

# 해외 바이오의약품 임상 현황 ('23년 8월 3주)

한국바이오의약품협회, 2023.08.22.

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

URL을 클릭하시면 세부 정보 페이지로 연결됩니다.

- 출처: ClinicalTrials.gov
- 모니터링 기간: 2023.08.14.~2023.08.20.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

## ○ 미국 20건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05702853</a>	Metabolically Fit CD19 CAR T-cell Therapy With CD34 Selection in Patients With CD19+ Relapsed/Refractory NHL, CLL/SLL	Drug: Cyclophosphamide injection Drug: Fludarabine Injection Biological: CD19-CD34t metabolically programmed CAR transduced T-cells	Medical University of South Carolina	Phase 1 Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05702853</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/NCT03735589</a>
<a href="#">NCT05964413</a>	Phase III Trial to Investigate Efficacy and Safety of Vilobelimab in Ulcerative Pyoderma Gangrenosum	Drug: vilobelimab Drug: Placebo	InflaRx GmbH	Phase 3	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05964413</a>
<a href="#">NCT05945875</a>	Evaluating the Use of Dual Imaging Techniques for Detection of Disease in Patients With Head and Neck Cancer	Drug: Panitumumab-IRDye800 Other: Indium In 111 Panitumumab Procedure: Single Photon Emission Computed Tomography Procedure: Computed Tomography Procedure: Resection Procedure: Fluorescence Imaging	Vanderbilt-Ingram Cancer Center National Cancer Institute (NCI)	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05945875</a>
<a href="#">NCT05887167</a>	Feasibility and Safety of Collecting and Combining Autologous Hematopoietic Stem Cells With Chimeric Antigen Receptor (CAR) T-Cell Therapy in Subjects With Relapsed/Refractory Hematological Malignancies	Biological: autologous hematopoietic stem cells added to planned CAR T	Joshua Sasine, MD, PhD Cedars-Sinai Medical Center	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05887167</a>
<a href="#">NCT05784246</a>	A Study of Mirikizumab (LY3074828) in Pediatric Participants With Moderately to Severely or Active Ulcerative Colitis	Drug: Mirikizumab IV Drug: Mirikizumab SC	Eli Lilly and Company	Phase 3	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05784246</a>
<a href="#">NCT05704634</a>	A Phase Ib Study to Evaluate the Safety and Preliminary Efficacy of IL6-receptor Antibody Sarilumab in Combination With antiPD1 Antibody Cemiplimab for Patients With Non-small Cell Lung Cancer.	Drug: Cemiplimab Drug: Kevzara (Sarilumab)	M.D. Anderson Cancer Center Regeneron Pharmaceuticals	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05704634</a>
<a href="#">NCT05667649</a>	RB-ADSC for Treatment of Mild to Moderate Alzheimer's Disease	Biological: RB-ADSC	Regeneration Biomedical, Inc.	Phase 1	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05667649</a>
<a href="#">NCT05654506</a>	Daratumumab for Treatment of Proliferative Glomerulonephritis With Monoclonal Immune Deposits	Drug: Daratumumab	Mayo Clinic	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05654506</a>
<a href="#">NCT05558982</a>	BXCL701 and Pembrolizumab in Patients With Metastatic Pancreatic Ductal Adenocarcinoma	Drug: BXCL701 Drug: Pembrolizumab	Georgetown University BioXcel Therapeutics Inc Merck Sharp & Dohme LLC	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05558982</a>
<a href="#">NCT05313243</a>	Pembrolizumab and Brentuximab Vedotin in Subjects With Relapsed/Refractory T-cell Lymphoma	Drug: Brentuximab vedotin Drug: Pembrolizumab	Tarshen Sethi Yale University	Phase 2	<a href="#">https://clinicaltrials.gov/ct2/show/study/NCT05313243</a>

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## ○ 미국 20건

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="#">NCT05944276</a>	A Study of HB0045 Injection in Patients With Advanced Solid Tumors	Drug: HB0045 Drug Product	Huabo Biopharm Co., Ltd. Gabrail Cancer Center Research Dana-Farber Cancer Institute M.D. Anderson Cancer Center	Phase 1 Phase 2	
<a href="#">NCT05981976</a>	A Study to Evaluate the Drug Levels of Abatacept Converted From Drug Substance by Two Different Processes in Healthy Participants	Biological: Abatacept	Bristol-Myers Squibb	Phase 1	
<a href="#">NCT05861895</a>	A Clinical Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity and Preliminary Efficacy of HF158K1 in Participants With HER-2 Positive or HER-2 Low Expression Advanced Solid Tumors	Drug: HF158K1 /Arm 2 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 6 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 15 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 30 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 45 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 60 mg/m <sup>2</sup>	HighField Biopharmaceuticals Corporation	Phase 1	
<a href="#">NCT05892718</a>	A Safety and Efficacy Study of HCB101, Fc-fusion Protein Targeting SIRPα-CD47 Pathway, in Solid or Hematological Tumors	Drug: HCB101	FBD Biologics Limited	Phase 1	
<a href="#">NCT05709821</a>	IMM60 and Pembrolizumab in Melanoma and NSCLC	Drug: IMM60 Drug: Pembrolizumab	iOx Therapeutics Merck Sharp & Dohme LLC Portage Biotech	Phase 1 Phase 2	
<a href="#">NCT05973006</a>	Phase 3 Adolescent Study for SARS-CoV-2 rS Variant Vaccines	Biological: NVX-CoV2601 co-formulated Omicron XBB.1.5 SARS-CoV-2 rS vaccine Biological: Prototype/XBB.1.5 Bivalent Vaccine (5 µg)	Novavax	Phase 3	
<a href="#">NCT05949684</a>	A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions	Biological: Luspatercept Biological: Epoetin Alfa	Bristol-Myers Squibb	Phase 3	
<a href="#">NCT05918250</a>	mRNA-2736 for Participants With Relapsed or Refractory Multiple Myeloma (RRMM)	Biological: mRNA-2736	ModernaTX, Inc.	Phase 1	

