

## 해외 바이오의약품 임상 현황 (2020.07.20~2020.07.26)

한국바이오의약품협회, 2020.7.28.  
출처: ClinicalTrials.gov

### ○ 미국 20건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04418219	A Breast Cancer Vaccine (SV-BR-1-GM) in Combination With Pembrolizumab for the Treatment of Persistent, Recurrent, or Metastatic Breast Cancer	Anatomic Stage IV Breast Cancer AJCC v8 Metastatic Breast Carcinoma Prognostic Stage IV Breast Cancer AJCC v8 Recurrent Breast Carcinoma Refractory Breast Carcinoma	Drug: Cyclophosphamide Biological: Allogeneic GM-CSF-secreting Breast Cancer Vaccine SV-BR-1-GM Biological: Pembrolizumab Biological: Recombinant Interferon Alpha 2b-like Protein Other: Questionnaire Administration Other: Quality of Life Assessment	Thomas Jefferson University	Phase 1  Phase 2
NCT04370704	Study of Combination Therapy With INCMGA00012 (Anti-PD-1), INCAGN02385 (Anti-LAG-3), and INCAGN02390 (Anti-TIM-3) in Participants With Select Advanced Malignancies	Melanoma	Drug: INCAGN02385 Drug: INCAGN02390 Drug: INCMGA00012.	Incyte Corporation	Phase 1  Phase 2
NCT04207190	Talazoparib and Gemtuzumab Ozogamicin for the Treatment of CD33 Positive Relapsed or Refractory Acute Myeloid Leukemia	Recurrent Acute Myeloid Leukemia Refractory Acute Myeloid Leukemia	Drug: Gemtuzumab Ozogamicin Other: Quality-of-Life Assessment Other: Questionnaire Administration Drug: Talazoparib Drug: Talazoparib Tosylate	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1  Phase 2
NCT04479267	Polatuzumab Vedotin and Combination Chemotherapy for the Treatment of Previously Untreated Double or Triple Hit Lymphoma	Diffuse Large B-Cell Lymphoma High Grade B-Cell Lymphoma With MYC and BCL2 or BCL6 Rearrangements High Grade B-Cell Lymphoma With MYC, BCL2 and BCL6 Rearrangements	Drug: Prednisone Drug: Prednisolone Drug: Methyprednisolone Biological: Rituximab Drug: Polatuzumab Vedotin Drug: Cyclophosphamide Drug: Doxorubicin Hydrochloride	Barbara Ann Karmanos Cancer Institute National Cancer Institute (NCI)	Phase 2
NCT04468061	Sacituzumab Govitecan +/- Pembrolizumab in Metastatic TNBC	Breast Cancer Triple Negative Breast Cancer PD-L1 Negative	Drug: Sacituzumab Govitecan Drug: Pembrolizumab	Dana-Farber Cancer Institute Immunomedics, Inc. Merck Sharp & Dohme Corp.	Phase 2
NCT04456452	Study of Ampion for the Treatment of Adult COVID-19 Patients Requiring Oxygen Supplementation	COVID-19	Biological: Ampion Other: Standard of Care	Ampio Pharmaceuticals, Inc.	Phase 1
NCT04414046	TCR Alpha Beta T-cell Depleted Haploidentical HCT in the Treatment of Primary Immunodeficiency and Inherited Metabolic Disorders in Children	Primary Immune Deficiency Disorders Metabolic Disease	Biological: Haploidentical Hematopoietic Cell Transplantation	Johns Hopkins All Children's Hospital	Phase 2
NCT04356469	TCR Alpha Beta T-cell Depleted Haploidentical HCT in the Treatment of Non-Malignant Hematological Disorders in Children	Hemoglobinopathy (Disorder) Severe Aplastic Anemia Bone Marrow Failure Syndrome	Biological: Haploidentical Hematopoietic Cell Transplantation	Johns Hopkins All Children's Hospital	Phase 2
