해외 바이오의약품 임상 현황 ('23년 10월 3주)

한국바이오의약품협회, 2023.10.24.

※ 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: 2023.10.16.~2023.10.22.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

○ 미국 14건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06091865	A Study to Compare How Well Odronextamab Combined With Chemotherapy Works and How Safe it is Against Rituximab Combined With Chemotherapy, in Patients With Previously Untreated Diffuse Large B-cell Lymphoma	Drug: Odronextamab|Drug: Rituximab|Drug: Cyclophosphamide|Drug: Doxorubicin|Drug: Vincristine|Drug: Prednisone/Prednisolone	Regeneron Pharmaceuticals	Phase 3	
NCT05993611	Allogeneic CD6 Chimeric Antigen Receptor T Regulatory Cells (CD6-CAR Tregs) for the Treatment of Patients With Chronic Graft Versus Host Disease After Allogeneic Hematopoietic Cell Transplantation	Procedure: Biopsy|Procedure: Biospecimen Collection|Biological: Chimeric Antigen Receptor T-Cell Therapy|Procedure: Computed Tomography|Procedure: Echocardiography|Other: Electronic Health Record Review|Procedure: Leukapheresis|Procedure: Lumbar Puncture|Procedure: Magnetic Resonance Imaging|Other: Quality-of-Life Assessment|Biological: Tafasitamab|Procedure: X-Ray Imaging	City of Hope Medical Center|National Cancer Institute (NCI)	Phase 1	
NCT05161533	Hypofractionated Radiation Therapy After Durvalumab and Chemotherapy for the Treatment of Stage IV Extensive Stage Small Cell Lung Cancer, CASPIAN-RT Trial	Drug: Carboplatin|Drug: Cisplatin|Biological: Durvalumab|Drug: Etoposide|Radiation: Hypofractionated Radiation Therapy|Other: Quality-of-Life Assessment|Other: Questionnaire Administration	University of Washington|AstraZeneca	Phase 2	
NCT05861895	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/m²|Drug: HF158K1 /Arm 6 mg/m²|Drug: HF158K1 /Arm 15 mg/m²|Drug: HF158K1 /Arm 30 mg/m²|Drug: HF158K1 /Arm 45 mg/m² |Drug: HF158K1 /Arm 60 mg/m²	HighField Biopharmaceuticals Corporation	Phase 1	
NCT05977907	Neoadjuvant Pembrolizumab and IO102-103 for Squamous Cell Carcinoma of the Head and Neck (SCCHN).	Drug: Pembrolizumab|Drug: IO102-103	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins|IO Biotech|Merck Sharp & Dohme LLC	Phase 2	
NCT06033209	A Trial to Evaluate an HIV Envelope Trimer, N332-GT5 gp140, Adjuvanted With SMNP in Adult Participants Without HIV	Biological: N332-GT5 gp140 (IM, Bolus)|Biological: N332-GT5 gp140 (IM, Fractioned)|Biological: N332-GT5 gp140 (SC, Bolus)|Biological: N332-GT5 gp140 (SC, Fractioned)|Biological: SMNP (IM, Bolus)|Biological: SMNP (IM, Fractioned)|Biological: SMNP (SC, Bolus)|Biological: SMNP (SC, Fractioned)	National Institute of Allergy and Infectious Diseases (NIAID)|National Institutes of Health (NIH)|Department of Health and Human Services	Phase 1	
NCT05968326	A Study of the Efficacy and Safety of Adjuvant Autogene Cevumeran Plus Atezolizumab and mFOLFIRINOX Versus mFOLFIRINOX Alone in Participants With Resected Pancreatic Ductal Adenocarcinoma	Drug: Autogene cevumeran|Drug: Atezolizumab|Drug: mFOLFIRINOX	Genentech, Inc.|BioNTech SE	Phase 2	
NCT05926349	A Study of Andexanet Alfa in Patients Requiring Urgent Surgery or Procedure	Drug: Andexanet alfa|Drug: Usual Care	AstraZeneca	Phase 3	

