

American Society of Clinical Oncology (ASCCO) 2022

Highly promising clinical innovations and breakthroughs at Institut Curie

From June 3 to 7 in Chicago (United States), after two years of virtual meetings due to the pandemic, the world's oncology community will reunite for the essential meeting of the *American Society of Clinical Oncology (ASCO)*. For five days, physicians from Institut Curie across all areas of oncology will be there in full force to share their very promising results to speed up the fight against cancer.

Prof. Steven Le Guill, director of the Hospital Group at Institut Curie: "Following two very unusual years in many respects, I am delighted that this year's ASCO meeting, with its highly promising results, can be held in Chicago. Physicians from Institut Curie will present unique and original research encompassing targeted therapies, treatment combinations and supportive care, geared towards developing new therapeutic strategies. This year again we have a great many papers accepted at ASCO, a testimony to the excellence of our teams, our international reputation and the importance of the productive collaborations that bring us further in the fight against cancer, for the benefit of patients."

• The highlights •

Breast and gynecological cancers

- **Elderly women: highly anticipated results from a major breast cancer study => June 7**

And also:

- Combining radiotherapy and targeted therapy to treat triple-negative breast cancer
- Real-life analysis of hormone therapy data in breast cancer
- Advanced cervical cancer: what is the role of immunotherapy?
- Screening for BRCA1 and BRCA2 mutations in ovarian cancer

Digestive cancers

- **Pancreatic cancer: an original study to assess the effectiveness of adapted physical activity (APA) => June 5**

And also:

- Vaccine therapy in metastatic pancreatic cancer
- Biliary tract cancers: new data on immunotherapy

Hematology

- **Early results of a new targeted therapy + immunotherapy combination in mantle cell lymphoma (non-Hodgkin's lymphoma affecting the B-cells) => June 3**

> Nanoparticle & ENT cancers: a phase-3 trial is underway

> Supportive care: "Early together", a brand-new trial in metastatic uveal melanoma

> 2 theme-based lectures on immunotherapy in pediatric cancers and on treatment of lymphoma

Breast cancer

!! Oral presentation to follow!!

Elderly women: highly anticipated results from a major breast cancer study

Almost half of all cancers occur in patients aged 70 and over; and the occurrence in this population will continue to rise in the coming years, bringing with it major public health challenges. This elderly portion of the population is too often excluded from therapeutic trials, which are necessary for developing appropriate treatments. The unique ASTER 70s trial, conducted on 2,000 women patients, is the first multi-center therapeutic trial based on the analysis of a prognostic biomarker for choosing to perform adjuvant chemotherapy in patients over the age of 70 after breast cancer surgery. The aim of the trial is to assess the effectiveness of post-surgical chemotherapy treatment when the tumor is aggressive (chemotherapy and hormone therapy versus hormone therapy alone). The results give information on therapeutic de-escalation and will provide valuable information in terms of quality of life, autonomy and acceptability of care. **Dr. Etienne Brain, medical oncologist at Institut Curie**, coordinated this ASTER 70s study sponsored by Unicancer, and will present its results orally on June 7 at the ASCO meeting.

Final results from a phase III randomized clinical trial of adjuvant endocrine therapy ± chemotherapy in women ≥ 70 years old with ER+ HER2- breast cancer and a high genomic grade index: The Unicancer ASTER 70s trial. Session "Breast Cancer — Local / Regional / Adjuvant". **Oral presentation on June 7 at 6:33pm (French time)**
 => **Institut Curie/Unicancer press release scheduled for June 7**



The ASCO award B.J. Kennedy Geriatric Oncology Award 2022 awarded to Etienne Brain

Created in honor of B.J. Kennedy, MD, former Chairman of ASCO, this award is given to a physician for her/his exceptional contributions to research, diagnosis and treatment of cancers in the elderly, and in recognition of her/his international leadership in education and policy. This year **Dr. Etienne Brain will receive the award on June 4 at the ASCO meeting**. Dr. Brain is the former chairman of the "Breast cancer" group at the EORTC (European

Organization for Research and Treatment of Cancer) and chairman of the DIALOG Intergroup (GERICO/UCOG) devoted to clinical research in elderly patients. He is also former chairman of the International Society of Geriatric Oncology (SIOG).

