



Comitato Etico per le Sperimentazioni Cliniche relative alle Terapie Avanzate

O.d.G. Seduta del 29/09/2026

Gli studi vengono inseriti all'Ordine del Giorno 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.

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2026-525367-40-00 INITIAL (Part I + Part II)	D8316C00001 (DURGA 6) Interventistico con farmaco - Profit Phase III Promotore: AstraZeneca AB Multinational	A Phase III, Open-label, Multicentre, Randomised Study Comparing Consolidation Treatment with AZD0120, an Autologous Dual Targeting Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible (TE NDMM) (DURGA-6)

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - RMS 2026-525714-59-00 INITIAL (Part I + Part II)	SNIPER-LTFU Interventistico con farmaco - Profit Phase I/II Promotore: Eir Biotherapies S.r.l. Mononational	SNIPER-LTFU: Long-term follow-up study of patients administered with RR001 in the interventional Parent SNIPER study
CTIS ITALY - MS 2023-505177-32-00 SUBSTANTIAL MODIFICATION SM-8 (Part I + Part II)	V940-004 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants With Renal Cell Carcinoma (INTerpath-004)
CTIS ITALY - MS 2023-510380-34-00 SUBSTANTIAL MODIFICATION SM-9 (Part I + Part II)	CYTB323K12201 Interventistico con farmaco - Profit Phase II Promotore: Novartis Pharma AG Multinational	A Phase II, multi-part, three-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis

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CTIS ITALY - MS2023-505530-10-00ADDED MEMBER STATE AM-4(Part I + Part II)	68284528MMY4002 (CARTinue)Interventistico con farmaco - ProfitPhase IVPromotore: Janssen - Cilag InternationalMultinational	Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel
CTIS ITALY - MS 2024-511188-26-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	KT-US-679-0788 Interventistico con farmaco - Profit Phase III Promotore: Kite Pharma Inc. Multinational	A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma
CTIS ITALY - RMS 2023-508355-39-00 SUBSTANTIAL MODIFICATION SM-4 (Part II)	CD7-CAR01 Interventistico con farmaco - No Profit Phase I/II Promotore: Ospedale Pediatrico Bambino Gesu' Mononational	Phase I/II study of anti-CD7 Chimeric Antigen Receptor-Expressing T cells in pediatric patients/young adult affected by relapsed/refractory CD7+ T-cell Acute Lymphoblastic Leukemia/Lymphoma

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CTIS ITALY - MS 2024-517335-46-00 SUBSTANTIAL MODIFICATION SM-4 (Part I + Part II)	V940-011 Interventistico con farmaco - Profit Phase II Promotore: Merck Sharp & Dohme LLC Multinational	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)
2022-500306-17-00 SM-4	Interventistico con farmaco Part I + Part II	A multi-center, randomized, active controlled clinical trial to evaluate the efficacy and safety of OTL-203 in subjects with mucopolysaccharidosis type I, Hurler syndrome (MPS-IH) compared to standard of care with allogeneic hematopoietic stem cell transplantation (allo-HSCT)
2024-511028-15-00 SM-4	No Profit Part II	A phase 2, randomized, patient and assessor blind, multicenter study comparing fetal neural stem cells transplantation to sham procedure in progressive multiple sclerosis (STEMS2)
2024-519278-37-00 SM-4	Profit Part I + Part 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)

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2024-512029-10-00 SM-5	Profit Part I + Part II	A phase 3b, Randomized, Controlled Trial of Nadofaragene Firadenovec vs. Observation in Subjects with Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR NMIBC)
2023-503652-27-00\SM-20	Profit Part II	A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants with High-risk Stage II-IV Melanoma (INTerpath-001)
CTIS ITALY - MS 2023-507220-23-00 SUBSTANTIAL MODIFICATION SM-9 (Part I + Part II)	ITL-2001-CL-301 Interventistico con farmaco - Profit Phase III Promotore: Intellia Therapeutics Inc. Multinational	MAGNITUDE: A Phase 3, Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM)
CEN ATMP RSO - 3770 INITIAL (Part I + Part II)	QOL-ONE PRO-CT Osservazionale con farmaco - No Profit Promotore: Associazione Culturale e di Ricerca QOL-ONE Mononational	A Real-World Observational Study on Patient-Reported Outcomes in Allogeneic Stem Cell Transplantation (Allo-SCT) and CAR-T Therapy

INFO GENERALI	Info Studio	Titolo
CTIS ITALY - MS 2024-514006-31-00 SUBSTANTIAL MODIFICATION SM-2 (Part I)	CYTB323R12101 Interventistico con farmaco - Profit Phase I/II Promotore: Novartis Pharma AG Multinational	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)
CEN ATMP RSO - 4408 INITIAL (Part I + Part II)	CART-T_PWH Osservazionale con farmaco - No Profit Promotore: Fondazione Policlinico Universitario A. Gemelli IRCCS Mononational	Sicurezza della terapia con CAR-T in persone con HIV e linfoma refrattario o recidivato: Studio retrospettivo multicentrico