Studi con Sponsor Industriale - attività di Radiologia Diagnostica (ruolo di principal investigator o coinvestigator):

1. BELLE-2. (CBKM120F2302). A phase III randomized, double blind placebo controlled study of BKM120 with fulvestrant, in postmenopausal women with hormone receptor-positive HER2-negative locally advanced or metastatic breast cancer which progressed on or after aromatase inhibitor treatment. Approvaz.: AUG/2012 (134/2013/O/Sper), EudraCT number: 2011-005524-17, cinicaltrials.gov ID: NCT01610284. Phase III, Sponsor NOVARTIS, APERTO solo F. U.
2. BAYER REFLEX: A Multicenter, Randomized, Open-Label, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib (E7080) Versus Sorafenib in First-Line Treatment of Subjects With Unresectable Hepatocellular Carcinoma. ClinicalTrials.gov Identifier: NCT01761266, EudraCT Number: 2012-002992-33 Phase III, Sponsor BAYER, APERTO SOLO F. U.
3. BAYER CELESTIAL. A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs Placebo in Subjects with Hepatocellular Carcinoma Who Have Received Prior Sorafenib. ClinicalTrials.gov Identifier: NCT01908426. Phase III, Sponsor BAYER, APERTO
4. PALOMA 3. A5481023 (Pfizer)- Multicenter, double-blind, randomized, placebo-controlled, Phase III trial of Fulvestrant (Faslodex) with or without PD-0332991 (Palbociclib)+/- Goserelin in women with hormone receptor-positive, HER2-negative metastatic breast cancer whose disease progressed after prior endocrine therapy. Clinical Trials.gov Identifier: NCT01942135. Phase III, Sponsor PFIZER, APERTO
5. PALOMA 2. A Study of Palbociclib (PD-0332991) + Letrozole vs. Letrozole For 1st Line Treatment Of Postmenopausal Women With ER+/HER2- Advanced Breast Cancer. ClinicalTrials.gov Identifier: NCT01740427 Phase III, Sponsor PFIZER, APERTO
6. ARIEL3. CO-338-014 (Clovis Oncology)- Studio di Fase 3 multicentrico, randomizzato, in doppio cieco, controllato con placebo verso Rucaparib come terapia di mantenimento nelle pazienti platino-sensibili con carcinoma ovarico recidivato, sierioso di alto grado o ovarico, carcinoma endometrioide, primario del peritoneo o delle tube di falloppio. A Study of Rucaparib as Switch Maintenance Following Platinum-Based Chemotherapy in Patients With Platinum-Sensitive, High-Grade Serous or Endometrioid Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer. ClinicalTrials.gov Identifier: NCT01968213. Phase III, Sponsor Clovis Oncology APERTO
7. MDV3100-12. Studio di fase 2, randomizzato, in doppio cieco, placebo-controllato, multicentrico sull'efficacia e la sicurezza di enzalutamide in combinazione con exemestane in pazienti con carcinoma mammario avanzato positivo per il recettore degli estrogeni o del progesterone e HER2-negativo. Safety Study of Enzalutamide in Combination With Exemestane in Patients With Advanced Breast Cancer. ClinicalTrials.gov Identifier: NCT02007512, EudraCT Number: 2013-002717-35.. Phase II Sponsor Medivation, Inc., APERTO
8. BAYER RESORCE (BAY 15982). A randomized, double blind, multicenter phase III study of regorafenib in patients with hepatocellular carcinoma (HCC) after sorafenib (59/2013/O/Sper), Numero EudraCT: 2012-003649-14, ClinicalTrials.gov Ide**n**tifier: NCT01774344. Phase III, Sponsor BAYER, APERTO SOLO F. U.
9. OLIMPYAD. Assessment of the Efficacy and Safety of Olaparib Monotherapy Versus Physicians Choice Chemotherapy in the Treatment of Metastatic Breast Cancer Patients With Germline BRCA1/2 Mutations. (OlympiAD). ClinicalTrials.gov Identifier: NCT02000622, EudraCT Number: 2013-005137-20. Phase III, Sponsor ASTRAZENECA, APERTO
10. COLUMBUS (CMEK162B2301). A phase III randomized, 3-arm, open label, multicenter study of LGX818 plus MEK162 and LGX 818 monotherapy compared with vemurafenib in patients with unresectable or metastatic BRAF V600 mutant melanoma. EudraCT

Number: 2013-001176-38, ClinicalTrials.gov Identifier: NCT01909453. Phase III, Sponsor Novartis, APERTO SOLO F. U.