> Combining radiotherapy and targeted therapy to treat triple-negative breast cancer

The development of new therapeutic strategies for triple negative breast cancer, which represents 10 to 20% of breast cancers, is crucial since its prognosis remains grim. Coordinated by **Dr. Youlia Kirova, oncological radiotherapist at Institut Curie**, the RADIOPARP study aims to assess the tolerance of a targeted therapy (PARP inhibitor) in combination with radiotherapy. The final results of the trial's phase 1 show that the PARP inhibitor used as radio-sensitizer in combination with radiotherapy is well tolerated. These results are very encouraging for the next clinical trials, which will assess the tumor-fighting power of this new combination in women with triple negative breast cancer.

Safety and tolerability of Olaparib combined with breast radiotherapy in patients with triple negative breast cancer: final results of the RADIOPARP phase 1 trial. **Poster available on June 6 at 2:00pm (French time)** – Session « Breast Cancer. Local/Regional/Adjuvant »

Breast and gynecological cancers

> Real-life analysis of hormone therapy data in breast cancer

70% of all breast cancer cases are hormone-dependent, with the cancerous cells containing hormone receptors (HR) to estrogen and to progesterone. Hormone therapy plays a very important role in their treatments. Among these HR+ tumors, for those that over-express HER2 (HER2+), the role of hormone therapy is less defined since anti-HER2 treatments are more frequently combined with chemotherapy. Thus the current standard first-line treatment for metastases is to administer chemotherapy combined with two anti-HER2 antibodies (double blocking). **Dr. Luc Cabel and Dr. Marcela Carausu, medical oncologists at Institut Curie**, performed an impact analysis of these strategies in patients with HR/HER2+ breast cancer compiled in the ESME French database containing more than 20,000 breast cancer records. Their work suggests that hormone therapy could be an interesting and less toxic alternative to chemotherapy, in combination with an anti-HER2 treatment, and that chemotherapy could then be delayed after a first-line treatment combining hormone therapy with anti-HER2 treatment. These retrospective studies should be confirmed in a randomized prospective trial with double anti-HER2 blocking.

Treatment patterns and their impact on the outcome of patients with HR+/HER2+ metastatic breast cancer in a large real-world cohort. **Poster available on June 6 at 2:00pm (French time)** - Session « Breast Cancer—Metastatic »

> Advanced cervical cancer: what is the role of immunotherapy?

Cervical cancer is one of the most common gynecological cancers. Although overall survival at 5 years is 75 to 85%, patients with locally advanced cervical cancer face a survival rate of only about 50%. The multi-center NICOL trial conducted by **Dr. Manuel Rodrigues and Dr. Emmanuela Romano, medical oncologists at Institut Curie**, aims to assess the addition of immunotherapy to the standard treatment that combines radiotherapy and chemotherapy for locally advanced cervical cancer. Although the results show that there is no added toxicity, translational analyses continue to identify factors that predict better effectiveness and thus identify sub-groups of patients that respond best to treatment.

Combination of nivolumab with chemoradiotherapy for locally advanced cervical cancer: NiCOL phase I trial. **Poster available on June 4 at 2:00pm (French time)** – Session « Gynecologic cancer »

> Screening for BRCA1 and BRCA2 mutations in ovarian cancer

With over 5,200 new cases estimated in 2018 in France, ovarian cancer is the 5th most common gynecological cancer. Diagnosed at an advanced stage in 3/4 of cases, its prognosis is uncertain with a 5-year survival rate of around 40-50%. In recent years, however, new therapeutic strategies such as targeted therapies (in particular PARP inhibitors) have brought considerable hope. It was recently shown that this treatment reduces the risk of recurrence in ovarian cancer patients by around 40%, with better results when there is a BRCA mutation (a 70% lower risk). To go even further, **Dr. Manuel Rodrigues, a medical oncologist at Institut Curie**, has explored data from the international PAOLA-1 study to find out whether the benefit of olaparib, a PARP inhibitor, was different according to the type of BRCA1 or BRCA 2 mutation and location of this mutation in the protein. The result was that there is indeed a benefit regardless of which BRCA mutation is involved, but the team also showed different scales of impact according to the location of the mutation. This work ultimately raises new questions on the biology of BRCA1/2 and will help customize the treatment of patients.

