

# INNOVATE

INTERNATIONAL NEOADJUVANT
IMMUNOTHERAPY ACROSS CANCERS

Naples, Royal Continental Hotel
via Partenope, 38

July 11<sup>th</sup> - 12<sup>th</sup>, 2025

#### UNDER THE AUSPICES OF



# 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 chairs: P. A. Ascierto, S. Patel

- 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 p.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?

- **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

  A. Di Leone
- **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

# 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

Y. Loriot

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

K.-K. Shiu

10:15 a.m. Melanoma overview

P. A. Ascierto

10:35 a.m. Head and neck and 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

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

## **SCIENTIFIC BOARD**

Paolo A. Ascierto

Director of Department of Melanoma, Cancer Immunotherapy and Development Therapeutics, National Cancer Institute IRCCS "Fondazione G. Pascale", Naples, Italy

Christian U. Blank Department of Medical Oncology and Division of Immunology, The Netherlands Cancer Institute Antoni van Leeuwenhoek Ziekenhuis (NKI); Professor in Cancer Immunotherapy, Leiden University Medical Center (LUMC), The Netherlands; Professor in Hematology/Oncology, University Clinic Regensburg, Germany

Elizabeth M. Burton

Executive Director, Strategic Translational Research Initiative Development, Department of Genomic Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, US

### **FACULTY**

Allison Betof Warner Assistant Professor of Medicine (Oncology), Mark and Mary Stevens Endowed Scholar in Melanoma; Director, Melanoma Program; Director, Solid Tumor Cell Therapy, Stanford University School of Medicine, Stanford, CA, US

Axel Bex Medical Oncologist, Urologic surgeon, The Netherlands Cancer Institute (NKI)/Antoni van Leeuwenhoek Ziekenhuis ; Professor, University College London, UK

Tullia Bruno Assistant Professor of Immunology, University of Pittsburgh School of Medicine, UPMC Hillman Cancer Center, Pittsburgh, PA, US

Corrado Caracò SC Chirurgia Melanoma e dei Tumori cutanei, Istituto Nazionale Tumori IRCCS "Fondazione G. Pascale", Napoli, Italia

Tina Cascone Associate Professor and Director of Translational Research, Department of Thoracic/Head & Neck Medical Oncology, Regular Faculty Member, Immunology and Cancer Biology Programs, Graduate School of Biomedical Sciences (GSBS), The University of Texas MD Anderson Cancer Center, Houston, TX, US

Giuseppe Curigliano

Professor of Medical Oncology, Department of Oncology and Hemato-Oncology, University of Milano La Statale; Clinical Director, Division of Early Drug Development, IEO European Institute of Oncology IRCCS, Milan, Italy

Julie S. Deutsch Assistant Professor of Dermatology, Pathology, and Oncology, Johns Hopkins University, School of Medicine, Baltimore, MD, US

Leisha A. Emens Medical Oncologist, indipendent consultant specialist in breast cancer - Pittsburgh, PA, US

Gerardo Ferrara Chief, Anatomic Pathology and Cytopathology Unit, National Cancer Institute IRCCS "Fondazione G. Pascale", Naples, Italy

Jeffrey E. Gershenwald John M. Skibber Endowed Professor, Department of Surgical Oncology, Medical Director, Melanoma and Skin Cancer, The University of Texas MD Anderson Cancer Center; Distinguished Senior Lecturer, The University of Texas MD Anderson Cancer Center UTHealth Houston Graduate School of Biomedical Sciences, Houston, TX, US

Neil D. Gross Professor, Department of Head and Neck Surgery, Division of Surgery; Section Chief, Oropharynx Cancer, Division of Surgery; Director, Perioperative Surgical Services, The University of Texas MD Anderson Cancer Center, Houston, TX, US

Omid Hamid Chief of Research/ Immuno-Oncology, The Angeles Clinic & Research Institute, Los Angeles, CA, US; Co-Director, Cutaneous Malignancy Program, The Angeles Clinic and Research Institute – Cedars-Sinai Director, Experimental Therapeutics at Cedars-Sinai Cancer ,Santa Monica, CA, US

Theresa LaVallee

 ${\it Chief Development Officer, Coherus BioSciences, Redwood City, CA, US}$ 

Georgina V. Long Medical Director, Melanoma Institute Australia, Chair of Melanoma Medical Oncology and Translational Research at Melanoma Institute Australia, The University of Sydney, North Sydney, NSW, Australia

Yohann Loriot Professor of Medicine, Paris-Saclay University; Deputy Chair of the Department of Early Drug Development, Gustave Roussy, Villejuif, France

Minke Lucas	MD, The Netherlands Cancer Institute, Amsterdam, Netherlands
Sapna Patel	Dr William Robinson Endowed Chair in Cancer Research, Director of Cutaneous Oncology; Professor of Medicine and Ophthalmology, University of Colorado, Aurora, CO, US
Piergiorgio Pettazzoni	Director Head of Drug discovery Biology, TRACTION MD Anderson Cancer Center, Houston, TX, US
Jennifer Seligmann*	Professor of Gastrointestinal and Translational Oncology and Honorary Consultant in Medical Oncology at the University of Leeds, UK
Janis M. Taube	Director, Division of Dermatopathology, Professor of Dermatology, Johns Hopkins University, School of Medicine, Baltimore, MD, US
Hussein A. Tawbi	Professor; Deputy Chair, Department of Melanoma Medical Oncology; Co-Director, Andrew M. McDougall Brain Metastasis Clinic & Program; Melanoma Medical Oncology; Investigational Cancer Therapeutics; UT MD Anderson Cancer Center, Houston, TX, US
Michael T. Tetzlaff	Professor of Pathology and Dermatology, Departments of Pathology and Dermatology, The University of California, San Francisco, US
Andrea Vecchione	Professore Ordinario di Anatomia Patologica; Direttore UOC Anatomia Patologica Morfologica e Molecolare, Facoltà di Medicina e Psicologia, Dipartimento di Medicina Clinica e Molecolare, Università degli Studi di Roma La Sapienza c/o Azienda Ospedaliero-Universtaria Sant'Andrea, Roma, Italia

## **CONTINUING MEDICAL EDUCATION**

#### **EACCME®**

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

The event registration is free for healthcare professionals.

To register, please send an e-mail to: registration@innovateconference.org

For more information:

Website: www.3psolution.it Email: daquino@3psolution.it Phone: +39 340 4639178

#### WITH THE UNRESTRICTED GRANT OF:

**GOLD SPONSOR** 



SILVER SPONSOR



**BRONZE SPONSOR** 









**SPONSOR** 









#### ORGANIZING SECRETARIAT



Sede legale: via Borgogna, 2 - 20122 Milano

Sede operativa: corso Europa, 13 - 20122 Milano

mail | info@3psolution.it







web | www.3psolution.it