NCT04293562	A Study to Compare Standard Chemotherapy to Therapy With CPX-351 and/or Gilteritinib for Patients With Newly Diagnosed AML With or Without FLT3 Mutations	Acute Myeloid Leukemia	Procedure: Allogeneic Hematopoietic Stem Cell Transplantation Drug: Asparaginase Erwinia chrysanthemi Behavioral: Cogstate Assessment Battery Drug: Cytarabine Drug: Daunorubicin Hydrochloride Drug: Dexamethasone Hydrochloride Drug: Etoposide Drug: Gemtuzumab Ozogamicin Drug: Gilteritinib Fumarate Drug: Liposome-encapsulated Daunorubicin-Cytarabine Drug: Methotrexate Drug: Mitoxantrone Hydrochloride Drug: Therapeutic Hydrocortisone	Children's Oncology Group National Cancer Institute (NCI)	Phase 3
NCT04290546	CIML NK Cell in Head & Neck Cancer	Squamous Cell Carcinoma of the Head and Neck Recurrent Head and Neck Squamous Cell Carcinoma	Drug: Interleukin-15 Superagonist (N-803) Biological: CIML NK cell Infusion Drug: Ipilimumab	Dana-Farber Cancer Institute Altor BioScience Bristol-Myers Squibb Milenyi Biomedicine GmbH	Phase 1
NCT04332523	A Study of JNJ-53718678 in Participants With Hepatic Impairment	Hepatic Impairment	Drug: JNJ-53718678	Janssen Research & Development, LLC	Phase 1
NCT04356729	A Phase II Trial of PD-L1 Therapy Combined With Anti-VEGF Therapy in Unresectable or Metastatic Melanoma	Clinical Stage III Cutaneous Melanoma AJCC v8 Stage IV Melanoma Unresectable Stage III Cutaneous Melanoma Unresectable Stage IV Cutaneous Melanoma	Drug: Atezolizumab Drug: Bevacizumab	Elizabeth Buchbinder Genentech, Inc. Dana-Farber Cancer Institute	Phase 2
NCT04381650	A Safety and Efficacy Study of TAK-981 Plus Pembrolizumab in Participants With Select Advanced or Metastatic Solid Tumors	Advanced or Metastatic Solid Tumors	Drug: TAK-981 Drug: Pembrolizumab	Takeda Takeda Development Center Americas, Inc.	Phase 1  Phase 2
NCT04472494	Study of Abatacept in the Treatment of Hospitalized COVID-19 Participants With Respiratory Compromise	COVID-19 SARS-CoV-2	Biological: Abatacept Other: Placebo	Bristol-Myers Squibb	Phase 2
NCT04437368	A Study to Evaluate the Safety and Efficacy of Two Doses of GT005	Dry Age-related Macular Degeneration	Drug: GT005; Dose 1 Drug: GT005; Dose 2	Gyroscope Therapeutics	Phase 2
NCT04423718	Study to Gather Information on Safety and Use of High Dose Aflibercept Injection Into the Eye in Patients With an Age Related Eye Disorder That Causes Blurred Vision or a Blind Spot Due to Abnormal Blood Vessels That Leak Fluid Into the Light Sensitive Lining Inside the Eye	Neovascular Age-Related Macular Degeneration	Drug: Aflibercept High Dose VEGF Trap-Eye (BAY86-5321) Drug: Aflibercept VEGF Trap-Eye (Eylea, BAY86-5321)	Bayer Regeneron Pharmaceuticals	Phase 3
NCT04350463	A Safety and Efficacy Study of CC-90011 in Combination With Nivolumab in Subjects With Advanced Cancers	Neoplasms	Drug: CC-90011 Drug: Nivolumab	Celgene	Phase 2
NCT04420884	TAK-676 as Single Agent (SA) and in Combination With Pembrolizumab in Advanced or Metastatic Solid Tumors	Solid Neoplasms	Drug: TAK-676 Drug: Pembrolizumab	Millennium Pharmaceuticals, Inc. Takeda	Phase 1
NCT04435600	A Study of Subcutaneous Risankizumab Injection for Pediatric Participants With Moderate to Severe Plaque Psoriasis to Assess Change in Disease Symptoms	Psoriasis	Drug: Risankizumab Drug: Ustekinumab	AbbVie	Phase 3
NCT04287985	Safety and Efficacy Study of VIS649 for IgA Nephropathy	Immunoglobulin A Nephropathy Glomerular Disease IgAN	Drug: Dose-Placebo Drug: Low Dose-VIS649 Drug: Medium Dose-VIS649 Drug: High Dose-VIS649	Visterra, Inc.	Phase 2

