

해외 바이오의약품 임상 현황 ('23년 12월 1주)

한국바이오의약품협회, 2023.12.12.

※ 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: 2023.12.04.~2023.12.10.
- 주간 업데이트 제공국가 : 미국, 유럽(영국, 프랑스, 독일), 중국, 일본

○ 미국 13건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|---|---|--|-----------------|--|
| NCT05828511 | A Window of Opportunity Trial to Learn if Linvoseltamab is Safe and Well Tolerated, and How Well it Works in Participants With Recently Diagnosed Multiple Myeloma Who Have Not Already Received Treatment. | Drug: Linvoseltamab | Regeneron Pharmaceuticals | Phase 1 Phase 2 | ClinicalTrials.gov/NCT05828511 |
| NCT06054776 | Acalabrutinib, Obinutuzumab, and Glofitamab for the Treatment of Relapsed or Refractory Mantle Cell Lymphoma | Drug: Acalabrutinib Procedure: Biospecimen Collection Procedure: Bone Marrow Biopsy Procedure: Computed Tomography Procedure: Echocardiography Biological: Glofitamab Procedure: Multigated Acquisition Scan Biological: Obinutuzumab Procedure: Positron Emission Tomography | City of Hope Medical Center National Cancer Institute (NCI) | Phase 2 | ClinicalTrials.gov/NCT06054776 |
| NCT05823480 | Magrolimab in Combination With Azacitidine After Allogeneic HCT in Treating Patients With High-Risk AML or MDS | Procedure: Allogeneic Hematopoietic Stem Cell Transplantation Drug: Azacitidine Procedure: Biospecimen Collection Procedure: Bone Marrow Aspirate Procedure: Bone Marrow Biopsy Procedure: Echocardiography Biological: Magrolimab Procedure: Multigated Acquisition Scan Other: Questionnaire Administration | City of Hope Medical Center National Cancer Institute (NCI) | Phase 1 | ClinicalTrials.gov/NCT05823480 |
| NCT05722327 | Phase I Trial of Adagrasib (MRTX849) in Combination With Cetuximab and Irinotecan in Patients With Colorectal Cancer | Drug: MRTX849 Drug: Irinotecan Drug: Cetuximab | M.D. Anderson Cancer Center Mirati Therapeutics | Phase 1 | ClinicalTrials.gov/NCT05722327 |
| NCT05716009 | Tagraxofusp-erzs, an IL-3 Diphtheria Fusion Protein, in Combination With Gemtuzumab Ozogamicin in Patients With Relapsed/Refractory AML | Drug: Dose Escalation -tagraxofusp-erzs Drug: Dose Expansion at RP2D - tagraxofusp-erzs | Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Stemline Therapeutics, Inc. | Phase 1 | ClinicalTrials.gov/NCT05716009 |
| NCT04482933 | HSV G207 With a Single Radiation Dose in Children With Recurrent High-Grade Glioma | Drug: Biological G207 | Pediatric Brain Tumor Consortium Treovir, LLC | Phase 2 | ClinicalTrials.gov/NCT04482933 |
| NCT06127043 | A Study of Efficacy and Safety of Rosnilimab in Subjects With Moderate to Severe Ulcerative Colitis (ROSETTA) | Drug: Rosnilimab Drug: Placebo | AnaptysBio, Inc. | Phase 2 | ClinicalTrials.gov/NCT06127043 |
| NCT05682443 | ONC-392 Plus Lutetium Lu 177 Vipivotide Tetraxetan in Patients With mCRPC | Drug: ONC-392 Drug: Lutetium Lu 177 vipivotide tetraxetan 7.4 GBq (200 mCi), IV infusion, Q6W for up to 6 doses. | OncoC4, Inc. Prostate Cancer Clinical Trials Consortium | Phase 1 Phase 2 | ClinicalTrials.gov/NCT05682443 |
| NCT06079281 | Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants With HPP Who Have Not Previously Been Treated With Asfotase Alfa | Drug: ALXN1850 Drug: Placebo | Alexion Pharmaceuticals, Inc. | Phase 3 | ClinicalTrials.gov/NCT06079281 |

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|-----------------------------|--|--|--|---------|---|
| NCT06034002 | A Study to Evaluate INCA033989 Administered in Participants With Myeloproliferative Neoplasms | Drug: INCA033989 | Incyte Corporation | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT06034002 |
| NCT06079372 | Phase 3 Study of ALXN1850 in Pediatric Participants With HPP Previously Treated With Asfotase Alfa | Drug: ALXN1850 Drug: asfotase alfa | Alexion Pharmaceuticals, Inc. | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT06079372 |
| NCT05997264 | Anthrax AV7909 Boost Evaluation Study | Biological: AV7909 Full Dose (0.5 mL) Biological: AV7909 Half Dose (0.25 mL) | Biomedical Advanced Research and Development Authority Rho Federal Systems Division, Inc. ICON plc | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT05997264 |
| NCT06090539 | A Study to Assess BMS-986458 Alone and in Combination With Anti-lymphoma Agents in Relapsed/Refractory Non-Hodgkin Lymphomas | Drug: BMS-986458 Drug: Rituximab | Bristol-Myers Squibb | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT06090539 |