11. APACT (ABI-007-PANC-003). A Phase 3, Multicenter, Open-label, Randomized Study of Nab-Paclitaxel Plus Gemcitabine Versus Gemcitabine Alone as Adjuvant Therapy in Subjects With Surgically Resected Pancreatic Adenocarcinoma. Cod. EudraCT: 2013-003398-91, ClinicalTrials.gov Identifier: NCT01964430 Phase III, Sponsor Celgene, APERTO
12. Studio di fase III, randomizzato in aperto con MK-3475 verso chemioterapia a base di platino, in prima linea, in pazienti con tumore al polmone non a piccole cellule, metastatico, con alti livelli di PD-L1. Cod. EudraCT: 2014-000323-25. Phase III, Sponsor Merck Sharp & Dohme Corp. APERTO
13. Phase 3, Randomized, Placebo-Controlled, Double-Blind, Multi-Center, Two-Part Study of Patritumab (U3-1287) In Combination With Erlotinib in EGFR Wild-type Subjects With Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) Who Have Progressed on at Least One Prior Systemic Therapy. ClinicalTrials.gov Identifier: NCT02134015. Fase III, Sponsor Daiichi Sankyo Inc. APERTO
14. CINC280X2105C. A phase Ib/II, multicenter, open-label study of EGF816 in combination with INC280 in adult patients with EGFR mutated non-small cell lung cancer. Numero EudraCT: 2014-000726-37. Phase Ib/II, Sponsor Novartis, APERTO
15. ALS-Gd64/001. Exploratory evaluation of the potential for long-term retention of Gadolinium (Gd) in the bones of patients who have received Gadolinium based Contrast Agents (GdCAs) according to their medical history. Sponsor Ecron Acunova. APERTO
16. Contrast enhanced uLtrasound for risk-stratification in patiEnts with liVer disEase by use of new softwaRe analysis: the CLEVER study. Numero Eudract:2016-000916-14. Sponsor: Eisai Ltd. APERTO
17. MDV3100-12 (Medivation, Inc.)- Studio di fase 2, randomizzato, in doppio cieco, placebo-controllato, multicentrico sull'efficacia e la sicurezza di enzalutamide in combinazione con exemestane in pazienti con carcinoma mammario avanzato positivo per il recettore degli estrogeni o del progesterone e HER2-negativo. Safety Study of Enzalutamide in Combination With Exemestane in Patients With Advanced Breast Cancer. ClinicalTrials.gov Identifier: NCT02007512. Phase II. Sponsor Medivation. APERTO
18. CC-486-BRSTM-001. Studio di Fase II, randomizzato, in aperto, a due bracci di trattamento per valutare l'efficacia e la sicurezza della terapia modificante epigenetica CC-486 (Azacitidina orale) somministrata in combinazione con Fulvestrant in donne in stato post-menopausale, con tumore della mammella metastatico ER+ e HER2- in progressione di malattia dopo trattamento con inibitori dell'aromatasi. NCT02374099. Phase II, Sponsor Celgene Corporation. APERTO
19. Abbvie M14-033. A double-blind, randomized, multicenter study of higher versus standard Adalimumab dosing regimens for induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis. Numero EudraCT: 2013-001682-16. SponsorAbbVie. APERTO
20. Abbvie M13-740. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Of Abt-494 For The Induction Of Symptomatic And Endoscopic Remission In Subjects With Moderately To Severely Active Crohn's Disease Who Have Inadequately Responded To Or Are Intolerant To Anti-Tnf Therapy". . Numero Eudract: 2014-003240-12. Sponsor: Novartis APERTO
21. ABI-007-NSCL-006. A Phase 2, randomized, open-label, multicenter study to assess Safety and efficacy of nab®-paclitaxel (ABI-007) with with epigenetic modifying therapy of cc-486, and nab®-paclitaxel monotherapy as Second-line treatment in subjects with advanced nonsquamous non-small cell lung cancer (NSCLC). ABOUND.2L . Numero EudraCT: 2014-001105-41. Fase II, Sponsor Celgene Corporation. APERTO

22. CLDK378A2112. A Phase I, multi-center, randomized open label study to assess the systemic exposure and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lungcancer (NSCLC). Numero Eudract:2014-004001-32. Phase I. Sponsor Novartis, APERTO
23. IPSEN PHARMA. Studio esplorativo di fase II per valutare l'efficacia e la sicurezza di tasquinimod in pazienti affetti da carcinoma prostatico metastatico, resistente alla castrazione (mcrpc), asintomatico o lievemente sintomatico, naive alla chemioterapia che hanno sviluppato una progressione durante la terapia con abiraterone acetato o enzalutamide. Numero EudraCT: 2014-003274-17. Phase II. Sponsor Ipsen Pharma APERTO
24. AGNOSTOS Trial 008-IRCC-10IIS-14. A Phase II, Randomized, Multicenter study to assess the efficacy of nab-paclitaxel-based douvblet as first line therapy in patients with cancer of unknown primary (CUP). Codice Eudract: 2014-005018-4. Phase II. Promotore: Fondazione del Piemonte per l'Oncologia FPO-IRCCS. APERTO
25. BMS-936558. A Phase I Dose Escalation Study to Investigate the Safety, Immunoregulatory Activity, Pharmacokinetics, and Preliminary Antitumor Activity of Anti-Programmed-Death-1 (PD-1) Antibody (BMS-936558) in Advanced Hepatocellular Carcinoma in Subjects with or without Chronic Viral Hepatitis. Numero EudraCT: 2012-001514-42. Phase I, Sponsor Bristol-Myers Squibb Research and Development. IN FASE DI ATTIVAZIONE
26. MORAb-003-011. A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) in Subjects with Low CA125 Platinum Sensitive Ovarian Cancer. Phase II, Sponsor Morphotek, Inc.- Eisai Co., Ltd. APERTO
27. CINC280A2201. A phase II, multicenter, two-cohort study of oral cMET inhibitor INC280 in adult patients with EGFR-wild type (wt), cMET-mutated or amplified, advanced NSCLC who failed first-line platinum-based chemotherapy. Numero EudracT: 2014-003850-15. Phase II. Sponsor: Novartis. APERTO
28. Roche GA29144. A phase III, randomized, double?blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Etrolizumab as an induction and maintenance treatment for patients with moderately to severely active CROHN'S DISEASE. Numero EudracT: 2014-003824-36. Phase III. Sponsor Roche. APERTO
29. GA29103. Studio multicentrico di fase III in doppio cieco, controllato con placebo per valutare l'efficacia e la sicurezza di eterolizumab durante la fase di induzione e di mantenimento nei pazienti affetti da colite ulcerosa da moderata a grave refrattari o intolleranti agli inibitori del TNF. Numero EudraCT: 2013-004282-14, Phase III. Sponsor: Hoffmann-La Roche. APERTO
30. CC-10004-UC-001. A PHASE 2, RANDOMIZED, PLACEBO-CONTROLLED, MULTICENTER STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF APREMILAST (CC-10004) FOR TREATMENT OF SUBJECTS WITH ACTIVE ULCERATIVE COLITIS. Numero EudraCT: 2014-002981-64. Phase II. Sponsor: Celgene. APERTO
31. AB12003. A prospective, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with docetaxel to placebo in combination with docetaxel in first line metastatic Castrate Resistant Prostate Cancer (mCRPC). Phase III. Codice Eudract: 2013-000809-23 . Phase III. Sponsor AB Science. IN FASE DI ATTIVAZIONE
32. ADAURA. Uno studio di fase III, in doppio cieco, randomizzato, controllato verso placebo, multicentrico, per valutare l'efficacia e la sicurezza di AZD9291 verso placebo, in pazienti con carcinoma polmonare Non a piccole cellule di stadio IB-IIIA positivo alla mutazione del recettore EGF (Epidermal Growth Factor), a seguito della resezione completa del

tumore con o senza chemioterapia adiuvante. Numero Eudract: 2015-000662-65. Phase III. Sponsor AstraZeneca. APERTO

