

해외 바이오의약품 임상 현황 (2019.09.24~2019.09.30)

한국바이오의약품협회, 2019.10.1
출처: ClinicalTrials.gov

○ 미국 26건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04109482	Trial to Evaluate the Safety and Efficacy of MB-102 in Patients With BPDEN, AML, and hrMDS.	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDEN) Acute Myeloid Leukemia Relapsed or Refractory HRMDS	Biological: MB-102 Drug: Decitabine Drug: Fludarabine Drug: Cyclophosphamide	Mustang Bio	Phase 1 Phase 2
NCT04083183	Total Body Irradiation and Astatine-211-Labeled BC8-B10 Monoclonal Antibody for the Treatment of Nonmalignant Diseases	Donor Non-Malignant Neoplasm	Biological: Astatine At 211 Anti-CD45 Monoclonal Antibody BC8-B10 Drug: Fludarabine Drug: Cyclophosphamide Biological: Lapine T-Lymphocyte Immune Globulin Radiation: Total-Body Irradiation Procedure: Hematopoietic Cell Transplantation Drug: Mycophenolate Mofetil Drug: Sirolimus	Fred Hutchinson Cancer Research Center National Cancer Institute (NCI)	Phase 1 Phase 2
NCT04081389	Chemokine Modulation Therapy and Standard Chemotherapy Before Surgery for the Treatment of Early Stage Triple Negative Breast Cancer	Anatomic Stage 0 Breast Cancer AJCC v8 Anatomic Stage I Breast Cancer AJCC v8 Anatomic Stage IA Breast Cancer AJCC v8 Anatomic Stage IB Breast Cancer AJCC v8 Anatomic Stage II Breast Cancer AJCC v8 Anatomic Stage IIA Breast Cancer AJCC v8 Anatomic Stage IIB Breast Cancer AJCC v8 Early-Stage Breast Carcinoma Estrogen Receptor Negative HER2/Neu Negative Progesterone Receptor Negative Prognostic Stage 0 Breast Cancer AJCC v8 Prognostic Stage I Breast Cancer AJCC v8 Prognostic Stage IA Breast Cancer AJCC v8 Prognostic Stage IB Breast Cancer AJCC v8 Prognostic Stage II Breast Cancer AJCC v8 Prognostic Stage IIA Breast Cancer AJCC v8 Prognostic Stage IIB Breast Cancer AJCC v8 Triple-Negative Breast Carcinoma	Drug: Celecoxib Drug: Cyclophosphamide Drug: Doxorubicin Drug: Doxorubicin Hydrochloride Drug: Paclitaxel Biological: Recombinant Interferon Alfa-2b Drug: Rintatolimod	Roswell Park Cancer Institute National Cancer Institute (NCI)	Phase 1 Phase 2
NCT04106414	Study of BMS-986205 and Nivolumab in Endometrial Cancer or Endometrial Carcinosarcoma That Has Not Responded to Treatment	Endometrial Adenocarcinoma Endometrial Carcinosarcoma	Drug: Nivolumab Drug: BMS- 986205	Memorial Sloan Kettering Cancer Center Bristol-Myers Squibb	Phase 2
NCT04105283	Tc99m-MAA Bronchial Artery Injection During Bronchial Embolization for Pulmonary Mass Induced Hemoptysis for Dosimetry Planning	Lung Cancer	Biological: Tc99m-MAA	Massachusetts General Hospital BTG International Inc.	Phase 1
NCT04096716	Mapping Draining Lymph Nodes in CNS Malignancies	Central Nervous System Neoplasms Central Nervous System Tumor	Drug: Tc-99m tilmanocept	Washington University School of Medicine	Phase 1
NCT04087018	Study to Evaluate Safety and Clinical Activity of AB122 in Biomarker Selected Participants With Advanced Solid Tumors	Advanced Solid Tumors	Drug: AB122	Arcus Biosciences, Inc. Strata Oncology	Phase 1
NCT04086121	A Study to Test the Long-term Safety of BI 655130 in Patients With Atopic Eczema Who Took Part in Study 1368-0032	Dermatitis, Atopic	Drug: Spesolimab	Boehringer Ingelheim	Phase 2
NCT04080804	Study of Safety and Tolerability of Nivolumab Treatment Alone or in Combination With Relatlimab or Ipilimumab in Head and Neck Cancer	Head and Neck Squamous Cell Carcinoma (HNSCC)	Drug: Nivolumab Drug: Relatlimab Drug: Ipilimumab	Robert Ferris Bristol-Myers Squibb University of Pittsburgh	Phase 2
NCT04056910	Ivosidenib (AG-120) With Nivolumab in IDH1 Mutant Tumors	Advanced Solid Tumor IDH1 Mutation Glioma	Drug: ivosidenib and nivolumab	Jason J. Luke, MD Agios Pharmaceuticals, Inc. Bristol-Myers Squibb (BMS) University of Pittsburgh	Phase 2
