

## Klinische Studien - mit möglichem Studieneinschluss

### Clinical trials - with possible study inclusion

#### **R3767-ONC-2011**

A Phase 3 Trial of Fianlimab (REGN3767,ANTI-LAG-3) + Cemiplimab versus pemrolizumab in Patients with previously untreated unresectable locally advanced or metastatic Melanoma.

#### **R3767-ONC-2055**

A Phase 3 Trial of Fianlimab (Anti-LAG-3) and Cemiplimab Versus Pembrolizumab in the Adjuvant Setting in Patients With Completely Resected High-risk Melanoma

## Klinische Studien - aktuell kein Studieneinschluss mehr möglich

### Clinical trials - currently no study inclusion possible

#### **Biontech - BNT111-01**

Open-label, randomized Phase II trial with BNT111 and cemiplimab in combination or as single agents in patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV melanoma

#### **IO102-IO103-013**

An open-label, randomized, Phase 3 clinical trial of IO102-IO103 in combination with pembrolizumab versus pembrolizumab alone in patients with previously untreated, unresectable, or metastatic (advanced) melanoma.

#### **Genentech - GO42273**

A phase Ib, open-label, multicenter study to evaluate the safety, pharmacokinetics, and activity of BELVARAFENIB as a single agent and in combination with either COBIMETINIB or COBIMETINIB plus ATEZOLIZUMAB in patients with NRAS-mutant advanced melanoma who have received anti-PD-1/PD-L1 therapy

#### **HBI-8000-303**

A Multicenter, Randomized, Double-Blind Phase 3 Study of HBI-8000 Combined with Nivolumab versus Placebo with Nivolumab in Patients with Unresectable or Metastatic Melanoma Not Previously Treated with PD-1 or PD-L1 Inhibitors

#### **Cemiskin**

Two cohort registry study for patients with advanced CSCC treated with Cemiplimab or other approaches.

#### **BERING**

Encorafenib plus binimetinib in patients with locally advanced, unresectable, or metastatic BRAFV600-mutated melanoma: a multicenter, multinational, prospective, longitudinal NIS study

**Genentech - GO40558**

A phase II, open-label, multicenter, randomized study of the efficacy and safety of RO7198457 in combination with pembrolizumab versus pembrolizumab in patients with previously untreated advanced melanoma

**Sanofi - TED15297**

A first-in-human dose escalation and expansion study to evaluate intratumoral administration of SAR441000 as monotherapy and in combination with cemiplimab in patients with advanced solid tumors

**Genmab - GCT1042-01**

A First-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety of GEN1042 in subjects with malignant solid tumors

**NivoMela**

Adjuvant nivolumab treatment in stage II high-risk melanoma – A randomized, controlled, phase III trial with biomarker-based risk stratification

**NEKTAR Therapeutics - 20-214-29**

A Phase 3, Randomized, Open-label Study to Compare Adjuvant Immunotherapy of Bempegaldesleukin Combined with Nivolumab Versus Nivolumab After Complete Resection of Melanoma in Patients at High Risk for Recurrence (PIVOT-12)

**Vaccibody - VB-N-01**

An open labelled first human dose phase 1/2a study to evaluate safety, feasibility and efficacy of multiple dosing with individualised VB10.NEO immunotherapy in patients with locally advanced or metastatic melanoma who did not reach complete responses with current standard of care immune checkpoint blockade

**BioNTech RNA Pharmaceuticals - Lipo-MERIT**

Clinical First-in-human Dose Escalation Study Evaluating the Safety and Tolerability of Intravenous Administration of a Tetravalent RNA-lipoplex Cancer Vaccine Targeting Four Tumour-associated Antigens in Patients With Advanced Melanoma

**MSD - MK3475-716**

Safety and efficacy of pembrolizumab compared to placebo in resected high-risk stage II melanoma

**IIT Essen - ADMEC-O**

Prospective randomized trial of an adjuvant therapy of completely resected merkel cell carcinoma (MCC) with immune checkpoint blocking antibodies versus observation.