33. EAGLE D4193C00002. Studio globale di fase III, randomizzato, in aperto, multicentrico di MEDI4736 in monoterapia e di MEDI4736 in combinazione con Tremelimumab rispetto alla terapia standard in pazienti affetti da carcinoma a cellule squamose della testa e del collo (SCCHN) ricorrente o metastatico – Numero Eudract: 2014/003863/40. Phase III. Sponsor AstraZeneca. APERTO
34. PEARLS. MK3475-091 / 1416-LCG. A randomized, phase 3 trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy. Numero Eudract: 2015-000575-27. Phase III. Sponsor Merck. APERTO
35. COLETTE. WO29479A multistage, Phase II study evaluating the safety and efficacy of cobimetinib in combination with paclitaxel as first-line treatment for patients with metastatic triple-negative breast cancer. Phase II. Sponsor Roche S.p.a. APERTO
36. CA209-227. Studio di fase III in aperto, randomizzato, con nivolumab o nivolumab più ipilimumab rispetto a una doppietta chemioterapica a base di platino in soggetti affetti da carcinoma polmonare non a piccole cellule (Non-Small Cell Lung Cancer, NSCLC) naïve alla chemioterapia, di stadio IV o recidivante. Numero EudracT: 2014-003630-23. Phase III. Sponsor Bristol-Myers Squibb s.r.l. APERTO
37. WO29636. STUDIO di fase III, multicentrico, randomizzato, in aperto sull'uso di atezolizumab (anticorpo anti-pd-l1) versus la sola osservazione come terapia adiuvante in pazienti con carcinoma vescicale muscolo-invasivo ad alto rischio, dopo cistectomia, selezionati in base allo stato di PD-L1. Codice EudracT: 2014-005603-25. Phase III. Sponsor Roche S.p.a. APERTO
38. L-PLUS 2. (1423M0634). Studio randomizzato di Fase 3, in doppio cieco, controllato con placebo per valutare la sicurezza e l'efficacia di S-888711 (Lusutrombopag) nel trattamento della trombocitopenia in pazienti affetti da malattia epatica cronica sottoposti a procedure elettive invasive. Codice EudracT: 2014-004942-91. Phase III. Sponsor Shionogi Inc. APERTO
39. ABI-007-NSCL-003. Studio di fase III in aperto, randomizzato, in aperto, multicentrico, per valutare la sicurezza e l'efficacia di nab-paclitaxel (Abraxane) come terapia di mantenimento dopo la fase di induzione con nab-paclitaxel più carboplatino in soggetti affetti da tumore al polmone non a piccole cellule squamoso (NSCLC) Numero Eudract 2014-003804-66. Phase III. Sponsor: Celgene Corporation. APERTO
40. ACH-UCP301. A Randomised, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of Topical Alicaforsen Enema in Subjects with Active, Chronic, Antibiotic Refractory Primary Idiopathic Pouchitis. Numero EudracT: 2013-002952-34. Sponsor Atlantic Pharmaceuticals Ltd. APERTO
41. CA209-032. Studio di fase I/ II, in aperto, con Nivolumab in monoterapia o Nivolumab in combinazione con Ipilimumab in soggetti con tumori solidi in fase avanzata o metastatica. Codice EudracT: 2014-003630-23. Phase I/II. Sponsor Bristol-Myers Squibb s.r.l. APERTO
42. CA 209-451. Studio randomizzato, multicentrico, in doppio cieco, di fase III di nivolumab, nivolumab in combinazione con ipilimumab o placebo come terapia di mantenimento in soggetti con carcinoma polmonare a piccole cellule in stadio esteso (ED-SCLC) che hanno completato una chemioterapia di prima linea a base di platino. Codice EudracT: 2015-002441-61. Phase III. Sponsor Bristol-Myers Squibb s.r.l. APERTO
43. ATREUS. Studio di fase II sull'attività della trabectedina in pazienti con mesotelioma pleurico mallignodi tipo epitelio ide pretrattato con tipo sarcomatoide misto. Codice EudracT: 2011-006330-16. Phase II. Sponsor IRCCS Istituto di Ricerche Farmacologiche Mario Negri. APERTO
44. A4091057. A phase 3 randomized, double-blind, placebo-controlled, multicenter study of the analgesic efficacy and safety of the subcutaneous administration of tanezumab in

subjects with ostheoartritis of the hip or knee. Numero Eudract: 2013-004508-21. Phase III. Sponsor Pfizer. APERTO

