# **THORAX**



|   |                   |       |   |                                  |                                      | COHORT TYPE   |  |
|---|-------------------|-------|---|----------------------------------|--------------------------------------|---|--|
| S | TUDY NAME         | PHASE | MOLECULE  | COHORT<br>NUMBER                 | TUMOR TYPE                           | SPECIFICITY   | PREVIOUS LINE  |
|   | AGADIR            | II    | Atezolizumab + BDB001 +<br>radiothérapie          | 3                                | NSCLC                                | Refractory anti PD-1/L1   |  |
| c | FT1946-1101       | 1/11  | CFT1946   | Phase 1<br>(escalade<br>de dose) | NSCLC                                | BRAFi, platinum-based therapy (if eligible),<br>and an immunotherapy regimen including ICI<br>(in any sequence or in combination) | If the immunotherapy regimen (or the immuno-<br>oncology combination) was given in the<br>neoadjuvant or adjuvant setting, subjects are<br>eligible if they progressed either on treatment or<br>within the 6 months following completion. |
|   | DS8201-A-<br>U106 | Ib    | Trastuzumab + Deruxtecan IV<br>+ Pembrolizumab iV | 3                                | NSCLC                                | HER2-expression (IHC 1+, 2+, or 3+)   | Patients must not have received prior treatment with anti-PDL-1, anti-PD-1, or anti-HER2   |
|   | IMC-F106          | I     | IMC-F106C (IV)                                    | Part 1<br>Arm A-1                | NSCLC                                | HLA-A*02:01- positive, PRAME-positive tumor   | Participants must not have received prior<br>treatment with an ImmTAC, including tebentafusp,<br>IMCnyeso, or IMC-C103C.   |
|   | Regomune          | II    | Regorafenib + Avelumab                            | P                                | Malignant<br>pleural<br>mesothelioma |   | At least one line and max 1 line of PD(L)1/CTLA-4<br>mAb (received at least 4 month), anti PDL1 not<br>mandatory   |



# **THORAX**

|                    |       |   |                  |  | COHORT TYPE   |   |   |
|--------------------|-------|---|------------------|--|---|---|---|
| STUDY NAME         | PHASE | MOLECULE                                | COHORT<br>NUMBER | TUMOR TYPE   | SPECIFICITY   | PF  | EVIOUS LINE   |
|                    | 1/11  | REGN7075 +<br>Cemiplimab+chimiotherapie | С                | NSCLC  | Advanced or metastatic NSCLC do not have previously documented targetable molecular alterations (eg, ALK, ROS1, EGFR, Met Ex14, etc)  | no prior systemi<br>metastatic NSCL   | D-1/PD-L1 naïve<br>c treatment for recurrent or<br>C (adjuvant or neoadjuvant<br>s will not be counted as a prior<br>line)  |
| R7075-ONC-<br>2009 |       | REGN7075 +<br>Cemiplimab+chimiotherapie | G                | EGFR-mutant<br>NSCLC post<br>third generation<br>TKI                       | NSCLC that harbors EGFR Exon 19 deletion -<br>NSCLC that harbors EGFR L858R mutation -<br>NSCLC with activating EGFR exon20 insertion-<br>NSCLC with exon 18/21 atypical mutations,<br>Stable CNS disease allowed, Small cell<br>transformation is excluded | Chen<br>Have received trea<br>TKI : For patients w<br>documented EFG<br>mutation, prior                             | D-1/PD-L1 naïve notherapy naïve tment with a third generation nose tumors harbor previously R Exon19 deletion or L858R osimertinib or other third KI treatment is required                        |
|                    |       | REGN7075 + Cemiplimab                   | н                | EGFR-mutant  | locally advanced or metastatic non-squamous<br>NSCLC, NSCLC that harbors EGFR Exon 19<br>deletion - NSCLC that harbors EGFR L858R<br>mutation - NSCLC with activating EGFR exon20<br>insertion- NSCLC with exon 18/21 atypical<br>mutations                 | Have received trea TKI : For patients wi<br>documented EFG<br>mutation, prior<br>generation T<br>Have received trea | D-1/PD-L1 naïve tment with a third generation nose tumors harbor previously R Exon19 deletion or L858R osimertinib or other third KI treatment is required tment with platinum-doublet emotherapy |
| TNG908-C101        | II    | TNG908                                  | 1                | Locally advanced or metastatic MTAP-deleted NSCLC squamous or non squamous |   |   | 1 standard-of-care targeted or the known alteration   |
|                    |       |   | 2                | Locally<br>advanced or<br>metastatic<br>MTAP-deleted<br>mesothelia         |   |   |   |





