# PROTOCOLLI CLINICI PATOLOGIA TORACO-POLMONARE

### CARCINOMA POLMONARE NON A PICCOLE CELLULE:

# FASE NEODIUVANTE/ADIUVANTE

INT 03/18 A phase III, randomized, placebo controlled trial of platinum doublet chemotherapy +/-pembrolizumab (Mk-3475) as neoadjuvant/adjuvant therapy for participants with resectable stage IIB [N1] or IIIA non-small cell lung cancer (NSCLC) (keynote-671)

INT 60/18 A phase III, double-blinded, multicenter, randomized study evaluating the efficacy and safety of neoadjuvant treatment with atezolizumab or placebo in combination with platinum-based chemotherapy in patients with resectable stage II, IIIA or select IIIB non-small cell lung cancer

INT 35/18 A phase III multicenter randomized double blind placebo controlled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UICC v. 8 II-IIIA and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC)

### STADI TERZI NON OPERABILI

INT 196/18 A Phase II, Open-Label, Multi-Centre, International Safety Study of Durvalumab Following Sequential Chemotherapy and Radiation Therapy in Patients with Stage III, Unresectable Non-Small Cell Lung Cancer (PACIFIC 6)

INT 172/19 A Phase 2, Open-label, Multicenter, Randomized, Multidrug Platform Study of Durvalumab Alone or in Combination with Novel Agents in Subjects with Locally Advanced, Unresectable, Stage III Non-small Cell Lung Cancer (COAST)

# MALATTIA METASTATICA ONCOGENE -ADDICTED

INT 81/16 A Phase II single-arm trial to investigate tepotenib in advanced (locally advanced or metastatic) non small cell lung cancer with MET exon 14 (METex14) skipping alterations or MET amplification (VISION)

INT 45/18 Exploiting metformin plus/minus cyclic FAsting Mimicking diet (FMD) to improve the Efficacy of platinum-pemetrexed chemotherapy in advanced LKB1-mutated lung adenocarcinoma: the FAME trial

INT 196/19 A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients with Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1)

INT 136/18 A Phase 2 Study of Poziotinib in Patients with Non-Small Cell Lung Cancer, Locally Advanced or Metastatic, with EGFR or HER2 Exon 20 Insertion Mutation (ZENITH20)

INT 88/19 A Phase II, Single Arm Study Assessing the Efficacy of Osimertinib in Combination with Savolitinib in Patients with EGFRm+ and MET+, Locally Advanced or Metastatic Non-Small Cell Lung Cancer who have Progressed Following Treatment with Osimertinib (The SAVANNAH Study).

INT 235/19 A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ-61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects with Advanced Non-Small Cell Lung Cancer

### MALATTIA METASTATICA NON ONCOGENE -ADDICTED

INT 178/17 Phase II study to test pembrolizumab MK-3475 in first line treatment of advanced NSCLC patients with PD-L1-negative tumors (<50%)-PEOPLE TRIAL (PEmbrOlizumab in Pd-L1 mild Expressors)

INT 137/18 A Phase 1b Dose-Escalation Study of Cabozantinib (XL184) Administered in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors

INT 195-18 A Phase II, Multicenter, Randomized, Open-Label, Controlled Study of M7824 versus Pembrolizumab as a First-line Treatment in Patients with PD-L1 Expressing Advanced Non Small Cell Lung Cancer

INT 74/19 A Phase 1, Open-label, Dose-escalation and Dose expansion Study to Evaluate the Safety, Tolerability Pharmacokinetics Immunogenicity, and Antitumor Activity of MEDI5752 in Subjects with Advanced Solid Tumors

INT 22/19 Phase II, open-label study of atezolizumab in a CoHort of pretreated, Advanced Non-small cell lung cancer (NSCLC) patients with rare histologiCal subtypEs (CHANCE trial)

INT 212/18 A Phase II, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants

INT37/18 MILES 5 – A randomized phase 2 study comparing immunotherapy with chemotherapy in the treatment of elderly patients with advanced NSCLC

INT 122/19 Phase 3, multicenter, randomized, open-label trial to compare the efficacy and safety of pembrolizumab (MK-3475) in combination with lenvatinib (E7080/MK-7902) versus docetaxel in previously treated participants with metastatic non-small cell lung cancer (NSCLC) and progressive disease (PD) after platinum doublet chemotherapy and immunotherapy (anti-PD-1/PD-L1 inhibitor) (LEAP-008)

## **MICROCITOMA**

INT 194/18 A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, International Study of Durvalumab or Durvalumab and Tremelimumab as Consolidation Treatment for Patients with Stage I-III Limited Disease Small-Cell Lung Cancer Who Have Not Progressed Following Concurrent Chemoradiation Therapy (ADRIATIC)

INT 123/19 A phase IIIB, single arm, multicenter study of atezolizumab (tecentriq) in combination with carboplatin plus etoposide to investigate safety and efficacy in patients with untreated extensive-stage small cell lung cancer

INT 125/19 A randomized, open label phase 3 study of irinotecan liposome injection (ONIVYDE®) versus topotecan in patients with small cell lung cancer who have progressed on or after platinum-based first-line therapy

#### TIMOMA E CARCINOMA TIMICO

INT 23/18 Phase II trial of ramucirumab, carboplatin and paclitaxel in previously untreated thymic carcinoma/B3 thymoma

INT 165/16 Phase II trial of sunitinib in patients with type b3 thymoma or thymic carcinoma in second and further lines (STYLE trial)

## **MESOTELIOMA PLEURICO**

INT 40/17 Randomized, Double-Blind Phase 2/3 Study in Subjects with Malignant Pleural Mesothelioma with Low Argininosuccinate Synthetase 1 Expression to Assess ADI-PEG 20 with Pemetrexed and Cisplatin (ATOMIC-Meso Phase 2/3 Study)

INT 137/16 A phase II/III randomized study of pembrolizumab in patients with advanced malignant pleural mesothelioma

INT 119/19 A multicentre randomised phase III trial comparing atezolizumab plus bevacizumab and standard chemotherapy versus bevacizumab and standard chemotherapy as first-line treatment for advanced malignant pleural mesothelioma