INNOVATE

INTERNATIONAL NEOADJUVANT IMMUNOTHERAPY ACROSS CANCERS

Naples, Royal Continental Hotel

July 11th - 12th, 2025

3PSOLUTION

SCIENTIFIC RATIONAL

Immune checkpoint blockade (ICB) has revolutionized outcomes for patients with advanced cancers. Building upon this marked success, evaluation of ICB in patients with surgically resectable disease has been pursued across **multiple cancer types**. Improving the anti-tumor immune response, as measured by pathologic response, neoadjuvant immunotherapy continues to demonstrate correlation with improved risk of recurrence across many tumor types, resulting in **changes in standard of care**. Complete pathologic response to neoadjuvant treatment has previously been established a surrogate endpoint in some cancers, but data continue to emerge supporting evaluation of this understanding in the context of neoadjuvant ICB and outcomes associated with pathologic response to immunotherapy is actively being pursued across cancers. Neoadjuvant studies also offer the opportunity for **deep translational evaluation** of serial tissue collection. Taken together, neoadjuvant treatment serves as powerful drug development platform as it provides the opportunity to leverage translational insights to gain a deeper understanding the outcomes associated with pathologic response as well as insights into mechanisms of immunotherapy response and resistance across multiple cancer types and **opportunities for treatment personalization**.

Notably, the majority of these clinical advances and translational insights are evaluated within disease groups. Many efforts continue to work towards a convergence and harmonization in pathology standardization, trial design, and data aggregation in order to transcend traditional paradigms and **leverage the innovative potential** of the neoadjuvant platform in cancer immunotherapy. As immunotherapy and checkpoint inhibitors continue to advance for patients with advanced disease, further evaluation in the neoadjuvant setting plays a critical role in contextualizing clinical response with deep pathologic and biomarker evaluation. There is an increasing need to expedite insights and facilitate impact for patients through the evaluation of neoadjuvant immunotherapy across cancers.

In this scenario, the importance of early-stage breast and lung cancer is crucial, as it offers the best chance of successful immunotherapy treatment and improved outcomes. Detecting cancer in its early stages allows for less aggressive treatment options, higher survival rates and a better quality of life for patients. Early detection also reduces the risk of metastasis, which can make treatment more difficult and reduce survival rates.

With this in mind, we seek to organize a **global meeting** to bring together field and industry leaders in **neoadjuvant immunotherapy clinical and translational research** with the goal of highlighting clinical advances, innovative research approaches, as well as possibilities for collaboration and opportunities to **harmonize approaches across cancers**. With the unique advantage of immunotherapy, we have the opportunity to advance the field forward in both improving outcomes for patients with surgically resectable disease as well as harnessing the true potential of the neoadjuvant platform for drug development.

The meeting will take place over two days and will consist of invited speakers, and panel discussions. Topics will range from disease specific field overviews, pathology, biomarker discovery, treatment personalization, and opportunity for consensus development.

SCIENTIFIC PROGRAM | Friday, July 11th

11:00 a.m. Opening remarks: summary of 2024 meeting and goals for 2025 meeting
P. A. Ascierto, C. U. Blank, E. M. Burton

11:15 a.m. - 01:05 p.m. | I SESSION | Neoadjuvant - practice changing and drug development platform
Session chair: P. A. Ascierto

11:15 a.m. Immunotherapy across cancers: clinical treatment landscape
P. A. Ascierto

11:35 a.m. Neoadjuvant therapy for breast cancer: lessons learned
L. A. Emens

12:05 a.m. Keynote: Neoadjuvant immunotherapy - practice changing clinical trials in early stage management and moving forward
T. Cascone

12:35 p.m. Panel discussion: neoadjuvant - practice changing and drug development platform
P. A. Ascierto

01:05 p.m. *Lunch*

02:05 p.m. - 03:35 p.m. | II SESSION | Pathology harmonization and surrogate endpoint
Session chairs: G. Ferrara*, A. Vecchione

02:05 p.m. Neoadjuvant path assessment in melanoma
M. T. Tetzlaff

02:25 p.m. Rationale for pathologic response assessment: where are we today?
J. M. Taube

