencic*	*≥ 18 years*	*A Phase I study of IDH305 in patients with advanced malignancies that harbor IDH1R132 mutations*	*open*
Hovon 135 *Dr. M. Jongen-Lavrencic*	≥ 66 years**.**	*A randomized phase II multicenter study to assess the tolerability and efficacy of the addition of ibrutinib to 10-day decitabine in UNFIT (i.e. HCT-CI ≥ 3) AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) patients*	*open*
Hovon 138 *Dr. M. Jongen-Lavrencic*	*≥18 and ≤ 65*	*A randomized Phase III study to compare arsenic trioxide (ATO) combined to ATRAand idarubicin versus standard ATRA and anthracycLine-based chemotherapy (AIDA regimen) for patients with newLy diagnosed, high-risk acute prOmyelocytic leukemia (APOLLO)*	*planned*
Hovon 103 Arm D Selinexor *Dr. M. Jongen-Lavrencic*	≥ 66 yrs and very poor risk AML ≥ 18 yrs	*Masterprotocol HOVON 103: A program of randomized phase II multicenter studies to assess the tolerability and efficacy of the addition of new drugs to standard induction chemotherapy in AML and RAEB*	*open*
Hovon 148 *Dr. M. Jongen-Lavrencic*	*≥ 18 years*	*A phase Ib feasibility study of the combination of panobinostat and midostaurin in recipients of allogeneic stem cell transplantation with FLT3-ITD AML*	*planned*
MDS			
Hovon 135 *Dr. M. Jongen-Lavrencic*	≥ 66 years**.**	*A randomized phase II multicenter study to assess the tolerability and efficacy of the addition of ibrutinib to 10-day decitabine in UNFIT (i.e. HCT-CI ≥ 3) AML and high risk myelodysplasia (MDS) (IPSS-R > 4.5) patients*	*open*
Janssen Research & Development, LLC 56022473MDS2002 *Dr. M. Raaijmakers*	*≥ 18 years*	*A Phase 2 Proof-of-Concept Study to Separately Evaluate the Activity of Talacotuzumab (JNJ-56022473) or Daratumumab in Transfusion-Dependent Subjects with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who are Relapsed or Refractory to Erythropoiesis-Stimulating Agent (ESA) Treatment*	*open*
Amyloidose			
Janssen-Cilag 54767414AMY3001		*Daratumumab is een humaan monoklonaal IgG1κ-antilichaam (mAb) dat met hoge affiniteit bindt aan een unieke epitoop op CD38, een*	*open*

Dr. A. Broijl		*transmembraanglycoproteïne. Het is een doelgerichte immunotherapie tegen tumorcellen waarop CD38 in hoge mate tot expressie komt, zoals plasmacellen van patiënten met AL-amyloïdose*	
CML			
DASTOP 2 *Dr. Te Boekhorst*	*≥ 18 years*	*Persistence of major molecular remission (MR³) in chronic myeloid leukemia after a second stop of TKI treatment in patients who failed an initial stop attempt.*	*planned*
MM			
Celgene CC-220-MM-001 *Prof. Dr. P. Sonneveld*	*≥ 18 years*	*A Phase 1b/2a Multicenter, Open-label, Dose-escalation Study to Determine the Maximum Tolerated Dose, Assess the Safety and Tolerability, Pharmacokinetics and Preliminary Efficacy of CC-220 Monotherapy and in Combination with Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma*	*open*
NIVO/DARA *Prof. Dr. P. Sonneveld*	*≥ 18 years*	*A phase 2 study of nivolumab combined with daratumumab with or without lenalidomide-dexamethasone in relapsed/refractory multiple myeloma*	*planned*
Oncopeptides OP-103 OCEAN (MM) Prof. Dr. P. Sonneveld	*≥ 18 years*	*A Randomized, Controlled, Open-Label, Phase 3 Study of Melflufen/Dexamethasone Compared with pomalidomide/ Dexamethasone for Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Lenalidomide*	*open*
Hovon 114 *Prof. Dr. P. Sonneveld*	*≥ 18 years*	*Pomalidomide combined with Carfilzomib and Dexamethasone (PCd) for induction and consolidation followed by Pomalidomide combined with examethason vs omalidomide maintenance for patients with Multiple Myeloma in first relapse after prior 1st line treatment with Lenalidomide and Bortezomib*	*open*
Hovon 129 *Dr. A. Broyl*	*≥ 18 years*	*Carfilzomib and lenalidomide-based treatment for younger and elderly newly diagnosed primary plasma cell leukemia patients*	*open*
Hovon 143 *Prof. Dr. P. Sonneveld*	*≥ 18 years*	*Efficacy and tolerability of ixazomib, daratumumab and low dose dexamethasone (IDd) followed by ixazomib and daratumumab maintenance therapy until progression for a maximum of 2 years in unfit and frail newly*	*open*

