Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate

Giorno 05 agosto ore 16:30

ORDINE DEL GIORNO

1. Comunicazioni del Presidente

2. Approvazione del verbale n. 6/2025 della seduta del 17.07.2025

3. Procedure in valutazione
   (dalla pagina seguente)

INFO GENERALI	Info Studio	Titolo	Scadenze
CTIS ITALY - MS 2024-512504-19-00 ADDED MEMBER STATE AM-1 (Part I + Part II) Multinational	1456-0001 Interventistico con farmaco - Profit Phase I	Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors.	Primo O.d.G: Data Fine: 02/04/2025 (Secondo Round)
CTIS ITALY - MS 2024-512504-19-00 SUBSTANTIAL MODIFICATION SM-7 (Part I + Part II) Multinational	1456-0001 Interventistico con farmaco - Profit Phase I	Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors.	Primo O.d.G: 05/08/2025 Data Fine: 18/08/2025 (Primo Round)
CTIS ITALY - MS 2022-500746-16-00 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II) Multinational	81201887MDG2001 Interventistico con farmaco - Profit Phase II	A Phase 2b, Randomized, Double-masked, Multicenter, Dose-ranging, Sham-controlled Clinical Trial to Evaluate Intravitreal JNJ-81201887 (AAVCAGsCD59) Compared to Sham Procedure for the Treatment of Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD)	Primo O.d.G: Data Fine: 09/06/2025 (Secondo Round)
CTIS ITALY - MS 2022-501489-24-00 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II) Multinational	KT-US-484-0136 Interventistico con farmaco - Profit Phase III	An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma (ZUMA-23)	Primo O.d.G: 08/07/2025 Data Fine: 03/07/2025 (Secondo Round)
CTIS ITALY - MS 2024-519278-37-00 INITIAL (Part I + 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	Primo O.d.G: Data Fine: 29/08/2025 (Primo Round)

CTIS ITALY - MS 2025-521349-25-00 INITIAL (Part I + Part II) Multinational	4D-150-C004 Interventistico con farmaco - Profit Phase III	A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-2)	Primo O.d.G: 05/08/2025 Data Fine: 29/08/2025 (Primo Round)
CTIS ITALY - MS 2023-503666-23-00 SUBSTANTIAL MODIFICATION SM-5 (Part I + Part II) Multinational	RGX-314-3101/M23-409 Interventistico con farmaco - Profit Phase III	A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)	Primo O.d.G: 05/08/2025 Data Fine: 15/07/2025 (Primo Round)
CTIS ITALY - MS 2022-503112-17-00 SUBSTANTIAL MODIFICATION SM-2 (Part I + Part II) Multinational	SRP-9003-301 Interventistico con farmaco - Profit Phase III	A Phase 3 Multinational, Open-label, Systemic Gene Delivery Study to Evaluate the Safety and Efficacy of SRP-9003 in Subjects with Limb Girdle Muscular Dystrophy 2E/R4	Primo O.d.G: Data Fine: 24/03/2025 (Secondo Round)
CTIS ITALY - MS 2023-510150-17-00 SUBSTANTIAL MODIFICATION SM-4 (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).	Primo O.d.G: 08/07/2025 Data Fine: 19/06/2025 (Secondo Round)
CTIS ITALY - MS 2024-512714-18-00 INITIAL (Part I + Part II) Multinational	CYTB323N12101 Interventistico con farmaco - Profit Phase I/II	An open-label, multi-center, phase 1/2 study to assess safety, efficacy, and cellular kinetics of YTB323 in participants with Relapsing Multiple Sclerosis with breakthrough disease activity during previous treatment with a highly efficacious therapy	Primo O.d.G: Data Fine: 24/03/2025 (Secondo Round)
CTIS ITALY - RMS 2024-518369-92-00 INITIAL (Part I + Part II) Mononational	WAS-TLT003-01 Interventistico con farmaco - No Profit Phase III	A Long-term Follow-up Study for Subjects Previously Treated with Autologous ex vivo Lentiviral Hematopoietic Stem and Progenitor Cell Gene Therapy for Wiskott-Aldrich Syndrome (WAS)	Primo O.d.G: Data Fine: 31/03/2025 (Secondo Round)

CTIS ITALY - MS 2024-514006-31-00 INITIAL (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)	Primo O.d.G: Data Fine: 17/03/2025 (Secondo Round)
CTIS ITALY - MS 2024-517335-46-00 INITIAL (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)	Primo O.d.G: 08/07/2025 Data Fine: 17/03/2025 (Secondo Round)
CTIS ITALY - MS 2024-517335-46-00 SUBSTANTIAL MODIFICATION SM-1 (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)	Primo O.d.G: 08/07/2025 Data Fine: 01/09/2025 (Secondo Round)
CTIS ITALY - RMS 2024-519317-66-00 INITIAL (Part I + Part II) Mononational	AT-W-CLI-2024-10 Interventistico con farmaco - Profit Phase II	(ESMERALD) A phase-2A, single-centre, prospective, uncontrolled, open label, single arm, exploratory clinical study to evaluate the safety and efficacy of cutaneous AUP1602-C with foam dressing as a treatment for non-healing neuroischemic diabetic foot ulcers	Primo O.d.G: 24/06/2025 Data Fine: 06/03/2025 (Secondo Round)
CTIS ITALY - MS 2024-513683-25-00 INITIAL (Part I + Part II) Multinational	NA Interventistico con farmaco - No Profit Phase II	Randomized, controlled, multi-center phase II clinical trial for the treatment of patellofemoral osteoarthritis with nasal chondrocyte-based tissue engineered cartilage implantation vs current standard of care (ENCANTO)	Primo O.d.G: 08/07/2025 Data Fine: 03/06/2025 (Secondo Round)

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

5. Varie ed eventuali