45. CNT01275UC03001. A phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group,Multicenter Protocol to Evaluate the safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis). Numero Eudract: 2014-005606-38. Phase III. Sponsor jansenn Cliag NV. APERTO
46. D4190C0006. Studio di fase 1b in aperto per valutare la sicurezza e la tollerabilità di MEDI4736 in combinazione con Tremelimumab in soggetti con carcinoma polmonare non a piccole cellule avanzato. Codice EudracT: 2015-003715-38. Phase Ib. Sponsor MedImmune, LLC. APERTO
47. CAIN457H2315. A randomized, double-blind, placebo-controlled multicenter study of secukinumab to evaluate the safety, tolerability and efficacy up to 2 years in patients with active non-radiographic axial spondyloarthritis. Numero EudraCT: 2015-001106-33. Sponsor Novartis Pharma Services AG. APERTO
48. CORAIL PM1183-C-004-14. Studio di fase III randomizzato con Lurbinectedina (PM01183) vs Doxorubicina pegilata liposomiale o Topotecan in pazienti con tumore dell'ovaio platino-resistente". Codice Eudract: 2014-005251-39. Phase III. Sponsor Pharma Mar S.A. APERTO
49. ATLANT. Efficacia e tollerabilità di Lanreotide ATG 120 mg in combinazione con Temozolomide in soggetti con tumore neuroendocrino ben differenziato del torace in progressione- A-93-52030-325. Codice EudracT: 2014-005579-10. Sponsor Ipsen SpA. APERTO
50. JAVELIN OVARIAN (B9991010). A randomized, open-label, multicenter, phase 3 study to evaluate the efficacy and safety of avelumab (msb0010718c) in combination with and/or following chemotherapy in patients with previously untreated epithelial ovarian cancer. Codice EudracT: 2015-003239-36.Phase III. Sponsor Pfizer. APERTO
51. 14T-MC-JVCY. Studio Multicentrico, Randomizzato in Doppio Cieco di Erlotinib in Combinazione con Ramucirumab o con Placebo, in Pazienti con Carcinoma Metastatico del Polmone Non a Piccole Cellule con Mutazione EGFR positiva, mai Trattati Precedentemente. Codice EudracT: 2014-003274-17. Sponsor: Eli Lilly. APERTO
52. MDV3100-20. A Phase 3, Randomized, International Study Comparing the Efficacy and Safety of Enzalutamide in Combination With Paclitaxel Chemotherapy or as Monotherapy Versus Placebo With Paclitaxel in Patients With Advanced, Diagnostic-Positive, Triple-Negative Breast Cancer. Codice EudracT: 2016-000796-25. Phase III. Sponsor: Medivation, Inc. APERTO
53. ASTRIS. Open Label, Multinational, Multicenter, Real World Treatment Study of Single Agent AZD9291 for Patients With Advanced/Metastatic Epidermal Growth Factor Receptor (EGFR) T790M Mutation-Positive Non-Small Cell Lung Cancer (NSCLC) Who Have Received Prior Therapy With an EGFR Tyrosine Kinase Inhibitor (EGFR-TKI). NCT02474355. Sponsor AstraZeneca. APERTO
54. TEMPO LUNG 01. Randomized Phase II study comparing single agent oral vinorelbine administered with two different schedules in patients with Advanced Non Small Cell Lung Cancer unfit for a platinum-based chemotherapy. Codice EudracT: 2014-003859-61. Phase II. Sponsor Pierre Fabbre. APERTO
55. WO39210. STUDIO DI FASE III, MULTICENTRICO, RANDOMIZZATO IN DOPPIO CIECO E CONTROLLATO VERSO PLACEBO PER VALUTARE ATEZOLIZUMAB (ANTICORPO ANTI-PD-L1) COME TERAPIA ADIUVANTE IN PAZIENTI AFFETTI DA IPERNEFROMA A SEGUITO DI NEFRECTOMIA E AD ALTO RISCHIO DI SVILUPPARE METASTASI. Codice EudracT: 2016-001881-27. Phase III. Sponsor F. Hoffmann-La Roche Ltd, Basilea Svizzera. APERTO
56. RAMES: A double-blind, placebo controlled, Randomized multicenter Phase II Study evaluating Gemcitabine with or without Ramucirumab as II line treatment for advanced malignant pleural mesothelioma (Protocol Code: GOIRC- 03-2016). EudraCT Number:

2016-001132-36. Phase II. Sponsor: Gruppo Oncologico Italiano di Ricerca Clinica (GOIRC). APERTO

57. CANSTEM-303C. A Phase III Study of BBI-608 in combination with 5-Fluorouracil, Leucovorin, Irinotecan (FOLFIRI) in Adult Patients with Previously Treated Metastatic Colorectal Cancer (CRCCodice EudracT: 2016-001627-31.). Phase III. Sponsor: Boston Biomedical Inc. APERTO
58. A Phase 2, Open-Label, Single-Agent, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations (INCB 54828-201). . Numero EudraCT: 2016-001321-14. Phase II. Sponsor: Incyte Corporation. APERTO
59. JAVELIN BLADDER 100 (B9991001). A PHASE 3, MULTICENTER, MULTINATIONAL, RANDOMIZED, OPEN-LABEL, PARALLEL-ARM STUDY OF AVELUMAB* (MSB0010718C) PLUS BEST SUPPORTIVE CARE VERSUS BEST SUPPORTIVE CARE ALONE AS A MAINTENANCE TREATMENT IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER WHOSE DISEASE DID NOT PROGRESS AFTER COMPLETION OF FIRST-LINE PLATINUM-CONTAINING CHEMOTHERAPY. EudraCT Number: 2015-003262-86. Phase III. Sponsor: Pfizer Inc. APERTO
60. CLEAR. Sperimentazione di fase 3 multicentrica, in aperto, randomizzata, per Confrontare l'efficacia e la sicurezza di Lenvatinib in combinazione con Everolimus o pembrolizumab rispetto a sunitinib in monoterapia nel trattamento di prima linea di soggetti con carcinoma a cellule Renali avanzato (CLEAR) - E7080-G000-307. Codice Eudract: 2016-000916-14. Phase III. Sponsor: Eisai Ltd. APERTO
61. Studio di fase IA/IB volto a valutare TAS-116 in pazienti con tumori solidi in stadio avanzato (a partire dall'Emendamento 7) precedentemente intitolato: Studio di fase I volto a valutare TAS-116 in pazienti con tumori solidi in stadio avanzato (Protocollo 10058010Numero EudraCT: 2015-005328-24Phase Ia/Ib.). Sponsor: Taiho Oncology, Inc. APERTO
62. EDEN Trial- GOIRC-04-2016. An open-label, randomized phase III study of Early switch maintenance vs delayed second-line Nivolumab in advanced stage squamous non-small cell lung cancer (NSCLC) patients after standard first-line platinum-based chemotherapy. Codice Eudract: 2016-003030-24. Phase III. Sponsor: Goirc. APERTO
63. MO39171 (TAIL). STUDIO DI FASE III/IV MULTICENTRICO, A SINGOLO BRACCIO DI TRATTAMENTO, VOLTO A VALUTARE LA SICUREZZA A LUNGO TERMINE E L'EFFICACIA DI ATEZOLIZUMAB (TECENTRIQ) IN PAZIENTI AFFETTI DA CARCINOMA POLMONARE NON A PICCOLE CELLULE LOCALMENTE AVANZATO O METASTATICO PRECEDENTEMENTE TRATTATI (TAIL). Numero EudraCT: 2017-001409-34. Phase III/IV. Sponsor: F. Hoffmann-La Roche Ltd, Basilea Svizzera. APERTO
64. ARASENS (BAY 94-9343/15834). Phase 1b multi-indication study of anetumab ravtansine (BAY 94-9343) in patients with mesothelin expressing advanced or recurrent malignancies. Numero EudraCT: 2016-004002-33. Phase Ib. Sponsor Bayer. APERTO
65. ERMES. Erbitux MEtastatic Colorectal Cancer Strategy Study: A Phase III Randomized Two Arm Study With FOLFIRI + Cetuximab Until Disease Progression Compared to FOLFIRI + Cetuximab for 8 Cycles Followed by Cetuximab Alone Until Disease Progression in First Line Treatment of Patients With RAS and BRAF Wild Type Metastatic Colorectal Cancer. Numero EudraCT:2014-004299-41. Promotore Dr. Barone Università Cattolica di Milano.. APERTO
66. AP26113-13-301. A Phase 3 Multicenter Open- label Study of Brigatinib (AP26113) versus Crizotinib in Patients with ALK- positive Advanced Lung Cancer. Codice EudracT: 2015-003447-19. Phase III. Sponsor: ARIAD Pharmaceuticals. APERTO
67. Millennium C31005. Studio di fase 2, in aperto per valutare l'efficacia e la sicurezza di MLN0128 come agente singolo e della combinazione MLN0128+MLN1117 rispetto ad everolimus nel trattamento di pazienti adulti con carcinoma a cellule renali a cellule chiare in stadio avanzato o metastatico progredito durante la terapia mirata al fattore di