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○ 미국 14건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06083922	A Study of CyBorD (Cyclophosphamide, Bortezomib, Dexamethasone) Plus Daratumumab in People With Monoclonal Gammopathy of Renal Significance (MGRS)	Drug: Cyclophosphamide|Drug: Bortezomib|Drug: Dexamethasone|Drug: Daratumumab	Memorial Sloan Kettering Cancer Center|Janssen Pharmaceuticals	Phase 2	
NCT06072612	Study of the Bria-IMT Regimen and CPI vs Physicians' Choice in Advanced Metastatic Breast Cancer.	Biological: SV-BR-1-GM|Drug: Cyclophosphamide|Drug: Interferon infiltration of the inoculation site|Drug: Retifanlimab|Drug: Treatment of Physician's Choice	BriaCell Therapeutics Corporation	Phase 3	
NCT06021457	Effect of RBT-1 on Reducing the Risk of Post-Operative Complications in Subjects Undergoing Cardiac Surgery	Drug: RBT-1|Drug: Placebo	Renibus Therapeutics, Inc.	Phase 3	
NCT06002503	Safety, Reactogenicity and Immunogenicity of a Venezuelan Equine Encephalitis DNA Vaccine Candidate Administered by Jet Injection	Drug: Venezuelan Equine Encephalitis DNA Vaccine|Device: PharmaJet Stratis Needle-free Injection System|Device: PharmaJet Tropis Needle-free Injection System	PharmaJet, Inc.	Phase 1	
NCT05925127	Phase 2/3 Heterologous Boosting Study With Different Dose Levels of Monovalent SARS-CoV-2 rS Vaccines	Biological: NVX-CoV2373 (5μg)|Biological: NVX-CoV2601 (5μg)|Biological: NVX-CoV2601(5μg)|Biological: NVX-CoV2601 (35μg)|Biological: NVX-CoV2601(35μg)|Biological: NVX-CoV2601(50μg)|Biological: Bivalent BA.4/5	Novavax	Phase 2|Phase 3	
NCT06045806	A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation	Biological: idecabtagene vicleucel|Drug: Lenalidomide|Drug: Fludarabine|Drug: Cyclophosphamide	Bristol-Myers Squibb	Phase 3	

○ 영국 3건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06080048	A Clinical Trial to Assess the Safety of SOR102 in Healthy Participants and Patients With Ulcerative Colitis	Drug: SOR102|Drug: Placebo	Sorriso Pharmaceuticals, Inc.	Phase 1	
NCT06045806	A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation	Biological: idecabtagene vicleucel|Drug: Lenalidomide|Drug: Fludarabine|Drug: Cyclophosphamide	Bristol-Myers Squibb	Phase 3	
NCT06068855	A Study to Assess the Effectiveness of BOTOX (Botulinum Toxin Type A) Injections for the Change of Masseter Muscle Prominence in Adult Participants	Drug: BOTOX|Drug: Placebo	AbbVie	Phase 3	

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○ 프랑스 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06067061	"neoBREASTIM": Atezolizumab Plus RP1 Oncolytic Immunotherapy in the NeoAdjuvant Setting of Triple-Negative Breast Cancer	Combination Product: Atezolizumab + RP1	Institut Curie|Replimune Inc.|Roche Pharma AG	Phase 1|Phase 2	
NCT06045806	A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation	Biological: idecabtagene vicleucel|Drug: Lenalidomide|Drug: Fludarabine|Drug: Cyclophosphamide	Bristol-Myers Squibb	Phase 3	

○ 독일 3건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06045689	A Study to Assess Luspatercept in Lower-risk Myelodysplastic Syndrome Participants	Drug: Luspatercept	Bristol-Myers Squibb	Phase 3	
NCT06045806	A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation	Biological: idecabtagene vicleucel|Drug: Lenalidomide|Drug: Fludarabine|Drug: Cyclophosphamide	Bristol-Myers Squibb	Phase 3	
NCT06068855	A Study to Assess the Effectiveness of BOTOX (Botulinum Toxin Type A) Injections for the Change of Masseter Muscle Prominence in Adult Participants	Drug: BOTOX|Drug: Placebo	AbbVie	Phase 3	