NCT04013672	Study of Pembrolizumab Plus SurVaxM for Glioblastoma at First Recurrence	Recurrent Glioblastoma	Drug: Pembrolizumab Drug: SurVaxM Drug: Sargramostim Drug: Montanide ISA 51	Manmeet Ahluwalia, MD Case Comprehensive Cancer Center	Phase 2
NCT03999424	Autologous Human Schwann Cells in Peripheral Nerve Repair	Peripheral Nerve Injuries	Biological: autologous human Schwann cells	W. Dalton Dietrich The Miami Project to Cure Paralysis University of Miami	Phase 1
NCT03991884	Inotuzumab Ozogamicin and Chemotherapy in Treating Patients With Recurrent or Refractory B-cell Acute Lymphoblastic Leukemia	Blasts 5 Percent or More of Bone Marrow Nucleated Cells Blasts 5 Percent or More of Peripheral Blood White Cells CD22 Positive Recurrent B Acute Lymphoblastic Leukemia Recurrent B Lymphoblastic Lymphoma Refractory B Acute Lymphoblastic Leukemia Refractory B Lymphoblastic Lymphoma	Drug: Etoposide Drug: Doxorubicin Drug: Doxorubicin Hydrochloride Drug: Vincristine Drug: Vincristine Sulfate Drug: Prednisone Drug: Cyclophosphamide Biological: Inotuzumab Ozogamicin Biological: Rituximab	University of Washington National Cancer Institute (NCI)	Phase 1
NCT03988283	Neopeptide-based Personalized DNA Vaccine Approach in Pediatric Patients With Recurrent Brain Tumors	Pediatric Recurrent Brain Tumor	Biological: Personalized neoantigen DNA vaccine Device: TDS-IM System Procedure: Peripheral blood draw	Washington University School of Medicine Children's Discovery Institute	Phase 1
NCT03892044	Duvelisib and Nivolumab in Treating Patients With Richter Syndrome or Transformed Follicular Lymphoma	Chronic Lymphocytic Leukemia Recurrent Diffuse Large B-Cell Lymphoma Refractory Diffuse Large B-Cell Lymphoma Richter Syndrome Small Lymphocytic Lymphoma Transformed Chronic Lymphocytic Leukemia to Diffuse Large B-Cell Lymphoma Transformed Follicular Lymphoma to Diffuse Large B-Cell Lymphoma Transformed Small Lymphocytic Lymphoma to Diffuse Large B-Cell Lymphoma	Drug: Duvelisib Biological: Nivolumab	Jennifer Woyach National Cancer Institute (NCI) Ohio State University Comprehensive Cancer Center	Phase 1
NCT03776864	Umbralisib and Pembrolizumab in Treating Patients With Relapsed or Refractory Classical Hodgkin Lymphoma	Hodgkin's Lymphoma	Biological: Pembrolizumab Drug: Umbralisib	University of Washington National Cancer Institute (NCI)	Phase 2
NCT03639324	Rituximab, Idelalisib, and Venetoclax in Relapsed/Refractory CLL	Chronic Lymphocytic Leukemia CLL Relapsed CLL Refractory Chronic Lymphocytic Leukemia Relapsed Chronic Lymphocytic Leukemia	Drug: Rituximab, Idelalisib, and Venetoclax	Virginia Commonwealth University	Phase 1
NCT03388008	Belatacept Pilot Study in Lung Transplantation Immunosuppression in Lung Transplantation	Lung Transplant Rejection Antibody-mediated Rejection	Drug: Belatacept Drug: Tacrolimus Drug: ATG Drug: Mycophenolate Mofetil Drug: Methylprednisolone Drug: Prednisone	Washington University School of Medicine National Heart, Lung, and Blood Institute (NHLBI) Bristol-Myers Squibb	Phase 2
NCT03068832	Neopeptide-based Personalized Vaccine Approach in Pediatric Patients With Recurrent Brain Tumors	Pediatric Brain Tumor	Biological: Personalized peptide vaccine Drug: Poly ICLC Procedure: Peripheral blood draw	Washington University School of Medicine	Phase 1
NCT04058145	AMD3100 Plus Pembrolizumab in Immune Checkpoint Blockade Refractory Head and Neck Squamous Cell Carcinoma	Head and Neck Cancer	Drug: AMD3100 Drug: Pembrolizumab	Massachusetts General Hospital Merck Sharp & Dohme Corp. AperiSys, Inc	Phase 2