# Senology

|                    |       |   |                     | COHORT TYPE   |  |   |
|--------------------|-------|---|---------------------|---|--|---|
| STUDY NAME         | PHASE | MOLECULE  | COHORT<br>NUMBER    | TUMOR TYPE  | SPECIFICITY  | PREVIOUS LINE   |
| INCB123667-<br>101 | 1     | INCB123667                                      | Part 1b<br>Group 4  | TNBC  |  | 2 prior lines of chemotherapy max   |
| REGOMUNE           | II    | Regorafenib +<br>Avelumab                       | L                   | TNBC  |  | At least one line and max 1 line of PD(L)1 mAb (received at least 4 month) anti PDL1 mandatory  |
|                    |       | RLY-2608 +<br>Fulvestrant                       | 2                   | group 1a : Advanced/metastatic<br>breast cancer PIK3CAmut | PIK3CAmut, HR+, HER2-<br>RP2D1 (600mg BID)<br>Expansion                | with NO prior PI3K alpha inhibitor<br>RP2D1 (dose recommended 1)  |
| RLY 2608-101       | 1     | RLY-2608 +<br>Ribociclib 400mg +<br>Fulvestrant | 1                   | Advanced/metastatic breast cancer                         | PIK3CAmut HR+ HER2-<br>Dose escalation                                 | with NO prior PIK3CA α inhibitor  |
|                    |       | RLY-2608 + Ribociclib 600mg + 1 Fulvestrant     |                     | Advanced/metastatic breast cancer                         | PIK3CAmut HR+ HER2-<br>Dose escalation                                 | with NO prior PIK3CA α inhibitor  |
| STX-487-101        | 1/11  | STX-478   | Part<br>1,2A1       | Breast cancer   | PI3KαH1047X mutation<br>or other kinase domain<br>mutations, HR+/HER2- | Must have received for stage III or IV disease: at least 1 CDK4/6 inhibitor regimen at least 1 anti-estrogen therapy and no more 2 prior systemic chemotherapy No prior treatment with PI3K/AKT/mTOR inhibitor    |
| 51X-48/-101        | 1/11  | STX-478+<br>Fulvestrant                         | Part 2<br>cohorte B | Breast cancer   | PI3Kα H1047X mutations<br>or other kinase domain<br>mutations          | No prior treatment with PI3K/AKT/mTOR inhibitor Have received CDK4/6 inhibitor, unless the participant is deemed by the investigator intolerant to these agents Antiestrogen therapy (see inclusion criterion 13) |





# Thyroid

Tous ces essais sont à retrouver sur ACTIS Oncology sur l'application Oncoclic pour un adressage facilité de vos patients, télécharger l'application :

|              | PHASE | MOLECULE                |             |       | COHORT TYPE   |                |                                    |
|--------------|-------|-------------------------|-------------|-------|---|----------------|------------------------------------|
| STUDY NAME   |       |                         | COHORT      | TUMOR | CDECIFICITY   |                | PDE VIOLIC LINE                    |
|              |       |                         | NUMBER      | TYPE  | SPECIFICITY   | PREVIOUS LINE  |                                    |
|              |       | CET1046 .               | Arm B       | ATC   | SoC therapy options per their physician's best judgment | All subjects m | ust have received ≥1 prior line of |
| CFT1946-1101 | 1/11  | CFT1946 +<br>Tramétinib | (CFT1946+   |       |   | SoC therap     | y for their unresectable locally   |
|              |       |                         | trametinib) |       | juagment  | advan          | ced or metastatic disease,         |
|              |       |                         |             |       |   |                |                                    |