crescita vascolare endotelial. Sponsor: Millenium Pharmaceuticals Inc. Phase II. Numero EudracT: 2015-002133-22. APERTO

68. A Phase I, open-label, multiple-ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity of MSB0011359C in subjects with metastatic or locally advanced solid tumors and expansion to selected indications. Sponsor. Codice EudracT: 2015-004366-28. Phase I. Merck KGaA EMR 200647-001. APERTO
69. CPDR001X2101. Open labelmulticenter phase I/ II study of the safety and efficacy of PDR001 administeredto patients with advanced malignancies. Numero EudracT: 2014-003929-17. Phase I/II. Sponsor: Novartis. APERTO
70. SAUL MO29983. Studio in aperto, a braccio singolo, multicentrico, sulla sicurezza di atezolizumab nel carcinoma uroteliale o non uroteliale delle vie urinarie localmente avanzato o metastatico. Codice Eudract: 2016-002625-11. Sponsor: F. Hoffmann-La Roche Ltd, Basilea Svizzera. APERTO
71. 0403/FORWARD 1. A Randomized, Open Label Phase 3 Study to Evaluate the Safety and Efficacy of Mirvetuximab Soravtansine (IMGN853) Versus Investigator's Choice of Chemotherapy in Women with Folate Receptor a-positive Advanced Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer. NCT number: NCT02631876. Phase III. Sponsor: ImmunoGen, Inc. APERTO
72. 64304500CRD2001 Protocollo di fase 2b, randomizzato, in doppio cieco, controllato verso placebo, a gruppi paralleli, multicentrico per valutare la sicurezza e l'efficacia di JNJ-64304500 in soggetti con morbo di Crohn attivo da moderato a grave. Phase IIB. Numero EudraCT: 2016-000634-21. Sponsor: Janssen-Cilag International. APERTO
73. A Phase 2b, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of JNJ-64304500 in Subjects with Moderately to Severely Active Crohn's Disease. Numero EudraCT: 2016-000634-21. Phase IIb. Sponsor: Janssen-Cilag International N. APERTO
74. AB12008 A prospective, multicenter, open-label, centrally allocated, active-controlled, phase 2/3 study to evaluate the efficacy and safety of masitinib in combination with gemcitabine versus gemcitabine alone in advanced/metastatic epithelial ovarian cancer patients in second line being refractory to first line platinum treatment or in third line. Numero EudraCT: 2013-000491-14. Phase II/III. Sponsor: AB Science IN FASE DI ATTIVAZIONE
75. ABBVIE ABT494. Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABT-494 for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis. Numero EudraCT: 2016-000641-31. Sponsor: AbbVie S.r.l APERTO
76. M14-533-1. CNTO1275CRD3005A Phase 3 Multicenter, Open-Label Extension (OLE) Study to Evaluate the Long-Term Safety and Efficacy of ABT-494 in Subjects with Ulcerative Colitis (UC. Numero Numero EudraCT: 2016-000674-38. Phase III. Sponsor: Abbvie. APERTO
77. ARIEL4 (Assessment of Rucaparib In Ovarian CancEr TriaL): A Phase 3 Multicenter, Randomized Study of Rucaparib versus Chemotherapy in Patients with Relapsed, BRCA-Mutant, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. Numero EudraCT: 2016-000816-14. Phase III. Sponsor Clovis Oncology-pfizer APERTO
78. ATTAIN. A Phase 3 Open-Label, Randomized, Multicenter Study of NKTR-102 versus Treatment of Physician's Choice (TPC) in Patients with Metastatic Breast Cancer Who Have Stable Brain Metastases and Have Been Previously Treated with an Anthracycline, a Taxane, and Capecitabine. NCT02915744.Phase III. Sponsor: Nektar Therapeutics. APERTO
79. BAY 94-9343/17631. An open label Phase Ib dose escalation study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and maximum tolerated dose of anetumab ravtansine in combination with pemetrexed 500 mg/m2 and cisplatin 75

mg/m2 in subjects with mesothelin-expressing predominantly epithelial mesothelioma or nonsquamous non-smallcell lung cancer. Numero EudraCT: 2016-003988-18. Phase Ib. Sponsor: Bayer HealthCare Pharmaceuticals Inc. APERTO