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NCT03915405	KHK2455 (IDO Inhibitor) Plus Avelumab in Adult Subjects With Advanced Bladder Cancer	Urothelial Carcinoma	Drug: KHK2455 Drug: Avelumab	Kyowa Kirin Pharmaceutical Development, Inc.	Phase 1
NCT03835819	A Phase 2 Study of Mirvetuximab Soravtansine (IMGN853) and Pembrolizumab in Endometrial Cancer (EC)	Endometrial Cancer	Drug: Pembrolizumab Drug: IMGN853	Dana-Farber Cancer Institute ImmunoGen, Inc. Merck Sharp & Dohme Corp.	Phase 2
NCT03804944	Converting HR+ Breast Cancer Into an Individualized Vaccine	Breast Cancer	Radiation: Focal Radiation therapy Drug: Pembrolizumab (200mg IV for 30 minutes) Biological: CDX-301	Weill Medical College of Cornell University	Phase 2
NCT04095273	Study to Test How Well Patients With Advanced Solid Tumors Respond to Treatment With the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab, to Find the Optimal Dose for Patients, How the Drug is Tolerated and the Way the Body Absorbs, Distributes and Discharges the Drug	Advanced Solid Tumors	Drug: BAY1895344 Drug: Pembrolizumab	Bayer	Phase 1
NCT03915184	Clinical Trial to Evaluate CT053 in Patients With Relapsed and/or Refractory Multiple Myeloma	Multiple Myeloma	Biological: CT053	Carsgen Therapeutics, Ltd.	Phase 1
NCT03996486	Study to Test the Safety of an Investigational Drug Given Repeatedly to Adult Men With Severe Hemophilia	Hemophilia	Drug: BAY1093884	Bayer	Phase 1

○ 영국 2건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04095273	Study to Test How Well Patients With Advanced Solid Tumors Respond to Treatment With the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab, to Find the Optimal Dose for Patients, How the Drug is Tolerated and the Way the Body Absorbs, Distributes and Discharges the Drug	Advanced Solid Tumors	Drug: BAY1895344 Drug: Pembrolizumab	Bayer	Phase 1
NCT04025879	A Study of Neoadjuvant Chemotherapy Plus Nivolumab Versus Neoadjuvant Chemotherapy Plus Placebo, Followed by Surgical Removal and Adjuvant Treatment With Nivolumab or Placebo for Participants With Surgically Removable Early Stage Non-small Cell Lung Cancer	Carcinoma, Non-Small-Cell Lung	Biological: Nivolumab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Pemetrexed Drug: Placebo	Bristol-Myers Squibb	Phase 3