○ 중국 11건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT06084962	A Study of DeepTag-GPRC5D Targeted CAR-T Cells Therapy for Refractory/Relapsed Multiple Myeloma	Biological: DeepTag-GPRC5D Targeted CAR T-cells	He Huang|Yake Biotechnology Ltd.|Zhejiang University	Phase 1	
NCT06082050	Efficacy and Safety of Intravenous YOLT-201 for Transthyretin Amyloidosis Cardiomyopathy	Drug: YOLT-201	Zhejiang University	Phase 1	
NCT05993858	Neoadjuvant PD-1 Inhibitor Combined With Cetuximab in Operable Locally Advanced HNSCC	Drug: 3cycles (Toripalimab + cetuximab)|Procedure: Surgery|Radiation: Radiotherapy or chemoradiotherapy	Wuhan Union Hospital, China	Phase 2	
NCT05296278	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	
NCT05266846	Pembrolizumab Plus Bevacizumab and Chemotherapy for ALK-rearranged NSCLC With Persistent 5'ALK	Drug: Pembrolizumab Combined With Bevacizumab and Chemotherapy	Hunan Province Tumor Hospital	Phase 2	
NCT06081621	A Clinical Study to Evaluate the Efficacy and Safety of REGEND001 Cell Therapy on Idiopathic Pulmonary Fibrosis (IPF)	Biological: REGEND001|Biological: Placebo	Regend Therapeutics|Peking Union Medical College Hospital|RenJi Hospital|Ruijin Hospital	Phase 2	

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○ 중국 11건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05861895	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/m²|Drug: HF158K1 /Arm 6 mg/m²|Drug: HF158K1 /Arm 15 mg/m²|Drug: HF158K1 /Arm 30 mg/m²|Drug: HF158K1 /Arm 45 mg/m² |Drug: HF158K1 /Arm 60 mg/m²	HighField Biopharmaceuticals Corporation	Phase 1	
NCT05944224	A Study to Efficacy and Safety of SPH4336 Monotherapy or in Combination With Cadonilimab in Patients With Advanced Solid Tumors.	Drug: SPH4336|Drug: Cadonilimab	Shanghai Pharmaceuticals Holding Co., Ltd	Phase 1|Phase 2	
NCT06049290	A Phase I/II Clinical Trial of LBL-034 in Patients With Relapsed Refractory Multiple Myeloma	Drug: LBL-034 for Injection	Nanjing Leads Biolabs Co.,Ltd	Phase 1|Phase 2	
NCT05926349	A Study of Andexanet Alfa in Patients Requiring Urgent Surgery or Procedure	Drug: Andexanet alfa|Drug: Usual Care	AstraZeneca	Phase 3	
NCT06084897	Radiotherapy in Patients With Metastatic Esophageal Cancer Responding to PD-1 Inhibitor Plus Chemotherapy	Drug: TP (Paclitaxel with cisplatin or carboplatin) or PF (Fluoropyrimidine with cisplatin or carboplatin) regimen depended on investigator's choice.|Biological: PD-1 inhibitor|Radiation: Consolidation Radiation|Radiation: Salvage Radiation	Cancer Institute and Hospital, Chinese Academy of Medical Sciences|Peking University Cancer Hospital & Institute	Phase 2	

○ 일본 2건

NCT Number	Title	Interventions	Sponsor/Collaborators	Phases	URL
NCT05926349	A Study of Andexanet Alfa in Patients Requiring Urgent Surgery or Procedure	Drug: Andexanet alfa|Drug: Usual Care	AstraZeneca	Phase 3	
NCT06045806	A Study to Compare the Efficacy and Safety of Idecabtagene Vicleucel With Lenalidomide Maintenance Therapy Versus Lenalidomide Maintenance Therapy Alone in Adult Participants With Newly Diagnosed Multiple Myeloma Who Have Suboptimal Response After Autologous Stem Cell Transplantation	Biological: idecabtagene vicleucel|Drug: Lenalidomide|Drug: Fludarabine|Drug: Cyclophosphamide	Bristol-Myers Squibb	Phase 3	