



<b>Indikation:</b>	<b>Studientitel:</b>	<b>Leiter klinische Prüfung:</b>	<b>Ansprechpartner:</b>
Hochrisiko Myelom Erstdiagnose	<b><u>GMMG-CONCEPT:</u></b> Eine klinische Phase II Studie zur Induktions-, Konsolidierungs- und Erhaltungstherapie mit Isatuximab, Carfilzomib, Lenalidomid und Dexamethason (I-KRd) in der Primärtherapie des Hochrisikomyeloms.	Prof. Dr. med. Katja Weisel, Hamburg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Erstdiagnose + Rezidiv	<b><u>NSMM 5001 Insight:</u></b> Eine internationale, prospektive, nicht-interventionelle Beobachtungsstudie zur Ausprägung, zu Behandlungsmustern und Ergebnissen bei Patienten mit Multiplem Myelom. <b>Rekrutierung abgeschlossen!</b>	Prof. Dr. med. Hartmut Goldschmidt, Heidelberg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<b><u>BIRMA:</u></b> LGX818 in combination with MEK162 in refractory or relapsed Multiple Myeloma patients with BRAFV600E or BRAFV600K mutation.	Prof. Dr. med. Hartmut Goldschmidt, Heidelberg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<b><u>DANTE:</u></b> Eine multizentrische Phase II Studie. Daratumumab in Kombination mit Bortezomib und Dexamethasone bei Patienten mit rezidiviertem oder rezidiviertem und refraktärem Multiplem Myelom und hochgradiger Nierenfunktionseinschränkung einschließlich Patienten unter Hämodialyse.	Prof. Dr. med. Katja Weisel, Hamburg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<b><u>Roche BO 39813:</u></b> A Phase IB/II Study of Cobimetinib administered as single Agent and in combination with Venetoclax, with or without Atezolizumab, in Patients with relapsed and refractory Multiple Myeloma. <b>Rekrutierung abgeschlossen!</b>	Prof. Dr. med. Hartmut Goldschmidt, Heidelberg	OÄ Dr. med. Britta Besemer, Tübingen



Myelom Rezidiv	<p><b>C16029:</b> A Phase 2/3, randomized, open-label Study comparing oral Ixazomib / Dexamethasone and oral Pomalidomide / Dexamethasone in relapsed and / or refractory Multiple Myeloma. <b>Rekrutierung abgeschlossen!</b></p>	OÄ Dr. med. Britta Besemer, Tübingen	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<p><b>IMROZ EFC 12522:</b> A Phase 3 randomized, open-label, multicenter study assessing the clinical benefit of Isatuximab in combination with Bortezomib, Lenalidomide and Dexamethasone in Patients with newly diagnosed Multiple Myeloma not eligible for transplant. <b>Rekrutierung abgeschlossen!</b></p>	Prof. Dr. med. Hartmut Goldschmidt, Heidelberg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<p><b>GSK2857916:</b> A Phase 2, open-label, randomized, two-arm Study to Investigate the Efficacy and Safety of two doses of the Antibody Drug Conjugate GSK2857916 in Participants with Multiple Myeloma who had 3 or more prior Lines of Treatment, are Refractory to a Proteasome Inhibitor and an Immunomodulatory Agent and have failed an Anti-CD38 Antibody. <b>Rekrutierung abgeschlossen!</b></p>	OÄ Dr. med. Britta Besemer, Tübingen	OÄ Dr. med. Britta Besemer, Tübingen
Smoldering Myelom	<p><b>Aquila SMM3001:</b> A Phase 3 randomized, multicenter study of subcutaneous Daratumumab versus active monitoring in Subjects with high-risk Smoldering Multiple Myeloma. <b>Rekrutierung abgeschlossen!</b></p>	Prof. Dr. med. Hartmut Goldschmidt, Heidelberg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<p><b>BB2121-MM001:</b> A Phase 2, Multicenter Study to determine the efficacy of BB2121 in Subjects with relapsed / refractory Multiple Myeloma. <b>Rekrutierung abgeschlossen!</b></p>	Prof. Dr. med. Hermann Einsele, Würzburg	OÄ Dr. med. Britta Besemer, Tübingen
Myelom Rezidiv	<p><b>EMN Apollo:</b> A Phase 3 Study Comparing Pomalidomide and Dexamethasone With or Without Daratumumab in Subjects With</p>	Prof. Dr. med. Stefan Knop, Würzburg	OÄ Dr. med. Britta Besemer, Tübingen



Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy With Both Lenalidomide and a Proteasome Inhibitor.  
**Rekrutierung abgeschlossen!**