### **DERMATOLOGY**

|                         | 1     |                           |                                 |  |   |                              |  |
|-------------------------|-------|---------------------------|---------------------------------|--|---|------------------------------|--|
|                         |       | MOLECULE                  |                                 |  | COHORT TYPE   |                              |  |
| STUDY NAME              | PHASE |                           | COHORT<br>NUMBER                | TUMOR<br>TYPE                              | SPECIFICITY   |                              | PREVIOUS LINE  |
| CFT1946-1101            | 1/11  | CFT1946                   | Phase 1<br>(dose<br>escalation) | Melanoma                                   | BRAFi and an immunotherapy regimen including ICI (in any sequence or in combination). NOTE: experimental small molecule checkpoint/BRAF inhibitors given in the context of a clinical trial are acceptable. | SoC therapy<br>advanced or m | st have received ≥1 prior line of<br>for their unresectable locally<br>letastatic disease, with disease<br>progression<br>iter last prior treatment. |
| EVICTION-ICT-<br>01-101 | I/IIa | ICT01 +<br>Pembrolizumab  | G                               | Melanoma<br>CPI-<br>refractory             | Circulating γ9δ2 T cell count ≥ 20000 cells/mL<br>Pembro Combo  |                              | At least one line  |
| KN-8702                 | lb    | KIN-2787 +<br>BINIMETINIB | A2                              | Melanoma                                   | NRAS mut  | •                            | ocally approved standard of care<br>r their tumor type and stage of<br>disease   |
| R7075-ONC-<br>2009      | 1/11  | REGN7075 +<br>Cemiplimab  | В                               | Cutaneous<br>squamous<br>cell<br>carcinoma | Metastatic CSCC or locally advanced CSCC  | Ant                          | ti-PD-1/PD-L1 naive  |



### **UROLOGY**

| I |            | PHASE |   |                  |                                      | COHORT TYPE             |   |
|---|------------|-------|---|------------------|--------------------------------------|-------------------------|---|
|   | STUDY NAME |       |   | COHORT<br>NUMBER | THIMOR TYPE                          | SPECIFICITY             | PREVIOUS LINE   |
|   | AGADIR     | II    | Atezolizumab +<br>BDB001 +<br>radiothérapie | 5                | UBC                                  | Refractory anti PD-1/L1 |   |
|   |            |       | Regorafenib + Avelumab O                    | J                | Urothélial                           |                         | At least one line and max 1 line of PD(L)1 mAb          |
|   | REGOMUNE   | II    |   | 0                | Non clear-cell<br>renal<br>carcinoma |                         | (received at least 4 month), anti PDL1 not<br>mandatory |



#### **GYNECOLOGY**

|             |                     |            |                   | C   | OHORT TYPE   |   |
|-------------|---------------------|------------|-------------------|---|--|---|
| STUDY NAME  | PHASE               | MOLECULE   | COHORT<br>NUMBER  | TUMOR TYPE  | SPECIFICITY  | PREVIOUS LINE   |
|             |                     |            | M2                | Ovarian clear cell carcinoma                                    | ARIDA1 mutated   | Previous treatement with EZH2 inhibitor forbidden   |
| CPI-0209    | CPI-0209 II CPI0209 |            | М3                | Endometrial carcinoma   | ARIDA1 mutated   | Previous treatement with EZH2 inhibitor<br>forbidden  |
| INCB123667- | 1                   | INCB123667 | grp 1             | Ovarian/fallopian/<br>primary peritoneal<br>cancer              | CCNE1 amplification  | With advanced platinum-based chemotherapy-<br>refractory or resistant + max 4 lines of systemic<br>therapy for advanced or metastatic disease |
| 101         |                     |            | Part 1b<br>grp 2  | endometrial/uterin<br>e cancer                                  | CCNE1 amplification  | 3 prior lines of systemic therapy max   |
| IMC-F106C   | I IMC-E106C (IV)    |            | Part 1,<br>Arm A1 | High Grade Serous<br>Ovarian Carcinoma                          | HLA-A*02:01- positive, PRAME-positive tumor                | Participants must not have received prior<br>treatment with an ImmTAC, including<br>tebentafusp, IMCnyeso, or IMC-C103C.                      |
| STX-487-101 | 1/11                | STX-478    | Part<br>1,2A2     | Endometrial<br>cancer, ovarian<br>cancer and cervical<br>cancer | PI3Kα H1047X mutations or other kinase<br>domain mutations | No prior treatment with PI3K/AKT/mTOR inhibitor   |



