Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate

Giorno 25 novembre ore 16:00 – 18:00

ORDINE DEL GIORNO

1. Comunicazioni del Presidente

2. Approvazione del verbale n. 10/2025 della seduta del 11 novembre 2025

3. Procedure in valutazione
   (dalla pagina seguente)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2024-514006-31-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II) Multinational	CYTB323R12101 Interventistico con farmaco - Profit Phase I/II	An open-label, multi-center, phase I/II study to assess safety, disease progression, and cellular kinetics following YTB323 administration in participants with non-active Progressive Multiple Sclerosis (PMS)
CTIS ITALY - MS 2023-508081-15-00 SUBSTANTIAL MODIFICATION SM-1 (Part I + Part II) Multinational	CCTL019G2201J Interventistico con farmaco - Profit Phase II	A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation (EOC) therapy
CTIS ITALY - MS 2024-519278-37-00 SUBSTANTIAL MODIFICATION SM-1 (Part II) Multinational	CA061-1011 Interventistico con farmaco - Profit Phase II	A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted NEX-T CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE
CTIS ITALY - MS 2023-508784-68-00 INITIAL (Part I + Part II) Multinational	RP2-202 Interventistico con farmaco - Profit Phase II/III	A Randomized, Phase 2/3, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients with Metastatic Uveal Melanoma

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2025-521500-21-00 INITIAL (Part I + Part II) Mononational	RESTORE Interventistico con farmaco - No Profit Phase II	Allogenic Umbilical Cord-Derived Mesenchymal Stromal Cells as Therapeutic Approach for Chronic Lumbar Back Pain Due to Multilevel Intervertebral Disc Degeneration: A Phase IIB double-blind Randomized Controlled Trial
CTIS ITALY - MS 2024-517335-46-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II) Multinational	V940-011 Interventistico con farmaco - Profit Phase II	A Phase 2 Open-label Randomized Study of V940 in Combination With BCG Versus BCG Monotherapy in Participants With High-risk Non-muscle Invasive Bladder Cancer (INTerpath-011)
CTIS ITALY - MS 2023-506267-33-00 ADDED MEMBER STATE AM-1 (Part I + Part II) Multinational	90014496LYM1001 Interventistico con farmaco - Profit Phase I/II	A Phase 1b Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma
CTIS ITALY - MS 2023-506327-29-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II) Multinational	V940-009 Interventistico con farmaco - Profit Phase III	A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2023-510150-17-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II) Multinational	CYTB323J12201 Interventistico con farmaco - Profit Phase II	A Phase 2, adaptive, randomized, open-label, assessor-blinded active-controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus Standard of Care in patients suffering from systemic lupus erythematosus (SLE) with active, refractory lupus nephritis (LN).
CTIS ITALY - MS 2024-514137-38-00 SUBSTANTIAL MODIFICATION SM-3 (Part I + Part II) Multinational	CYTB323L12201 Interventistico con farmaco - Profit Phase II	A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucelversus comparator in participants with severe refractory idiopathic inflammatory myopathies

Si specifica che gli studi vengono inseriti all'Ordine del Giorno (O.d.G.) esclusivamente nel momento in cui risulta disponibile l'intera documentazione validata e ritenuta idonea per avviare la fase di valutazione. È importante sottolineare che l'inserimento in O.d.G. non garantisce che la valutazione venga completata o deliberata nella stessa seduta: esso rappresenta invece l'avvio formale dell'iter valutativo della procedura, che potrà richiedere ulteriori approfondimenti, integrazioni o successive discussioni in riunioni future.

4. Revisione/adozione Regolamento del CEN ATMP (Tutti i componenti)

5. Varie ed eventuali