

# 해외 바이오의약품 임상 현황 ('23년 6월 2주)

한국바이오의약품협회, 2023.06.20.

※ ClinicalTrials.gov에 등록된 국가별 바이오의약품 임상시험 목록(병용요법 포함)을 한국바이오의약품협회에서 주간 업데이트하여 제공합니다.

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- 출처: ClinicalTrials.gov

- 모니터링 기간: 2023.06.12.~2023.06.18.

- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

## ○ 미국 15건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05616793</a>	Safety and Tolerability Subretinal OPGx-001 for LCA5-Associated Inherited Retinal Degeneration (LCA5-IRD)	Biological: AAV8.hLCA5	Opus Genetics, Inc	Phase 1 Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05616793&amp;rank=1</a>
<a href="#">NCT03735589</a>	Specialized Immune Cells (nCTLs) and a Vaccine (Alpha-type-1 Polarized Dendritic Cells) in Treating Patients With Stage II-IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Biological: Alpha-type-1 Polarized Dendritic Cells Biological: Autologous Natural Killer Cell-like CTLs	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1 Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT03735589&amp;rank=1</a>
<a href="#">NCT05887492</a>	Study of TNG260 and an Anti-PD Antibody in STK11 Mutated Solid Tumors	Drug: TNG260 Drug: Pembrolizumab	Tango Therapeutics, Inc.	Phase 1 Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05887492&amp;rank=1</a>
<a href="#">NCT05800015</a>	A Trial to Learn How the Combination of Fianlimab With Cemiplimab and Chemotherapy Works Compared With Cemiplimab and Chemotherapy for Treating Adult Patients With Advanced Non-small Cell Lung Cancer	Drug: fianlimab Drug: cemiplimab Drug: Pemetrexed Drug: Paclitaxel Drug: Carboplatin Drug: Cisplatin Drug: Placebo	Regeneron Pharmaceuticals	Phase 2 Phase 3	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05800015&amp;rank=1</a>
<a href="#">NCT05785767</a>	A Study to Learn if a Combination of Fianlimab and Cemiplimab Versus Cemiplimab Alone is More Effective for Adult Participants With Advanced Non-Small Cell Lung Cancer (NSCLC)	Drug: fianlimab Drug: cemiplimab Drug: Placebo	Regeneron Pharmaceuticals	Phase 2 Phase 3	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05785767&amp;rank=1</a>
<a href="#">NCT05786404</a>	Study to Evaluate the Fecal Microbiota Transplantation (FMT) in the Treatment of Ulcerative Colitis	Drug: PRIM-DJ2727 - FROZEN Drug: PRIM-DJ2727 - CAPSULES	The University of Texas Health Science Center, Houston	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05786404&amp;rank=1</a>
<a href="#">NCT05443971</a>	Durvalumab and Grid Therapy for the Treatment of Non-small Cell Lung Cancer in Patients Who Progressed During or After Treatment With the PACIFIC Regimen	Biological: Durvalumab Radiation: Radiation Therapy	Mayo Clinic	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05443971&amp;rank=1</a>
<a href="#">NCT05361798</a>	T-Cell Clonality After Stereotactic Body Radiation Therapy Alone and in Combination With the Immunocytokine M9241 in Localized High- and Intermediate-Risk Prostate Cancer Treated With Androgen Deprivation Therapy	Drug: M9241 Radiation: Stereotactic Body Radiation Therapy (SBRT)	National Cancer Institute (NCI) National Institutes of Health Clinical Center (CC)	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05361798&amp;rank=1</a>
<a href="#">NCT05321940</a>	Safety Trial of STING-dependent Activators and Stimulated Dendritic Cells for Aggressive Relapsed/Refractory Leukemias	Biological: STING-Dependent Activators (STAVs) Loaded Autologous Leukemic Cells Biological: Dendritic Cell Vaccine	Juan C. Ramos, MD University of Miami	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05321940&amp;rank=1</a>
<a href="#">NCT05134740</a>	(TAA)-Specific Cytotoxic T-Lymphocytes to Pediatric Patients With Lymphomas (pediTACTAL).	Biological: TAA-specific CTLs	Baylor College of Medicine Center for Cell and Gene Therapy, Baylor College of Medicine	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study?term=NCT05134740&amp;rank=1</a>