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### ○ 영국 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04423718	Study to Gather Information on Safety and Use of High Dose Aflibercept Injection Into the Eye in Patients With an Age Related Eye Disorder That Causes Blurred Vision or a Blind Spot Due to Abnormal Blood Vessels That Leak Fluid Into the Light Sensitive Lining Inside the Eye	Neovascular Age-Related Macular Degeneration	Drug: Aflibercept High Dose VEGF Trap-Eye (BAY86-5321) Drug: Aflibercept VEGF Trap-Eye (Eylea, BAY86-5321)	Bayer Regeneron Pharmaceuticals	Phase 3
NCT04350463	A Safety and Efficacy Study of CC-90011 in Combination With Nivolumab in Subjects With Advanced Cancers	Neoplasms	Drug: CC-90011 Drug: Nivolumab	Celgene	Phase 2

### ○ 프랑스 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04423718	Study to Gather Information on Safety and Use of High Dose Aflibercept Injection Into the Eye in Patients With an Age Related Eye Disorder That Causes Blurred Vision or a Blind Spot Due to Abnormal Blood Vessels That Leak Fluid Into the Light Sensitive Lining Inside the Eye	Neovascular Age-Related Macular Degeneration	Drug: Aflibercept High Dose VEGF Trap-Eye (BAY86-5321) Drug: Aflibercept VEGF Trap-Eye (Eylea, BAY86-5321)	Bayer Regeneron Pharmaceuticals	Phase 3
NCT04350463	A Safety and Efficacy Study of CC-90011 in Combination With Nivolumab in Subjects With Advanced Cancers	Neoplasms	Drug: CC-90011 Drug: Nivolumab	Celgene	Phase 2

### ○ 독일 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04423718	Study to Gather Information on Safety and Use of High Dose Aflibercept Injection Into the Eye in Patients With an Age Related Eye Disorder That Causes Blurred Vision or a Blind Spot Due to Abnormal Blood Vessels That Leak Fluid Into the Light Sensitive Lining Inside the Eye	Neovascular Age-Related Macular Degeneration	Drug: Aflibercept High Dose VEGF Trap-Eye (BAY86-5321) Drug: Aflibercept VEGF Trap-Eye (Eylea, BAY86-5321)	Bayer Regeneron Pharmaceuticals	Phase 3
NCT04483739	Isa-KRd vs KRd in Newly Diagnosed Multiple Myeloma Patients Eligible for Autologous Stem Cell Transplantation (IsKia TRIAL)	Multiple Myeloma	Drug: Carfilzomib Lenalidomide Dexamethasone Drug: Isatuximab Carfilzomib Lenalidomide Dexamethasone	European Myeloma Network EMN Research Italy Sanofi Amgen	Phase 3

### ○ 중국 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04428255	A Clinical Study on the Efficacy and Safety of HBM9161 in Patients With ITP	Primary Immune Thrombocytopenic Purpura	Drug: HBM9161 Dose A Drug: HBM9161 Dose B Drug: Placebo	Harbour BioMed (Guangzhou) Co. Ltd.	Phase 2  Phase 3
NCT04477772	A Phase I Clinical Study of JS004 in Subjects With Recurrent/Refractory Malignant Lymphoma of China	Recurrent/Refractory Malignant Lymphoma	Biological: JS004 , Recombinant humanized IgG4k monoclonal antibody specific to BTLA for injection Intravenous infusion	Shanghai Junshi Bioscience Co., Ltd.	Phase 1

### ○ 일본 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04423718	Study to Gather Information on Safety and Use of High Dose Aflibercept Injection Into the Eye in Patients With an Age Related Eye Disorder That Causes Blurred Vision or a Blind Spot Due to Abnormal Blood Vessels That Leak Fluid Into the Light Sensitive Lining Inside the Eye	Neovascular Age-Related Macular Degeneration	Drug: Aflibercept High Dose VEGF Trap-Eye (BAY86-5321) Drug: Aflibercept VEGF Trap-Eye (Eylea, BAY86-5321)	Bayer Regeneron Pharmaceuticals	Phase 3
NCT04287985	Safety and Efficacy Study of VIS649 for IgA Nephropathy	Immunoglobulin A Nephropathy Glomerular Disease IgAN	Drug: Dose-Placebo Drug: Low Dose-VIS649 Drug: Medium Dose-VIS649 Drug: High Dose-VIS649	Visterra, Inc.	Phase 2