**EORTC 1208 - Minitub**

Prospective registry of sentinel node (SN) positive melanoma patients with minimal SN tumor burden who undergo completion lymph node dissection (CLND) or nodal observation

**EORTC 1325**

Adjuvant immunotherapy with anti-PD-1 monoclonal antibody Pembrolizumab (MK-3475) versus placebo after complete resection of high-risk stage III melanoma: A randomized, double-blind phase 3 trial of the EORTC Melanoma Group

**MSD - MK3475-629**

Study of pembrolizumab in adults with recurrent/metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced unresectable cSCC

**Roche - coveNIS**

A non-interventional study to investigate the effectiveness, safety and utilization of cobimetinib and vemurafenib in patients with and without brain metastasis with BRAF V600 mutant melanoma under real world conditions

**IIT ImmunoCobiVem**

Evaluating the efficacy and safety of a sequencing schedule of cobimetinib plus vemurafenib followed by immunotherapy with an anti-PD-L1 antibody in patients with unresectable or metastatic BRAF V600 mutant melanoma

**IIT BrainIP**

Eine offene Phase II-Studie zur Evaluierung der Sicherheit und Wirksamkeit einer Kombinationstherapie mit Ipilimumab und Nivolumab bei Patienten mit vier und mehr symptomatischen Hirnmetastasen eines Melanoms

**IIT ImmunoPax**

Immunomonitoring of patients with metastatic melanoma under chemotherapy

**Roche - IMspire170/ CO39722**

A study of cobimetinib plus atezolizumab versus pembrolizumab in participants with previously untreated advanced BRAFv600 wild-type melanoma

**IIT IMMUNED**

Immunotherapy With Nivolumab or Nivolumab Plus Ipilimumab vs. Double Placebo for Stage IV Melanoma w. NED

**BMS - 986213**

A study of relatlimab plus nivolumab versus nivolumab alone in participants with advanced melanoma

**Novartis - COMBI-r**

Eine nicht-interventionelle Studie bei Patienten mit fortgeschrittenem Melanom zur Bewertung der Kombinationstherapie mit Dabrafenib und Trametinib in der klinischen Routine

**Amgen - KEYNOTE-034**

Pembrolizumab with or without Talimogene Laherparepvec or Talimogene Laherparepvec placebo in unresected melanoma

**Novartis COMBI-i**

Randomisierte, doppelblinde, Placebo-kontrollierte, Phase III-Studie in der Kombination von Dabrafenib und Trametinib mit PDR001 (PD-1 Antikörper) versus Placebo bei unbehandelten, nicht-reserzierbaren oder metastasierten, BRAF V600 mutierten Patienten mit malignem Melanom

**IIT BOTTOM**

Biopsy- and Biology-driven Optimization of Targeted Therapy in Subjects with Advanced Melanoma

**BMS - CheckMate 401 (CA209401)**

Clinical trial of nivolumab combined with ipilimumab followed by nivolumab monotherapy as first-line therapy of subjects with histologically confirmed stage III (unresectable) or stage IV melanoma

**EORTC 18081**

Adjuvant pegylated - interferon-alpha2b (Sylatron™) for 2 years vs. observation in patients with a ulcerated primary cutaneous melanoma with T(2-4)bN0M0: a randomized phase III trial of the EORTC Melanoma Group

**Novartis - COLUMBUS**

A 2-part Phase III Randomized, Open Label, Multicenter Study of LGX818 Plus MEK162 Versus Vemurafenib and LGX818 Monotherapy in Patients With Unresectable or Metastatic BRAF V600 Mutant Melanoma

**Roche GO27826**

A Phase III, randomized, double blind, placebo-controlled study of vemurafenib (RO5185426) adjuvant therapy in patients with surgically resected, cutaneous BRAF-mutant melanoma at high risk for recurrence

**ADO - Sentinel Studie**

Kontrollierte und prospektiv randomisierte Therapiestudie zum Vergleich einer radikalen Lymphadenektomie versus Beobachtung bei Patienten mit malignem Melanom >1,0 mm Tumordicke und positivem Wächter-Lymphknoten

**BioNTech RNA Pharmaceuticals - IVAC MUTANOME**

Clinical first-in-human study evaluating the safety, tolerability and immunogenicity of intra-nodal administration of a personalized vaccination with IVAC MUTANOME vaccine with or without initial treatment with RBL001/RBL002 vaccine in patients with advanced melanoma

**Novartis NEMO**

A randomized Phase III, open label, multicenter, two-arm study comparing the efficacy of MEK162 versus dacarbazine in patients with advanced unresectable or metastatic NRAS mutation-positive melanoma

**Roche GO28141 co-BRIM**

A Phase III, double-blind, placebo-controlled study of vemurafenib + placebo versus vemurafenib in combination with GDC-0973 (MEK-inhibitor) in previously untreated BRAFV600-mutation positive patients with unresectable locally advanced or metastatic melanoma

**BMS IMAGE**

A multi-national, prospective, observational study in patients with unresectable or metastatic melanoma

**BioNTech RNA Pharmaceuticals - MERIT**

Clinical first-in-human dose escalating study evaluating the safety and tolerability of intranodal administration of an RNA-based cancer vaccine targeting the tumor-associated antigens NY-ESO-1 and tyrosinase in patients with advanced melanoma.