#### **DIGESTIF**



| STUDY NAME         | PHASE | MOLECULE               |                                   | COHORT TYPE                                 |   |   |  |
|--------------------|-------|------------------------|-----------------------------------|---|---|---|--|
|                    |       |                        | COHORT<br>NUMBER                  | TUMOR TYPE                                  | SPECIFICITY   | PREVIOUS LINE   |  |
| CFT1946-1101       | 1/11  | CFT1946                | Arm A<br>(CFT1946<br>monotherapy) | CRC   | Systemic chemotherapy based regimen per SoC for unresectable locally advanced or metastatic disease, and a BRAFi in combination with an EGFR mAb. NOTE: Both MSS and MSI-H CRC are eligible for inclusion in this study, although required prior therapy differs (MSI-H requires prior immunotherapy) | Subjects with microsatellite instability-high (MS<br>I) or mismatch repair-deficient (dMMR) CRC mu<br>have received immunotherapy.<br>Subjects with microsatellite stable (MSS) CRC ar<br>eligible, provided they have received at least 2<br>prior treatments. |  |
| INCB123667-<br>101 | 1     | INCB123667             | Part1b group 3                    | Gastric, GEJ and esophageal adenocarcinomas | CCNE1 amplification   | 3 prior lines of systemic therapy max   |  |
| MK-345-158         | Ш     | Pembrolizumab          | К                                 | Gastric Small intestine Billary             | MSI-high  | At least one line   |  |
| REGOMUNE           | II    | Regorafenib + Avelumab | A'                                | Colorectal                                  | Not MSI-high or MMR<br>deficient (macrophage<br>infiltrate)   | At least one line   |  |



# **DIGESTIF**



| STUDY NAME         | PHASE | MOLECULE              |                  | COHORT TYPE   |  |  |
|--------------------|-------|-----------------------|------------------|---|--|--|
|                    |       |                       | COHORT<br>NUMBER | TUMOR TYPE  | SPECIFICITY  | PREVIOUS LINE  |
| R7075-ONC-<br>2009 | 1/11  | REGN7075 + Cemiplimab | F                | Microsatellite stable<br>colorectal cancer (MSS-CRC)  | of screening Only sites of   | Patients with previously documented RAS wild type disease must have received anti-EGFR therapy Patients must have received anti-VEGF therapy or have a documented reason why anti-VEGE |
| TNG908-C101        | II    | TNG908                | 4                | Locally advanced or metastatic MTAP-deleted pancreatic ductal adenocarcinoma or adenosquamous carcinoma with predominantly adenocarcinoma histology | Documented bi-allelic<br>(homozygous) deletion of<br>MTAP in a tumor detected<br>by a<br>validated NGS test, or<br>absence of MTAP protein in<br>a tumor detected by a<br>validated<br>IHC test. |  |



#### **SARCOMAS**

| ſ |            | PHASE |                         |                  | cc         | HORT TYPE                          |  |
|---|------------|-------|-------------------------|------------------|------------|------------------------------------|--|
|   | STUDY NAME |       |                         | COHORT<br>NUMBER | TUMOR TYPE | SPECIFICITY                        | PREVIOUS LINE  |
|   | Multisarc  | 11    | Olaparib-<br>Durvalumab |                  |            | Unresecable, targetable alteration | At least one line for metastatic disease or locally advanced disease |