**Speakers invited*

02:45 p.m. Pan-cancer scoring system: updates and lessons learned
J. S. Deutsch

03:05 p.m. Panel discussion: pathology harmonization and surrogate endpoint
G. Ferrara*, A. Vecchione

03:35 p.m. - 05:25 p.m. | III SESSION | Neoadjuvant and personalizing treatment approaches
Session Chairs - C. Caracò, J. E. Gershenwald

03:35 p.m. Neoadjuvant data and staging criteria
J. E. Gershenwald

03:55 p.m. Optimizing pathologic response and minimizing toxicity - which biomarker can we use?
M. Lucas

04:15 p.m. Surgical de-escalation in breast cancer
R. Masetti*

04:35 p.m. Using all our tools to escalate or deescalate treatment in the melanoma neoadjuvant setting
G. V. Long

04:55 p.m. Panel discussion: neoadjuvant and personalizing treatment approaches
C. Caracò, J. E. Gershenwald

05:25 p.m. - 05:35 p.m. Closing day 1
P. A. Ascierto, C. U. Blank, E. M. Burton

**Speakers invited*

SCIENTIFIC PROGRAM | Saturday, July 12th

08:15 a.m. - 12:05 p.m. | IV SESSION | Cancer specific updates in neoadjuvant immunotherapy

Session Chairs - P. A. Ascierto, E. M. Burton

08:15 a.m. Bladder
Tbd

08:35 a.m. RCC
A. Bex

08:55 a.m. Colorectal cancer (CRC)
J. Seligmann*

09:15 a.m. Lung
T. Cascone

09:35 a.m. Breast
G. Curigliano

09:55 a.m. Gastroesophageal
A. Avallone*

10:15 a.m. Melanoma overview
P. A. Ascierto

10:35 a.m. Non melanoma skin cancer
N. D. Gross

10:55 a.m. News and research updates

11:35 a.m. Panel discussion: cancer specific updates in neoadjuvant immunotherapy
P. A. Ascierto, E. M. Burton

**Speakers invited*

12:05 p.m. – 03:35 p.m. | V SESSION | Translational insights - biomarkers across cancers
Session Chairs - O. Hamid, H. A. Tawbi

12:05 a.m. Keynote on translational insights
T. Bruno

12:25 p.m. ctDNA clearance in the context of neoadjuvant immunotherapy
G. Curigliano

12:45 p.m. Patient-Derived organoids as predictive biomarkers for neoadjuvant therapy
A. Betof Warner

01:05 p.m. Taking translational insights to proof of concept back to the clinic
T. Heffernan*

01:25 p.m. The regulatory landscape and opportunity in drug development for neoadjuvant immunotherapy
T. LaVallee

01:45 p.m. *Lunch*

02:35 p.m. News and research updates

03:05 p.m. Panel discussion: translational insights - biomarkers across cancers
O. Hamid, H. A. Tawbi

03:35 p.m. – 05:35 p.m. | VI SESSION | Building consensus -"Where do we go from here?"
Session Chairs – P. A. Ascierto, C. U. Blank, E. M. Burton

- Summary of key points, panel discussion and agreement

05:35-05:45 p.m. Closing remarks
P. A. Ascierto

**Speakers invited*

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Paolo A. Ascierto	Director of Department of Melanoma, Cancer Immunotherapy and Development Therapeutics, National Cancer Institute IRCCS "Fondazione G. Pascale", Naples, Italy
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The I.N.N.O.VA.TE - International Neoadjuvant Immunotherapy Across Cancers, Naples, Italy 11/07/2025 - 12/07/2025, has submitted the request for accreditation to the European Accreditation Council for Continuing Medical Education (EACCME®) . Each medical specialist will be able to claim only those hours of credit that he/she actually spent in the educational activity.
Through an agreement between the Union Européenne des Médecins Spécialistes and the American Medical Association, physicians may convert EACCME® credits to an equivalent number of AMA PRA Category 1 CreditsTM. Information on the process to convert EACCME® credit to AMA credit can be found at https://edhub.ama-assn.org/pages/applications
Live educational activities, occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC®s are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

REGISTRATION

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