80. ARASENS BAY 1841788 / 17777. A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer. Numero EudraCT: 2015-002590-38. Phase III. Sponsor: BAYER AG. APERTO
81. The BEACON CRC. The BEACON CRC Study (Binimetinib, Encorafenib, And Cetuximab COmbined to Treat BRAF-mutant ColoRectal Cancer): A Multicenter, Randomized, Open-label, 3-Arm Phase 3 Study of Encorafenib + Cetuximab Plus or Minus Binimetinib vs. Irinotecan/ Cetuximab or Infusional 5- Fluorouracil (5-FU)/Folinic Acid (FA) /Irinotecan (FOLFIRI)/Cetuximab with a Safety Lead-in of Encorafenib + Binimetinib + Cetuximab in Patients with BRAF V600E-mutant Metastatic Colorectal Cancer. Numero EudraCT: 2015-005805-35. Phase III. Sponsor:Array BioPharma Inc. APERTO
82. CBYL719X2402. A phase II, multicenter, open-label, two-cohort, noncomparative study to assess the efficacy and safety of alpelisib plus fulvestrant or letrozole in patients with PIK3CA mutant, hormone receptor (HR) positive, HER2- negative advanced breast cancer (aBC), who have progressed on or after CDK 4/6 inhibitor treatment.. Numero EudraCT: 2016-004586-67. Phase II. Sponsor: Novartis. APERTO
83. CDKO-125a-010 Phase IIA Exploratory Study of Oral Milciclib Maleate in Patients with Unresectable or Metastatic Hepatocellular Carcinoma.. Numero EudraCT: 2017-000144-18. Phase II. Sponsor: Tiziana Life Sciences, PLC. APERTO
84. CLEE011X2110C. Study of Safety and Efficacy of LEE011 and Ceritinib in Patients With ALK-positive Non-small Cell Lung Cancer (CLEE0110C).. NCT02292550. Sponsor: Novartis Pharmaceuticals. APERTO
85. CO40016. A double-blind, placebo-controlled, randomized phase III study of IPATASERTIBIN combination with paclitaxel as a treatment for patients with PIK3CA/AKT1/PTEN-altered, locally advanced or metastatic, triple negative brest cancer or hormone receptor-positive, HER2-negative breast cancer. Numero EudraCT: 2017-00154836. Phase III. Sponsor: F. Hoffmann- La Roche Ltd. APERTO
86. CPDR001E2201. An open label phase II study to evaluate the efficacy and safety of PDR001 in patients with advanced or metastatic non-functional neuroendocrine tumors of pancreatic, gastrointestinal (GI), or thoracic origin who have progressed on prior treatment. Numero Eudract: 2016-002522-36. Phase II. Sponsor: Novartis APERTO.
87. DIADEM. A phase II study to investigate the activity and safety of anti-PD-L1 antibody (Durvalumab) in advanced pretreated malignant pleural mesothelioma. Numero EudracT: 2016-000617-67. Phase II Promotore: IRCCS Istituto di Ricerche Farmacologiche Mario Negri. IN FASE DI ATTIVAZIONE.
88. ENTERPRISE. A Randomized Double-Blind Phase 4 Study to Evaluate the Safety and Efficacy of 2 Dose Regimens of Entyvio (Vedolizumab IV) in the Treatment of Fistulizing Crohn's Disease. Numero EudraCT: 2015-000852-12. Phase IV. Sponsor: Takeda. APERTO.
89. FINCH 301. A Randomized, Double-blind, Placebo- and Active-controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 52 weeks in Combination with Methotrexate to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate. Numero EudraCT: 2016-000568-41. Phase III. Sponsor: Gilead Sciences, Inc APERTO
90. FINCH 302. A Randomized, Double-blind, Placebo-controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 24 weeks in Combination with Conventional Synthetic Disease-modifying Anti-rheumatic Drug(s) (csDMARDs) to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Biologic DMARD(s) Treatment (GS-US-417-0302). Numero EudraCT: 2016-000569-21. Phase III. Sponsor: Gilead Sciences, Inc. APERTO.