#### **NEUROLOGY**

|             |       | MOLECULE      |                  |                                     | COHORT TYPE  |   |
|-------------|-------|---------------|------------------|-------------------------------------|--|---|
| STUDY NAME  | PHASE |               | COHORT<br>NUMBER | TUMOR TYPE                          | SPECIFICITY  | PREVIOUS LINE   |
| MegaMOST    | II    | Alectinib BID | С                | Neuroblastoma                       | Activating ALK alterations : translocation, mutation | ne line for metastatic disease, no<br>ALK inhibitor (except crizotinib) |
| TNG908-C101 | II    | TNG908        | 6                | MTAP-deleted<br>R/R<br>Glioblastoma |  |   |



# Solid tumors

|               |                                       |  |  | C  | OHORT TYPE   |   |
|---------------|---------------------------------------|--|--|--|--|---|
| STUDY NAME    | PHASE                                 | MOLECULE                                 | COHORT<br>NUMBER   | TUMOR TYPE   | SPECIFICITY  | PREVIOUS LINE   |
| CFT1946-1101  | 1/11                                  | CFT1946 + Tramétinib                     | Arm B  | Other [non-CNS]<br>Solid tumors  | including BRAFi if available and of benefit to<br>the subject  | With disease progression on or after last prior treatment |
|               |                                       |  |  | HNSCC  | PI3KCA TUMOR TISSUE OR LIQUID BIOPSY   | Must have received standard therapy                       |
| CO42800       | I                                     | Inavolisib + taxol                       | 2  | Ovarian  | PI3KCA<br>TUMOR TISSUE OR LIQUID BIOPSY  | Must have received standard therapy                       |
| EZH-1201      |                                       | Tazemetostat                             | 1  | Solid Tumors   | Moderate hepatic impairment (NCI-ODWG)   | At least one line, no prior anti-EZH2                     |
| E2H-1201      | •                                     | razemetostat                             | 2  | Solid Tumors   | Severe hepatic impairment (NCI-ODWG)   | At least one line, no prior anti-EZH2                     |
| F8394-201     | 1/11                                  | FORE8394 (900mg) +<br>Cobicistat (150mg) | Subproto A   | solid tumors with or without CNS metastases or recurrent/progressi ve primary CNS tumors   | Fusion of BRAF in tumor tissue or liquid biopsy  | At least on standard line                                 |
| IDE397-001    | 7-001 I IDE397 monotherapy Part2/expa |  | Lung (squamous and<br>adenocarcinoma)<br>and urothelial<br>cancers (bladder<br>and upper urinary<br>tract) |  | At least 1 line and no more 3 prior lines (no more 2 prior lines of cytotoxic chemotherapy)  |   |
| IMMUNE 132-15 | MUNE 132-15 I Sacituzimab Govitecan   |  | Advanced or<br>metastatic solid<br>tumors and<br>moderate liver<br>impairement                             | Histologically confirmed advanced or<br>metastatic solid tumor . Creatinine<br>clearance ≥ 30 mL/min, 1.5 x ULN < Total<br>Bilirubin < 3 x ULN | Histologically confirmed advanced or metastatic solid<br>tumor for which no standard therapy is available<br>(TNBC must have received 2 or more prior systemic<br>therapies, including at least 1 for advanced disease |   |