Efficacy of maintenance olaparib plus bevacizumab in patients with newly diagnosed advanced ovarian cancer according to BRCA mutation genotype in the phase III PAOLA-1/ENGOT-ov25 trial. **Poster available on June 4 at 2:00pm (French time)** - "Gynecological cancer" session

Digestive cancers

!! Oral
 presentation to

Pancreatic cancer: an original study to assess the effectiveness of adapted physical activity

Among the different types of supportive care, adapted physical activity (APA) in patients receiving chemotherapy is a truly innovative treatment that combats fatigue and sarcopenia (cancer-related muscle loss) and improves quality of life. Its beneficial effects have already been demonstrated in patients treated for breast cancer with an adjuvant treatment. The data for digestive cancers, in particular advanced ones (inoperable), are more limited. **Dr. Cindy Neuzillet, a gastroenterologist and specialist in digestive cancers at Institut Curie**, is getting ready to present the final results of a unique study that she coordinated with Prof. Pascal Hammel (AP-HP) for 8 years. Sponsored by GERCOR, this phase-3 trial, APACaP, evaluated the role of adapted physical activity among over 300 patients with advanced pancreatic cancer.

Adapted physical activity in patients (Pts) with advanced pancreatic cancer (APACaP): Results from a prospective national randomized GERCOR trial. Session "Gastrointestinal Cancer — Gastroesophageal, Pancreatic, and Hepatobiliary", **Oral presentation on June 5 at 4:48pm (French time)**

> Vaccine therapy in metastatic pancreatic cancer

With 14,000 new cases diagnosed each year, the frequency of pancreatic cancer has doubled since the 1980s. Apart from chemotherapy, and in some rare cases (5-10%) of targeted therapies, medicine has not yet found an effective solution for this disease when diagnosed at a late stage. Classic immunotherapy has so far been disappointing in this type of cancer. Among the new strategies being studied, **Dr. Cindy Neuzillet, gastroenterologist at Institut Curie**, is conducting a multi-center phase-2 clinical trial, PRODIGE TEDOPRAM, sponsored by GERCOR, to assess the effectiveness in maintenance treatment (i.e. after a course of chemotherapy to control the disease) of immunotherapy using the polypeptide vaccine OSE2101 (Tedopi), already studied in lung cancer. The first results show that the vaccine in monotherapy is well tolerated and that some patients survive for an extended period after receiving it. Recruitment is continuing, combining the vaccine with chemotherapy that is lighter than the chemotherapy alone: 45 patients have already been included of the 106 patients planned.

A randomized, non-comparative, phase II study of maintenance OSE2101 vaccine alone or in combination with nivolumab (nivo) or FOLFIRI after induction with FOLFIRINOX in patients (Pts) with advanced pancreatic ductal adenocarcinoma (aPDAC): First interim results of the TEDOPAM GERCOR D17-01 PRODIGE 63 STUDY. Session "Gastrointestinal Cancer-Gastroesophageal, Pancreatic, & Hepatobiliary" **Poster available on June 4 at 2:00pm (French time)**

> Biliary tract cancers: new data on immunotherapy

Cancers of the biliary tract are the second most frequent cause of liver cancer and develop from the lining of the biliary canals; around 4,000 cases are diagnosed each year in France. The advanced (inoperable) forms are treated using chemotherapy. A phase-3 trial presented at ASCO GI (ASCO symposium on gastrointestinal cancers) last January showed that the combination of an immunotherapy antibody (durvalumab) with first-line chemotherapy helped increase patient survival. The multi-center phase-2 trial PRODIGE IMMUNOBIL, sponsored by GERCOR, aims to assess the effectiveness and tolerance of a combination of immunotherapies (durvalumab plus tremelimumab) as a second line of treatment. Two patient cohorts (106 in each cohort) were included and received the combination of these two immunotherapy antibodies according to two different administration protocols. **Dr. Cindy Neuzillet, gastroenterologist at Institut Curie**, will present the results of the first cohort in this trial. Molecular studies are underway to identify the patients who would most benefit from this approach.

"Durvalumab (D) plus tremelimumab (T) immunotherapy in patients (Pts) with advanced biliary tract carcinoma (BTC) after failure of platinum-based chemotherapy (CTx): Interim results of the IMMUNOBIL GERCOR D18-1 PRODIGE-57 study. Session "Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary". **Poster available on June 4 at 2:00pm (French time)**

Hematology

!! Oral
presentation to

>Mantle cell lymphoma: what are the results of a new combination of a targeted therapy and immunotherapy?

With around 600 patients diagnosed each year in France, mantle cell lymphoma accounts for 2 to 10% of lymphomas. These are non-Hodgkins lymphomas (NHL) that affect the B-cells of the immune system in a region of the lymph node, known as "mantle zone". These tumors are aggressive with frequent relapses. For some years now, new treatments and clinical trials could change the landscape for patients. This is the case for the SHINE study, which assessed the effectiveness of a targeted therapy (a Bruton's tyrosine kinase inhibitor) combined with immuno-chemotherapy in the first-line treatment. **Prof. Steven Le Guill, hematologist**, coordinated the French portion of this study. The principal results of the SHINE study will be part of an oral presentation at ASCO and **simultaneous publication in the New England Journal of Medicine**.