91. FINCH 303. Studio di Fase 3, randomizzato, in doppio cieco, controllato con placebo e controllo attivo, multicentrico per valutare l'efficacia e la sicurezza di filgotinib somministrato per 52 settimane in monoterapia e in combinazione con metotrexato (MTX) in soggetti affetti da artrite reumatoide da moderatamente a gravemente attiva che sono naïve alla terapia con MTX (GS-US-417-0303). Numero EudraCT: 2016-000570-37. Phase III. Sponsor: Gilead Sciences, Inc. APERTO
92. GS-US-350-1937. Studio di Fase 1b seguito da uno studio randomizzato a gruppi paralleli di Fase 2 volto a valutare la sicurezza, la tollerabilità e l'efficacia di GS-5829 in combinazione con exemestane o fulvestrant rispetto a exemestane o fulvestrant in monoterapia in soggetti affetti da carcinoma mammario positivo per i recettori degli estrogeni HER2-negativo in stadio avanzato. Numero EudraCT: 2016-002365-63. Phase Ib. Sponsor: Gilead Sciences Inc. APERTO
93. I4T-MC-JVDC. Studio di Fase 3, Randomizzato, in Doppio Cieco, Controllato con Placebo di Ramucirumab più Docetaxel verso Placebo più Docetaxel in Pazienti con Carcinoma Uroteliale Localmente Avanzato Non resecabile o Metastatico, che hanno avuto Progressione durante o dopo la terapia a Base di Platino. Codice EudracT: 2014-003655-66. Phase III. Sponsor: Eli Lilly Italia S.p.A APERTO
94. IRENE 1. Studio interventistico senza medicinale, multicentrico in pazienti affetti da adenocarcinoma localmente avanzato del pancreas: radioterapia stereotassica. U.O. di Radioterapia. APERTO. ClinicalTrials.gov ID: NCT03460925. APERTO
95. IRMA-RE. Studio interventistico senza medicinali, spontaneo, monocentrico, prospettico. Radioterapia preoperatoria short-course accelerata con tecnica IMRT nel carcinoma del retto (Radiotherapy with Modulated Accelerated technique in rectal carcinoma). Cod. 119/2016/O/Sper. No profit. APERTO.
96. KATE2. WO30085. Studio di fase II, randomizzato, multicentrico, in doppio cieco, controllato con placebo, sull'efficacia e la sicurezza di Trastuzumab emtansine in associazione ad atezolizumab o placebo in pazienti con tumore mammario HER-2-positivo localmente avanzato o metastatico che hanno ricevuto in precedenza una terapia a base di Trastuzumab e un taxano. Codice EudracT: 2015-004189-27. Phase II. Sponsor: F. Hoffmann- La Roche Ltd. APERTO.
97. M14-237. A multicenter, phase I/Ib, open label, dose escalation study of ABBV-399, an antibody drug conjugate, in subjects with advanced solid tumorsNumero EudraCT: 2014-003154-14.Phase I/Ib. Sponsor: Abbvie Inc. IN FASE DI ATTIVAZIONE
98. METRIC. A Randomized Multicenter Pivotal Study of CDX-011 (CR011-vcMMAE) in Patients with Metastatic, GPNMB Over-Expressing, Triple-Negative Breast Cancer (The "METRIC" Study, prot. number CDX011-04). Numero EudraCT: 2015-003693-33. Sponsor: Celldex Therapeutics, Inc. APERTO
99. ML39453 AMADEUS. studio multicentrico a braccio singolo di fase II con ATEZOLIZUMAB nel mesiotelioma pleurico metastatico in progressione durante o dopo uno o due trattamenti sistemici. Numero EudraCT: 2016-004972-23. Phase II. Sponsor: F. Hoffmann- La Roche Ltd, Basilea, Svizzera. APERTO
100. NASH. Uno studio randomizzato in doppio-cieco, controllato verso placebo, in 2 parti, con disegno adattativo, multicentrico, della durata di 12 settimane per valutare sicurezza, tollerabilità ed efficacia di LJN452 in pazienti con steatoepatite non alcolica. Study of Safety and Efficacy of Tropifexor (LJN452) in Patients With Non-alcoholic Steatohepatitis (NASH) (FLIGHT-FXR). LJN452/CLJN452A2202. Numero EudraCT: 2015-005215-33. . Sponsor: Novartis. APERTO
101. NORM-ENDO1. Definizione dei range di normalità degli steroidi in condizioni basali e in condizioni di stimolo/soppressione. APERTO
102. ODO-TE-B301. A Multinational, Multicenter, Randomized, Phase 3 Study of Tesetaxel plus a Reduced Dose of Capecitabine versus Capecitabine Alone in Women with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer

Previously Treated with a Taxane (CONTESSA). NCT03326674. Phase III. Sponsor: Odonate Therapeutics, LLC.

103. Oncothyreon. Cascadian HER2CLIMB (ONT-380-206). Phase 2 Randomized, Double-Blinded, Controlled Study of ONT-380 vs. Placebo in Combination with Capecitabine and Trastuzumab in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma. EudraCT Number: 2015-002801-12. Phase II. Sponsor: Oncothyreon, Inc. APERTO
104. M14-533 COLITE ULCEROSA. Studio di fase IIB in doppio cieco randomizzato, controllo verso-placebo, a gruppi paralleli su PF-06651600 E PF-06700841 a vari dosaggi somministrati per via orale come terapia di induzione e cronica in soggetti affetti da colite ulcerosa da moderata a grave. (Prot. N° B7981005). Numero Eudract: 2016-003708-29. Phase IIb. Sponsor: Pfizer. APERTO
105. BAYER PROGRESS. An investigator-initiated, multicentre, randomized, trial comparing anticoagulation alone versus transjugular intrahepatic portosystemic shunt (TIPS) and anticoagulation in patients with recent obstructive portal vein thrombosis. NCT03422419. Sponsor: BAYER. APERTO
106. Protocol CMCS110Z2201. A randomized phase II study of MCS110 combined with carboplatin and gemcitabine in advanced Triple Negative Breast Cancer (TNBC). Numero EudracT: 2015-000179-29. Phase II. Sponsor: Novartis APERTO
107. Roche BP39261. A Study of RO7123520 to Evaluate the Safety and Efficacy in Participants With Moderately To Severely Active Rheumatoid Arthritis (RA) Who Are Inadequately Responding to Anti-Tumor Necrosis Factor (TNF)-Alpha Therapy. Numero EudracT: 2016-002126-36. Sponsor: Hoffmann-La Roche. APERTO
108. Roche IMagyn050 YO39523. A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination with Paclitaxel, Carboplatin & Bevacizumab to Patients with Newly Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube or Primary Peritoneal Cancer. EudraCT Number: 2016-003472-52. Phase III. Sponsor: F. Hoffmann- La Roche Ltd. APERTO
109. SGN LIV1A. Studio di fase 1b/2, a braccio singolo, in aperto, di SGN LIV1A in combinazione con pembrolizumab per il trattamento di prima linea di pazienti con tumore mammario triplo negativo non resecabile localmente avanzato o metastatico. Numero EudraCT: 2017-002289-35. Sponsor: Seattle Genetics, Inc. APERTO
110. SHERBOC. A Double-blind, Placebo-controlled, Phase 2 trial of Seribantumab Plus Fulvestrant in Postmenopausal Women with Hormone Receptor-positive, Heregulin Positive (HRG+), HER2 Negative Metastatic Breast Cancer Whose Disease Progressed After Prior Systemic Therapy. Codice Eudract: 2017-000565-76. Phase II. Sponsor: Merrimack Pharmaceuticals, Inc. APERTO
111. SPECT-HR-17-01. Uso della scintigrafia epatobiliare SPECT/TC in pazienti candidati ad epatectomia in uno o due tempi. Studio osservazionale prospettico. Promotore: U.O. Chirurgia Generale e dei Trapianti Bologna. APERTO
112. TRANSMET Curative potential of liver transplantation in patients with definitively unresectable colorectal liver metastases (CLM) treated by chemotherapy: a prospective multicentric randomized trial. NCT02597348 Phase III. Sponsor: Assistance Publique – Hôpitaux de Paris. APERTO
113. TULIP-SYD985.002. A phase III, multi-centre, open-label, randomized clinical trial comparing the efficacy and safety of the antibody-drug conjugate SYD985 to physician's choice in patients with HER2-positive unresectable locally advanced or metastatic breast cancer. NCT03262935. Phase III. Sponsor: Synthon Biopharmaceuticals. APERTO
114. M14-327 A Phase 2, Multicenter, Open-Label Extension (OLE) Study to Observe the Long-Term Efficacy, Safety, and Tolerability of Repeated Administration of ABT-494 in Subjects with Crohn's Disease (M14-327).. Numero EudraCT: 2015-003759-23. Phase II. Sponsor: AbbVie APERTO