○ 프랑스 3건

NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT03220932	Cytoreductive Surgery and HIPEC in First or Secondary Platinum-resistant Recurrent Ovarian Epithelial Cancer	Ovarian Epithelial Cancer	Procedure: Cytoreductive surgery combined with HIPEC Drug: Chemotherapy and bevacizumab (CT-BEV)	Hospices Civils de Lyon	Phase 3
NCT04006262	Peri-operative Association of Immunotherapy (Pre-operative Association of Nivolumab and Ipilimumab, Post-operative Nivolumab Alone) in Localized Microsatellite Instability (MSI) and/or Deficient Mismatch Repair (dMMR) Oeso-gastric Adenocarcinoma	Localized Oesogastric Adenocarcinoma MSI and or dMMR	Drug: Nivolumab 10 MG/ML Drug: Ipilimumab 200 MG in 40 ML Injection	GERCOR - Multidisciplinary Oncology Cooperative Group Bristol-Myers Squibb	Phase 2
NCT04025879	A Study of Neoadjuvant Chemotherapy Plus Nivolumab Versus Neoadjuvant Chemotherapy Plus Placebo, Followed by Surgical Removal and Adjuvant Treatment With Nivolumab or Placebo for Participants With Surgically Removable Early Stage Non-small Cell Lung Cancer	Carcinoma, Non-Small-Cell Lung	Biological: Nivolumab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Pemetrexed Drug: Placebo	Bristol-Myers Squibb	Phase 3

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04075604	A Study of Neoadjuvant Nivolumab + Abemaciclib or Palbociclib + Anastrozole in Post-Menopausal Women and Men With Primary Breast Cancer	Breast Cancer Cancer	Biological: Nivolumab Drug: Abemaciclib Drug: Anastrozole Drug: Palbociclib	Bristol-Myers Squibb	Phase 2
NCT04025879	A Study of Neoadjuvant Chemotherapy Plus Nivolumab Versus Neoadjuvant Chemotherapy Plus Placebo, Followed by Surgical Removal and Adjuvant Treatment With Nivolumab or Placebo for Participants With Surgically Removable Early Stage Non-small Cell Lung Cancer	Carcinoma, Non-Small-Cell Lung	Biological: Nivolumab Drug: Carboplatin Drug: Cisplatin Drug: Paclitaxel Drug: Pemetrexed Drug: Placebo	Bristol-Myers Squibb	Phase 3

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NCT Number	Title	Conditions	Interventions	Sponsor/Collaborators	Phases
NCT04106180	SBRT in Combination With Sintilimab and GM-CSF for the Treatment of Advanced NSCLC	NSCLC Stage IV	Drug: GM-CSF Drug: Sintilimab Radiation: SBRT	Fudan University	Phase 2
NCT04044651	Lenvatinib Plus Nivolumab Versus Lenvatinib for Advanced Hepatocellular Carcinoma With Hepatitis B Virus Infection	Hepatocellular Carcinoma	Drug: Lenvatinib Drug: Nivolumab	Shi Ming First Affiliated Hospital, Sun Yat-Sen University Guangzhou No.12 People's Hospital Guangdong Provincial People's Hospital Third Affiliated Hospital, Sun Yat-Sen University Sun Yat-sen University	Phase 2 Phase 3
NCT04024462	A Two-Arm Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Combination With Chemotherapy in Chinese Participants With HER2-Positive Early Breast Cancer	HER2-positive Early Breast Cancer	Drug: Pertuzumab IV Drug: Trastuzumab IV Drug: FDC of Pertuzumab and Trastuzumab SC Drug: Doxorubicin Drug: Cyclophosphamide Drug: Docetaxel Procedure: Surgery Radiation: Post-Operative Radiotherapy Drug: Hormone Therapy	Hoffmann-La Roche	Phase 3