		diagnosed multiple myeloma patients; an open-label phase II trial	
CLL			
Celgene MEDI4736-NHL-001 Dr. P. Lugtenburg	*≥18- ≤ 80 years and > 80 yrs*	*A Phase 1/2, open label, multicenter study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia (MEDI4736-NHL-001)*	*open*
Hovon 141 *Dr. J.K. Doorduijn*	*≥ 18 years*	A prospective, multicenter, phase-II trial of ibrutinib plus venetoclax in patients with creatinine clearance ≥ 30 ml/min who have relapsed or refractory chronic lymphocytic leukemia (RR-CLL) with or without TP53 aberrations	*open*
NHL			
Celgene CC-122-NHL-001 *Dr. J.K. Doorduijn*	*≥ 18 years*	*A phase 1B open label study to evaluate the safety and efficacy of CC-122 in combination with Obinutuzumab ((GA101) in subjects with relapsed/refractory diffuse large B-CELL lymphoma and indolent N*HL	*open*
Celgene MEDI4736-NHL-001 *Dr. P.J. Lugtenburg*	*≥ 18 years and ≤ 80 years*	*A Phase 1/2, open label, multicenter study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia (MEDI4736-NHL-001)*	*open*
Celgene JCAR017-BCM-001 *Dr. P.J. Lugtenburg*	*≥ 18 years and ≤ 80 years*	*A Phase 2, Single-Arm, Multi-Cohort, Multi-Center Trial to Determine the Efficacy and Safety of JCAR017 in ADULT Subjects with Aggressive B-Cell NON-HODGKIN Lymphoma. JCAR017-BCM-001.*	*Planned*
Celgene JCAR017-BCM-003 *Dr. P.J. Lugtenburg*	*≥ 18 and ≤ 75 years.*	*A global randomized multicenter Phase 3 trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell non-Hodgkin lymphomas (TRANSFORM).*	*planned*
IELSG 42 *Dr. J.K. Doorduijn*	*18-70 years*	*An international phase II trial assessing tolerability and efficacy of sequential Methotrexate-Aracytin-based combination and R-ICE combination, followed by high-dose chemotherapy supported by autologous stem cell transplant, in patients with systemic B-cell lymphoma with central nervous system involvement at diagnosis or relapse (MARIETTA regimen)*	*open*

KTE-C19-101-NHL ZUMA-1 Dr. P.J. Lugtenburg	*≥ 18 years*	*A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL) (ZUMA-1)*	*open*
KTE-C19-102-MCL ZUMA-2 *Dr. P.J. Lugtenburg*	*≥ 18 years*	*A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-C19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (r/r MCL)* ***(ZUMA-2)***	*planned*
KTE-C19-103 (r/r ALL) (ZUMA-3 *Dr. P.J. Lugtenburg*	*≥ 18 years*	*A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Adult Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) (ZUMA-3)*	*planned*
Pfizer B991011 Javelin (DLBDL *Dr.P.Lugtenburg*	*≥ 18 years*	*multi-center, international, randomized, open-label, 2-component (Phase 1b followed by Phase 3), parallel-arm study of avelumab in combination with various agents for the treatment of Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL). Agents that will be tested include:*	*planned*
Hovon 110 *Dr. J.K. Doorduijn*		*Lenalidomide and rituximab with or without bendamustine in patients ≥ 18 years with relapsed follicular lymphoma*	*open*
Hovon 119 *Dr. J.K. Doorduijn*	*≥ 18 years*	*Efficacy of alternating immunochemotherapy consisting of R-CHOP + RHAD versus R-CHOP alone, followed by maintenance therapy consisting of additional lenalidomide with rituximab versus rituximab alone for older patients with mantle cell lymphoma*	*open*
Hovon 124 *Dr. J.K. Doorduijn*	*≥ 18 years*	*A prospective phase I/II trial of the combination of ixazomib citrate, rituximab and dexamethasone in patients with relapsed or progressive Waldenström's macroglobulinemia A HOVON/Greek Myeloma Study Group study*	*open*