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## ○ 미국 15건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT04876248</a>	Belantamab Mafodotin and Lenalidomide for the Treatment of Multiple Myeloma in Patients With Minimal Residual Disease Positive After Stem Cell Transplant	Biological: Belantamab Mafodotin Drug: Lenalidomide	Roswell Park Cancer Institute GlaxoSmithKline	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT04876248</a>
<a href="#">NCT05814627</a>	Study to Assess Change in Disease Activity and Adverse Events of Oral Upadacitinib Compared to Subcutaneous Adalimumab in Adult Participants With Moderate to Severe Rheumatoid Arthritis	Drug: Upadacitinib Drug: Adalimumab Drug: Upadacitinib Matching Placebo Drug: Adalimumab Matching Placebo	AbbVie	Phase 3	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05814627</a>
<a href="#">NCT05743270</a>	Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN	Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab	Replimune Inc. Bristol-Myers Squibb	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05743270</a>
<a href="#">NCT05551117</a>	A Study of Two Dose Levels of Vobramitamab Duocarmazine in Participants With Metastatic Castration Resistant Prostate Cancer	Biological: vobramitamab duocarmazine 2.0 mg (Arm A) Biological: vobramitamab duocarmazine 2.7 mg (Arm B)	MacroGenics	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05551117</a>
<a href="#">NCT05875961</a>	Study to Evaluate Immunogenicity, Safety and Tolerability of Adjuvanted and Non-Adjuvanted H2N3 Influenza Vaccines in Adults	Biological: Low dose A/H2N3c + standard dose MF59 Biological: Intermediate dose A/H2N3c + standard dose MF59 Biological: High dose A/H2N3c + standard dose MF59 Biological: High dose A/H2N3c non-adjuvanted Biological: Lowest dose A/H2N3c + high dose MF59 Biological: Low dose A/H2N3c + high dose MF59	Seqirus Department of Health and Human Services	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05875961</a>

## ○ 영국 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05551117</a>	A Study of Two Dose Levels of Vobramitamab Duocarmazine in Participants With Metastatic Castration Resistant Prostate Cancer	Biological: vobramitamab duocarmazine 2.0 mg (Arm A) Biological: vobramitamab duocarmazine 2.7 mg (Arm B)	MacroGenics	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05551117</a>
<a href="#">NCT05743270</a>	Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN	Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab	Replimune Inc. Bristol-Myers Squibb	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05743270</a>

## ○ 프랑스 3건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05726916</a>	Eculizumab in Hypertensive Emergency-associated Hemolytic Uremic Syndrome	Drug: Soliris® Drug: Renin angiotensin system blockers	Assistance Publique - Hôpital de Paris	Phase 3	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05726916</a>
<a href="#">NCT05743270</a>	Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN	Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab	Replimune Inc. Bristol-Myers Squibb	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05743270</a>
<a href="#">NCT05551117</a>	A Study of Two Dose Levels of Vobramitamab Duocarmazine in Participants With Metastatic Castration Resistant Prostate Cancer	Biological: vobramitamab duocarmazine 2.0 mg (Arm A) Biological: vobramitamab duocarmazine 2.7 mg (Arm B)	MacroGenics	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05551117</a>

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## ○ 독일 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05743270</a>	Study of RP3 in Combination With Nivolumab and Other Therapy in Patients With Locoregionally Advanced or Recurrent SCCHN	Biological: RP3 Other: CCRT(concurrent chemoradiation therapy) Other: carboplatin and paclitaxel Biological: nivolumab	Replimune Inc. Bristol-Myers Squibb	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05743270</a>

## ○ 중국 4건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05896046</a>	SHR1701 Alone or in Combination With SHR2554 in Relapsed or Refractory Classical Hodgkin Lymphoma	Drug: SHR2554+ SHR1701 Drug: SHR-1701	Chinese PLA General Hospital	Phase 1 Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05896046</a>
<a href="#">NCT05900765</a>	A Study of Zimberelimab(GLS-010) Combined With AVD for Newly Diagnosed Early-stage Hodgkin's Lymphoma	Drug: Zimberelimab 240mg	Sun Yat-sen University Guangzhou Gloria Biosciences Co., Ltd.	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05900765</a>
<a href="#">NCT05893056</a>	Cryoablation Combined With Tislelizumab Plus Lenvatinib In Previously Treated Gastric Cancer Liver Metastasis (CASTLE-09)	Procedure: Cryoablation Drug: Tislelizumab Drug: Lenvatinib	Fudan University	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05893056</a>
<a href="#">NCT05872685</a>	Perioperative Chemotherapy Combined With Serplulimab or Placebo for pMMR Locally Advanced Gastric Adenocarcinoma (FOCUS-05)	Drug: S1 Drug: Oxaliplatin Drug: Serplulimab Drug: Placebo	Yu jiren First Affiliated Hospital of Zhejiang University	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05872685</a>

## ○ 일본 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05838768</a>	Study of HRO761 Alone or in Combination in Cancer Patients With Specific DNA Alterations Called Microsatellite Instability or Mismatch Repair Deficiency.	Drug: HRO761 Biological: tislelizumab Drug: irinotecan	Novartis Pharmaceuticals Novartis	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05838768</a>
<a href="#">NCT05769595</a>	Single Dose Study of MK-2060 to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Older Japanese Participants on Dialysis (MK-2060-012)	Biological: MK-2060 Drug: Placebo	Merck Sharp & Dohme LLC	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05769595</a>