# Solid tumors

|  |             |       |  | COHORT TYPE      |                            |   |  |
|--|-------------|-------|--|------------------|----------------------------|---|--|
|  | STUDY NAME  | PHASE | MOLECULE                               | COHORT<br>NUMBER | TUMOR TYPE                 | SPECIFICITY   | PREVIOUS LINE  |
|  | KN-8701     | lb    | KIN-2787 + Binimetinib                 | A2               | Solid tumor                | BRAF class II   | received prior locally approved standard of care appropriate for their tumor type and stage of disease |
|  | M21-404     | ı     | ABBV400                                | 5                | Solid tumour MET amplified |   | At least 1 line or no alternative  |
|  | MegaMOST    | 11    | Cabozantinib QD                        | В                | Solid Tumors               | AXL, MET, VEGFR, VEGF, RET, ROS1, MER,<br>TRKB, TIE-2 and/or Tyro3 activating<br>mutations/amplification, and/or NTRK<br>translocation<br>TUMOR TISSUE OR LIQUID BIOPSY   | At least one line for metastatic disease   |
|  |             |       | Alectinib BID                          | С                | Solid Tumors               | Activating ALK alterations : translocation, mutation  | At least one line for metastatic disease, no previous<br>ALK inhibitor (except crizotinib)             |
|  |             |       | Regorafenib<br>3 weeks on / 1 week off | D                | Solid Tumors               | Activating mutation and/or amplification of VEGFR1-3, TIE-2, KIT, RET, RAF1, BRAF (other than V600 mutations), CRAF, HRAS, KRAS, PDGFR, FGFR1-2, FLT3 and/or CSFR1; amplification of the ligands; biallelic inactivation of SMAD4 TUMOR TISSUE OR LIQUID BIOPSY | At least one line for metastatic disease   |
|  |             |       | Trametinib QD +<br>Dabrafenib BID      | F                | Solid Tumors               | BRAF V600 mutation, tumor tissus or liquid<br>biopsy<br>Except melanoma, lung and CRC   | At least one line for metastatic disease   |
|  | MK-7339-002 | II    | Olaparib                               | 3                | Solid tumors               | HRD positif<br>Except ovarian and sarcoma   | At least one line and max 2 lines, platine-sensitive if applicable                                     |





# Solid tumors

|             |       | COHORT TYPE                  |                  |                    |   |  |
|-------------|-------|------------------------------|------------------|--------------------|---|--|
| STUDY NAME  | PHASE | MOLECULE                     | COHORT<br>NUMBER | TUMOR TYPE         | SPECIFICITY   | PREVIOUS LINE  |
|             | II    | Nilotinib                    |                  | PVNS               | ABL1, KIT, PDGFRA, PDGFRB, DDR1, DDR2,<br>CSF1R mutations   | At least one line  |
| MOST PLUS   |       | Olaparib                     |                  | Solid tumors       | HDR pathway mutations   | At least one line  |
|             |       | Durvalumab +<br>Tremelimumab |                  | Solid tumors       | Immunogenic, MSI high<br>Except lung, head, neck and CNS cancer   | At least one line and max 2 lines  |
| PMV586-101  | 1/11  | Olaparib                     | 3                | Solid tumors       | HRD positif except ovarian and sarcoma  | At least one line and max 2 lines, platine-sensitive if applicable   |
| PRT3789-01  | la    | PRT3789                      | Dose escalation  | Solid tumors       | SMARCA4   | Participants with NSCLC with driver mutations in oncogenes (e.g., EGFR, MET, RET, ALK, BRAF, KRAS, ROS1, etc.) are eligible after progression on approved targeted therapies |
| REGOMUNE    | II    | Regorafenib +<br>Avelumab    | М                | Solid tumors       | TMB-H (>16 mut/mgb on tissue or blood sample)   | At least one line and max 1 line of PD(L)1 mAb<br>(received at least 4 month) anti PDL1 not<br>mandatory   |
| REGOMONE    |       |                              | N                | Solid tumors       | MSI-H   | At least one line, anti PDL1 not mandatory   |
| STX-487-101 | 1/11  | STX-478                      | Part 1,2A4       | Other solid tumors | PI3Kα H1047X mutations or other kinase domain mutations other than the tumor types permitted in Cohorts A1, A2, and A3Disease | No prior treatment with PI3K/AKT/mTOR inhibitor  |
| TAPISTRY    | II    | ALECTINIB                    | С                | Solid tumors       | ALK fusion-positive (except NSCLC) TUMOR TISSUE OR LIQUID (VALIDATION NEEDED)   |  |