Primary results from the double-blind, placebo-controlled, phase III SHINE study of ibrutinib in combination with bendamustine-rituximab (BR) and R maintenance as a first-line treatment for older patients with mantle cell lymphoma (MCL). Session « Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia » – **Oral presentation on June 3 at 8:24pm (French time)**
=> **Institut Curie press release scheduled for June 3**

Nanoparticles

> ENT cancer: a phase-3 trial is underway

Institut Curie is working with the company Nanobiotix for the clinical development of nanoparticles of hafnium, from its origins in oncology in ENT cancers. The phase-1 trial, which assessed for the first time the intra-tumoral injection of nanoparticles in combination with radiotherapy in patients with locally advanced ENT cancers, showed that the combination was promising in terms of effectiveness. **Prof. Christophe Le Tourneau, oncologist and head of the early trials department at Institut Curie**, is leading an international comparative phase-3 trial to formally demonstrate the contribution of nanoparticles in the treatment of patients with locally advanced ENT cancer. The population of the trial is a population that is not eligible for the standard use of chemotherapy (cisplatin) for reasons of age or co-morbidity, and whose prognosis is poor. Recruitment has already begun in several countries.

NANORAY-312: A phase III pivotal study of NBTXR3 activated by investigator's choice of radiotherapy alone or radiotherapy in combination with cetuximab for platinum-based chemotherapy-ineligible elderly patients with locally advanced head and neck squamous cell carcinoma. **Poster disponible le 6 juin à 14h (heure française)**. Session « Head and Neck Cancer »

Supportive care

> “Early together”, a brand-new trial in metastatic uveal melanoma

With 500 to 600 new cases each year in France, uveal melanoma is the most common form of eye cancer in adults. Institut Curie is a leading national and European center for treatment of this disease. When the disease becomes metastatic, the symptoms generally occur at a very late stage and very rapidly. It is therefore difficult to implement supportive care. The multi-center phase-3 clinical trial “Early Together”, coordinated by **Dr. Sophie Piperno-Neumann, oncologist at Institut Curie**, began in 2020 and aims to assess the benefit of supportive care from the very start of metastatic treatment in patient with metastatic uveal melanoma, according to their need for supportive care and their quality of life. This study will be presented by **Dr. Alexis Burnod, head of the Pain and Palliative Care department at Institut Curie**.

Early together: A randomized phase III study of early palliative care in metastatic uveal melanoma (MUM). Session « Melanoma/Skin Cancers”. **Poster available on June 6 at 2:00pm (French time)**

• THE THEME-BASED TALKS •

> **LYMPHOMA: Dr. Carole Soussain, hematologist at Institut Curie**, is invited to ASCO to take part in a lecture on the treatment of brain lymphomas.

« Contemporary Treatment of Patients with Primary Central Nervous System Lymphoma” Ticketed Session “Meet the Professors: Comprehensive Care of Patients With Primary Central Nervous System Lymphoma” – **June 6 at 5:00pm**

> **PEDIATRIC CANCERS - Dr. Franck Bourdeaut, pediatric oncologist at Institut Curie**, will lead a session devoted to immunotherapy in pediatric cancers. He will present his work on rhabdoid tumors and the discovery of an immune reaction that point to the possibility of conducting clinical trials in immunotherapy to treat children with these rare tumors...

“SMARCB1-Deficient Tumors: A Unique Opportunity for Checkpoint Inhibitor Therapy - **June 6 at 8:15pm**

About Institut Curie

Institut Curie, France's leading cancer center, combines an internationally-renowned research center with a cutting-edge hospital group, which treats all types of cancer, including the rarest. Founded in 1909 by Marie Curie, Institut Curie employs 3,700 researchers, physicians, and health professionals across three sites (Paris, Saint-Cloud, and Orsay), all of whom contribute to its three missions of treatment, teaching, and research. A private foundation with public utility status, Institut Curie is authorized to accept donations and bequests, and thanks to the support of its donors, is able to accelerate discoveries and improve patient treatment and quality of life. *Find out more at curie.fr*

PRESS CONTACTS:

Havas / Jean-Wilfried Kemajou : jean-wilfried.kemajou-yanzeu@havas.com - 06 23 34 93 18
Elsa Champion : elsa.champion@curie.fr - 07 64 43 09 28