Hovon 127 *Dr. P.J. Lugtenburg*	*18-75 years*	*Randomized phase II study comparing R-CODOX-M/R-IVAC versus dose-adjusted EPOCH-R (DA-EPOCH-R) for patients with newly diagnosed high risk Burkitt lymphoma*	*open*
Hovon 130/HO900 *Dr. P.J. Lugtenburg*	*≥ 18 year*	*A phase II study evaluating the effect of the addition of lenalidomide to R-CHOP for patients with newly diagnosed MYC positive DLBCL and BCL-U.*	*open*
Hovon 133 *Dr. J.K. Doorduijn*	*≥ 18 years and ≤ 65 years*	***TRIANGLE**: autologous **T**ransplantation after a **R**ituximab/**Ibrutinib/A**ra-c containing i**N**duction in **G**eneralized mantle cell **L**ymphoma – a randomized **E**uropean MCL Network trial*	*open*
Hovon 136 *Dr. P.J. Lugtenburg*	*≥ 18 year*	*Phase I-II study combining Brentuximab Vedotin with second line salvage chemotherapy (R-DHAP) in CD30 positive diffuse large B-cell lymphoma patients refractory to first line chemotherapy or in first relapse who are eligible for high dose treatment followed by autologous stem cell transplantation*	*open*
HO900 *Dr. P.J. Lugtenburg*	*≥ 18 year*	*DLBCL:* *A national MYC screening study in relation to the HOVON 130 protocol*	*open*
Hovon 144 *Dr. P.J. Lugtenburg*	*≥ 18 year*	A Phase 1/2 study of the combination of pixantrone, etoposide,bendamustine and, in CD-20 positive tumors, rituximab in patients with relapsed aggressive non-Hodgkin lymphomas of B- or T-cell phenotype – The P[R]EBEN study	*planned*
Hodgkin			
Millenium Arroven *Dr.P.Lugtenburg*	*≥ 18 years*	*Post-Authorisation Safety Study (PASS) MA25101: An Observational Cohort Study of the Safety of Brentuximab Vedotin in the Treatment of Relapsed or Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma*	*open*
Transplantaties			
Cord Blood Expansion (SR-1) *Prof dr. J. Cornelissen*	*≥ 18 years*	*Umbilical cord blood transplantation in high-risk hematological patients using stemregenin-1 expanded hematopoietic stem cells. A feasibility study focussing on engraftment and hematopoietic recovery.*	*open*

Hovon 96 *Dr.A.E.C.Broers*	*18-65 years*	*Prevention and treatment of severe GVHD after allogeneic hematopoietic SCT, applied as consoldation immunotherapy in patients with hematological malignancies. Randomized Phase III*	*open*
Hovon 113 *Prof J.J. Cornelissen*	*≥ 18 years*	*Treatment of severe steroid-refractory acute GvHD with mesenchymal stromal cells. A phase III randomized double-blind multi-center HOVON study.*	*open*
MPN			
HOVON 134 *Dr.P.A.W.te Boekhorst*	*18-65 years*	*A phase II trial in patients with myelofibrosis (primary, post-ET or post PV-MF) treated with the selective JAK2 inhibitor Pacritinib before reduced-intensity conditioning allogeneic stem cell transplantation*	*planned*
Novartis /CINC424BIC04 *Dr.P.A.W.te Boekhorst*	*≥ 18 years*	*An International Multi-Centric Observational Study on the Use of Ruxolitinib in the Treatment of Patients with Polycythemia Vera resistant or intolerant to hydroxyurea*	*open*
Sanquin ***Incyte INCB039110*** ***DRAIHA study*** *Dr.P.A.W.te Boekhorst*	*≥ 18 years*	*Data Registry of Autoimmune Hemolytic Anemia, to improve diagnostic testing for the development of personalized treatment protocols in AIHA patients.*	*planned*
Stolling			
Baxalta 071301 (willebrand) *Prof. Dr. F. Leebeek*	*≥ 18 years*	*prospective, open label, uncontrolled, non-randomized, international, multicenter phase 3 study to evaluate efficacy, safety, including immunogenicity and* thrombogenicity, and HRQoL of a prophylactic treatment regimen with rVWF in patients with severe VWD.	*open*
Caravaggio *Dr MJHA Kruip*	*≥ 18 years*	Apixaban for the treatment of venous thromboembolism in patients with cancer: a prospective randomized open blinded end-point (PROBE) study - the Caravaggio study	*open*
Novo Nordisk ***NN7088-3859*** ***(Pathfinder 2)*** *Prof. Dr. F. Leebeek*	*≥ 18 years*	*Heamophilia A in surgery* *NNC01290000-1003*	*open*
Novo Nordisk ***NN7088-3860*** ***(Pathfinder 3)***	*≥ 18 years*	*Heamophilia A in surgery* *NNC01290000-1003*	*open*

Prof. Dr. F. Leebeek			
DAVID study *Dr MJHA Kruip*	*≥ 12 years*	*DDAVP treatment combIneD with* *FVIII clotting factor concentrates* *in patients with mild hemophilia A; DAVID study*	*open*
Little DAVID *Dr MJHA Kruip*	*≥ 12 years*	*DDAVP and FVIII concentrate combination treatment in* *non-severe haemophilia A patients undergoing minor* *surgical interventions (DAVID studies)*	*planned*
Crescendo study *Dr MJHA Kruip*	*≥ 12 years*	*The Clinical Relevance and Significance of New Diagnostic* *Options in patients with unexplained bleeding* *The CRESCENDO – study*	*planned*
Highlow *Dr MJHA Kruip*	*≥ 18 years*	*Highlow study* *Low-molecular-weight heparin to prevent recurrent VTE in pregnancy: a randomized controlled trial of two doses*	*open*
Sickle cell disease			
GBT440-031 - SCD ***Dr. A. Rijneveld***	*≥ 18 years*	*A Phase 3, Double-blind, Randomized, Placebo-controlled, Multicenter Study of GBT440 Administered Orally to Patients With Sickle Cell Disease*	*open*
Sickle Cell Screen Lorrka ***Dr. A. Rijneveld***		*Investigating Red blood cell deformability of sickle cell patients before and after the start of therapy*	*planned*