115. CNTO1275CRD3005. Study of Treat to Target Versus Routine Care Maintenance Strategies in Crohn's Disease Patients Treated With Ustekinumab (STARDUST). Numero EudraCT: 2016-002918. Sponsor: Janssen-Cilag Ltd. APERTO
116. CAIN457F3301 ACHILLES. Study of Efficacy and Safety of Secukinumab in Psoriatic Arthritis and Axial Spondyloarthritis Patients With Active Enthesitis Including One Achilles Tendon Site. Numero Eudract: 2016-000972-91. Phase IIIb. Sponsor: Novartis. APERTO
117. CAIN457F3302 MAXIMISE protocol. Study of the efficacy and safety of secukinumab in participants with active psoriatic arthritis with axial skeleton involvement. Numero EudraCT: 2016-000814-31. Sponsor: Novartis. APERTO
118. VIOLETTE. A phase II, open label, randomised, multi-centre study to assess the safety and efficacy of agents targeting DNA damage repair in combination with Olaparib versus olaparib monotherapy in the treatment of metastatic triple negative brest cancer patients stratified by alterations in homologus recombinant repair (HRR)-related genes (including BRCA ½). Phase II. Sponsor: AstraZeneca. EudraCT N°: 2017-002361-22. ClinicalTrials.gov ID: NCT03330847. APERTO
119. KEYNOTE 826. A Phase 3 Randomized, double-blind, placebo-controlled trial of Pembrolizumab (MK-3475) plus chemotherapy versus chemotherapy plus placebo for the first-line treatment of persistent, recurrent, or metastatic Cervical Cancer. Phase III. Sponsor: Merck Sharp & Dohme Corp. EudraCT N°: 2018-001440-53. ClinicalTrials.gov ID: NCT03635567. APERTO
120. Studio ADMIRE-CD II. Tigenix Cx601-0303. Phase-III randomized, double-blind, parallel-group, placebo-controlled, multicentre study to assess efficacy and safety of Cx601, allogeneic expanded adipose-derived stem cells for complex perianal fistula(s) in Crohn's Disease. Phase III. Sponsor: TiGenix S.A.U. EudraCT N°: 2017-000725-12. ClinicalTrials.gov ID: NCT03279081. APERTO.
121. GCT1015-04. A single arm, multicenter, international trial of Tisotumab Vedotin (HuMax-TF-ADC) in previously treated, recurrent or metastatic cervical cancer. Phase II. Sponsor: Genmab A/S. EudraCT N°: 2017-003413-25. ClinicalTrials.gov ID: NCT03438396. APERTO
122. B9991030 - JAVELIN OVARIAN PARP 100. A randomized, open-label, multicenter, phase III study to evaluate the efficacy and safety of Avelumab in combination with chemotherapy followed by maintenance therapy of Avelumab in combination with the poly (ADENOSINE DIPHOSPHATE [ADP]-RIBOSE) polymerase (PARP) inhibitor talazoparib in patients with previously untreated advanced ovarian cancer. Sponsor: Pfizer. EudraCT N°: 2017-004456-30. IN FASE DI ATTIVAZIONE
123. B9991032 - JAVELIN BRCA/ATMN. A phase 2 study to evaluate safety and anti-tumor activity Avelumab in combination with Talazoparib in patients with BRCA or ATM mutant tumors. APERTO
124. DS8201-A-U301. DESTINY-Breast02 - A Phase 3, Multicenter, Randomized, Open-label, Active-controlled Study of DS-8201a, an Anti-HER2-antibody Drug Conjugate, Versus Treatment of Investigator's Choice for HER2-positive, Unresectable and/or Metastatic Breast Cancer Subjects Pretreated With Prior Standard of Care HER2 Therapies, Including T-DM1. Sponsor: Daiichi Sankyo Inc. EudraCT N°: 2018-000221-31 ClinicalTrials.gov Identifier: NCT03523585. APERTO
125. DS8201-A-U302. DESTINY-Breast03 - A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study of DS-8201a (Trastuzumab Deruxtecan), an Anti-HER2 Antibody Drug Conjugate (ADC), Versus Ado Trastuzumab Emtansine (T-DM1) for HER2-Positive, Unresectable and/or Metastatic Breast Cancer Subjects Previously Treated With Trastuzumab and Taxane. Sponsor: Daiichi Sankyo Inc. EudraCT N°: 2018-000222-61 ClinicalTrials.gov Identifier: NCT03529110. APERTO