## ○ 영국 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05995275</a>	A Study to Investigate The Safety, Tolerability, And Immune Response of a Range of Doses of mRNA-1769 Compared With Placebo in Healthy Participants From ≥8 Years of Age to <50 Years of Age	Biological: mRNA-1769 Other: Placebo	ModernaTX, Inc.	Phase 1 Phase 2	
<a href="#">NCT05709821</a>	IMM60 and Pembrolizumab in Melanoma and NSCLC	Drug: IMM60 Drug: Pembrolizumab	iOx Therapeutics Merck Sharp & Dohme LLC Portage Biotech	Phase 1 Phase 2	

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## ○ 프랑스 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05949684</a>	A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions	Biological: Luspatercept Biological: Epoetin Alfa	Bristol-Myers Squibb	Phase 3	

## ○ 독일 1건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05949684</a>	A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions	Biological: Luspatercept Biological: Epoetin Alfa	Bristol-Myers Squibb	Phase 3	

## ○ 중국 12건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05924776</a>	Plasmodium Immunotherapy for Advanced Ovarian Cancer	Biological: Plasmodium immunotherapy	CAS Lamvac (Guangzhou) Biomedical Technology Co., Ltd. The Third Affiliated Hospital of Southern Medical University CAS Lamvac Biotech Co., Ltd.	Phase 2 Phase 3	
<a href="#">NCT05993884</a>	Safety and Preliminary Efficacy of Allogeneic Endothelial Progenitor Cells (EPCs) in Patients With Acute Ischemic Stroke	Drug: iEPCs Combination Product: Clinical standard treatment (CST)	Allife Medical Science and Technology Co., Ltd.	Phase 1	
<a href="#">NCT05985707</a>	KN026 Plus Chemotherapy ± KN-046 in HER2 Positive Colorectal Cancer and Biliary Carcinoma	Drug: KN026 Drug: KN046 Drug: XELOX	Peking University Cancer Hospital & Institute	Phase 2	
<a href="#">NCT05975463</a>	Hepatic Artery Infusion of Adebrelimab Combined With Bevacizumab in the Treatment of Advanced Hepatocellular Carcinoma With Failure of Systemic Therapy Combined With Interventional Therapy	Procedure: HAIC Drug: Adebrelimab Drug: Bevacizumab	HuiKai Li Tianjin Medical University Cancer Institute and Hospital	Phase 2	
<a href="#">NCT05972473</a>	A Study to Evaluate the Efficacy and Safety of IBI302 in Subjects With nAMD	Drug: Aflibercept Ophthalmic Biological: IBI302	Innovent Biologics (Suzhou) Co. Ltd.	Phase 3	
<a href="#">NCT05969847</a>	Organ Preservation Following Enverolimab-based Total Neoadjuvant Therapy for Locally Advanced Very Low Rectal Cancer	Radiation: split-course hypofraction radiotherapy Drug: CAPOX Drug: Envafohimab Procedure: Local excision	池畔 Fujian Medical University Union Hospital	Phase 2	
<a href="#">NCT05296278</a>	Efficacy and Biomarker Explanation of IBI-323 + Bevacizumab Plus Platinum Based Chemotherapy on ALK-Rearranged NSCLC	Drug: IBI-323 combined with bevacizumab plus Platinum	Hunan Province Tumor Hospital	Phase 2	
<a href="#">NCT05861895</a>	A Clinical Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity and Preliminary Efficacy of HF158K1 in Participants With HER-2 Positive or HER-2 Low Expression Advanced Solid Tumors	Drug: HF158K1 /Arm 2 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 6 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 15 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 30 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 45 mg/m <sup>2</sup>  Drug: HF158K1 /Arm 60 mg/m <sup>2</sup>	HighField Biopharmaceuticals Corporation	Phase 1	
<a href="#">NCT05932212</a>	A Phase II Study of AK104 for Recurrent or Metastatic Vulvar Cancer	Drug: AK104	Akeso	Phase 2	

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## ○ 중국 12건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
<a href="#">NCT05996848</a>	A Research Study to See How Well CagriSema Helps People in China With Excess Body Weight Lose Weight	Drug: Cagrilintide Drug: Semaglutide Drug: Placebo Semaglutide Drug: Placebo Cagrilintide	Novo Nordisk A/S	Phase 3	
<a href="#">NCT05946226</a>	A Phase I Trial to Evaluate the Safety of IMC002 in Advanced Digestive System Tumors	Biological: IMC001 injection	Suzhou Immunofoco Biotechnology Co., Ltd	Phase 1	
<a href="#">NCT05949684</a>	A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions	Biological: Luspatercept Biological: Epoetin Alfa	Bristol-Myers Squibb	Phase 3	