**GSK BRF115532 - COMBI-AD**

Randomisierte, doppelblinde Phase III-Studie zur Dabrafenib in Kombination mit Trametinib im Vergleich zu zwei Placebos bei der adjuvanten Behandlung des Hochrisiko-Melanoms mit BRAF-V600-Mutation nach chirurgischer Resektion

**ROCHE ZESS**

A prospective safety study of patients with BRAFV600 mutation-positive unresectable or metastatic melanoma treated with vemurafenib.

**NYESO1-AS15-MEL-001 (MET)**

Recombinant His/NY-ESO-1 protein combined with the AS15 immunological Adjuvant System (GSK2241658A)

**AB Science AB08026**

A prospective, multicenter, randomized, open-label, active-controlled, two-parallel groups, phase 3 study to compare the efficacy and safety of masitinib at 7.5 mg/kg/day to dacarbazine in the treatment of patients with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a mutation in the juxta membrane domain of c-kit

**MSD MK-3475 - 006**

A multicenter, randomized, controlled, three-arm, phase III study to evaluate the safety and efficacy of two dosing schedules of MK-3475 compared to ipilimumab in patients with advanced melanoma

**MSD MK-3475 - 002**

Randomized, Phase II study of the PD-1 inhibitor MK-3475 versus chemotherapy in patients with advanced melanoma

**Roche GO28397**

A phase I, open-label, multicenter, 3-period, fixed-sequence study to investigate the effect of vemurafenib on the pharmacokinetics of a single dose of acenocoumarol in patients with BRAFV600 mutation-positive metastatic malignancy

**GSK MEK116513 - COMBI-v**

A Phase III, randomised, open-label study comparing the combination of the BRAF inhibitor, dabrafenib, and the MEK inhibitor, trametinib, to the BRAF inhibitor vemurafenib in subjects with unresectable (Stage IIIc) or metastatic (Stage IV) BRAF V600E/K mutation positive cutaneous melanoma

**GSK PRAME**

An open, dose-escalation Phase I/II study to assess the safety, immunogenicity and clinical activity of recPRAME + AS15 Antigen-Specific Cancer Immunotherapeutic as first-line treatment of patients with PRAME-positive metastatic melanoma

**ROCHE BRAIN-METS**

An open-label, single-arm phase II, multicenter study to evaluate the efficacy of Vemurafenib in patients with brain metastases.

**GSK MEK115306 - COMBI-d**

Randomisierte, doppelblinde Studie der Phase III zum Vergleich der Kombination des BRAF-Hemmers Dabrafenib und des MEK-Hemmers Trametinib mit Dabrafenib und Placebo als First-Line-Therapie bei Patienten mit nicht resezierbarem (Stadium IIIc) oder metastasiertem (Stadium IV) kutanen Melanom mit BRAF-V600E/K-Mutation

**GSK MEK114267**

A phase III randomized, open-label study comparing GSK1121212 to chemotherapy in subjects with advanced or metastatic BRAF V600E/K mutation-positive melanoma

**DeCOG-MM-PAL11**

The IPI - Multibasket Trial in advanced uveal melanoma: Prospective clinical phase II multibasket study in Melanoma patients with advanced disease

**ADO ChemoSensMM**

Prospectively randomized phase III study of an individualized sensitivity-directed combination chemotherapy versus DTIC as first-line treatment in stage IV metastatic melanoma

**ROCHE MO25515**

An open-label, multicenter expanded access study of RO5185426 in patients with metastatic melanoma

**BMS CA 184-029**

Adjuvant immunotherapy with anti-CTLA-4 monoclonal antibody (ipilimumab) versus placebo after complete resection of high-risk Stage III melanoma: a randomized, double-blind Phase III trial of the EORTC Melanoma Group

**GSK Predict**

Predictive gene signature fore REsponse to recMAGE-A3 in unresecteD metastatic CuTaneous melanoma Recombinant MAGE-A3 protein (recMAGE-A3) combined with the AS15 immunological Adjuvant System

**GSK Derma**

A double-blind, randomized, placebo-controlled phase III study to assess the efficacy of recMAGE-A3+AS15 ASCI as adjuvant therapy in patients with MAGE-A3 positive resected stage III melanoma

**BMS CA 184-025**

a multicenter, open-label, phase II study of Ipilimumab (MDX-010) extended-treatment Monotherapy or follow-up for patients previously enrolled in Ipilimumab (MDX-010) protocols

**BMS CA 184-024**

a multicenter, randomized, double-blind, two-arm, phase III Study in Patients with untreated stage III (unresectable) or IV Melanoma receiving Dacarbazine plus 10 mg/kg of Ipilimumab (MDX-010) vs. Dacarbazine with placebo