Amyloidose  
Erstdiagnose

**54767414AMY3001 Andromeda:** A Randomized Phase 3 Study to Evaluate the Efficacy and Safety of Daratumumab in Combination with Cyclophosphamide, Bortezomib and Dexamethasone (CyBorD) Compared With CyBorD Alone in Newly Diagnosed Systemic AL Amyloidosis.  
**Rekrutierung abgeschlossen!**

PD Dr.med.  
Stefan  
Schönland,  
Heidelberg

OÄ Dr. med. Britta Besemer,  
Tübingen

Myelom  
Erstdiagnose

**GMMG – HD7:** A randomized phase III trial assessing the benefit of the addition of isatuximab to lenalidomide / bortezomib / dexamethasone (RVd) induction and lenalidomide maintenance in patients with newly diagnosed multiple myeloma.

Prof. Dr. med.  
Hartmut  
Goldschmidt,  
Heidelberg

OÄ Dr. med. Britta Besemer,  
Tübingen

Myelom  
Rezidiv

**54767414MMY2040 Pleiades:** A Multicenter Phase 2 Study to Evaluate Subcutaneous Daratumumab in Combination with Standard Multiple Myeloma Treatment Regimens.

Prof.Dr.med.  
Hartmut  
Goldschmidt,  
Heidelberg

OÄ Dr. med. Britta Besemer,  
Tübingen

Myelom  
Erstdiagnose

**Protocol 54767414MMY3019 Cepheus:** A Phase 3 Study comparing Daratumumab, Velcade, Lenalidomide and Dexamethasone with Velcade, Lenalidomide and Dexamethasone in Subjects with untreated Multiple Myeloma and for whom Hematopoietic Stem Cell Transplant is not planned as Initial Therapy.  
**Rekrutierung abgeschlossen!**

Prof. Dr. med.  
Monika  
Engelhardt,  
Freiburg

OÄ Dr. med. Britta Besemer,  
Tübingen

Myelom  
Rezidiv

**Protocol 54767414MMY2065 Lynx:** A Phase 2 Study of Daratumumab Subcutaneous Administration in Combination with Carfilzomib and

Prof.Dr.med.  
Hartmut  
Goldschmidt,  
Heidelberg

OÄ Dr. med. Britta Besemer,  
Tübingen



Dexamethasone Compared with Carfilzomib and Dexamethasone in Participants with Multiple Myeloma who have been Previously Treated with Daratumumab Intravenous to Evaluate Daratumumab Retreatment.

Myelom  
Rezidiv

**CC-220-MM-001:** A PHASE 1B/2A MULTICENTER, OPEN-LABEL, DOSEESCALATION 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.

Prof. Dr. med.  
Katja Weisel,  
Hamburg

OÄ Dr. med. Britta Besemer,  
Tübingen

Myelom  
Rezidiv

**GSK 209664 DREAMM-9:** A Phase III, Randomized, Open-Label Study of Belantamab Mafodotin Administered in Combination with Bortezomib, Lenalidomide and Dexamethasone Versus Bortezomib, Lenalidomide and Dexamethasone in Participants with Transplant Ineligible Newly Diagnosed Multiple Myeloma.

Prof. Dr. med.  
Marc-Steffen  
Raab,  
Heidelberg

OÄ Dr. med. Britta Besemer,  
Tübingen

Myelom  
Rezidiv

**Protocol 68284528MMY4001**  
**LocoMMotion:** A Prospective, Multinational Study of Real-Life Current Standards of Care in Patients with Relapsed and/or Refractory Multiple Myeloma Who Received at Least 3 Prior Lines of Therapy Including PI, IMiD, and CD38 Monoclonal Antibody Treatment

OÄ Dr. med. Britta Besemer,  
Tübingen

## **Geplant in 2020:**

Myelom  
Rezidiv

**JNJ-68284528MMY3002 Cartitude 4:**  
A Phase 3 Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T)

OÄ Dr. med. Britta Besemer,  
Tübingen



Therapy Directed Against BCMA vs  
Carfilzomib and Dexamethasone (Kd) or  
Daratumumab, Pomalidomide and  
Dexamethasone (DPd) in Participants  
with Relapsed and Lenalidomide-  
Refractory Multiple Myeloma.

Myelom  
Rezidiv

**GSK2857916 DREAMM 3**: A Phase III,  
Open-Label, Randomized Study to  
Evaluate the Efficacy and  
Safety of Single Agent Belantamab  
Mafodotin Compared to Pomalidomide  
plus Lowdose Dexamethasone  
(pom/dex) in Participants with  
Relapsed/Refractory Multiple  
Myeloma.

OÄ Dr. med. Britta Besemer,  
Tübingen