○ 영국 3건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|---|-------------------------------|---------|---|
| NCT06079281 | Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants With HPP Who Have Not Previously Been Treated With Asfotase Alfa | Drug: ALXN1850 Drug: Placebo | Alexion Pharmaceuticals, Inc. | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT06079281 |
| NCT06109779 | A Study of Rilvegostomig Plus Chemotherapy as Adjuvant Therapy for Biliary Tract Cancer After Resection | Drug: Rilvegostomig Drug: Placebo Drug: Capecitabine Drug: Gemcitabine/Cisplatin Drug: S-1 [Tegafur/Oteracil/gimeracil] | AstraZeneca | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT06109779 |
| NCT06079372 | Phase 3 Study of ALXN1850 in Pediatric Participants With HPP Previously Treated With Asfotase Alfa | Drug: ALXN1850 Drug: asfotase alfa | Alexion Pharmaceuticals, Inc. | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT06079372 |

○ 프랑스 5건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|---|--|-----------------|---|
| NCT06150040 | Acute Myeloid Leukemia Treated With With NETrin Abs in Combination With [AZACITIDINE + VENETOCLAX] | Drug: NP137 Drug: Azacitidine Injection Drug: Venetoclax | Centre Leon Berard NETRIS Pharma | Phase 1 Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT06150040 |
| NCT06045975 | Durvalumab/Tremelimumab in Neoadjuvant and Adjuvant Setting in Patients With HCC Treated by Electroporation Ablation | Drug: Durvalumab/Tremelimumab in neoadjuvant and Durvalumab in adjuvant setting | Assistance Publique - Hôpital de Paris AstraZeneca | Phase 2 | https://clinicaltrials.gov/ct2/show/study/NCT06045975 |
| NCT06090539 | A Study to Assess BMS-986458 Alone and in Combination With Anti-lymphoma Agents in Relapsed/Refractory Non-Hodgkin Lymphomas | Drug: BMS-986458 Drug: Rituximab | Bristol-Myers Squibb | Phase 1 | https://clinicaltrials.gov/ct2/show/study/NCT06090539 |
| NCT06079281 | Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants With HPP Who Have Not Previously Been Treated With Asfotase Alfa | Drug: ALXN1850 Drug: Placebo | Alexion Pharmaceuticals, Inc. | Phase 3 | https://clinicaltrials.gov/ct2/show/study/NCT06079281 |
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| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|---|-------------------------------|---------|-----|
| NCT06109779 | A Study of Rilvegostomig Plus Chemotherapy as Adjuvant Therapy for Biliary Tract Cancer After Resection | Drug: Rilvegostomig Drug: Placebo Drug: Capecitabine Drug: Gemcitabine/Cisplatin Drug: S-1 [Tegafur/Oteracil/gimeracil] | AstraZeneca | Phase 3 | |
| NCT06079281 | Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants With HPP Who Have Not Previously Been Treated With Asfotase Alfa | Drug: ALXN1850 Drug: Placebo | Alexion Pharmaceuticals, Inc. | Phase 3 | |
| NCT06079372 | Phase 3 Study of ALXN1850 in Pediatric Participants With HPP Previously Treated With Asfotase Alfa | Drug: ALXN1850 Drug: asfotase alfa | Alexion Pharmaceuticals, Inc. | Phase 3 | |

○ 중국 6건

| NCT Number | Title | Interventions | Sponsor/Collaborators | Phases | URL |
|-----------------------------|--|---|--|-----------------|-----|
| NCT06135168 | A Clinical Trail to Compare Pharmacokinetics of Two PEG-rhGH Injections With Different Preparations | Drug: PEG-rhGH with new preparation Drug: PEG-rhGH with present preparation | Changchun GeneScience Pharmaceutical Co., Ltd. | Phase 1 | |
| NCT06148649 | Phase 2 Study of HEC88473 Injection in Subjects With Type 2 Diabetes Mellitus | Drug: HEC88473, Placebo, Dulaglutide | Dongguan HEC Biopharmaceutical R&D Co., Ltd. | Phase 2 | |
| NCT05939167 | Mesenchymal Stem Cells Treatment for AIDS Patients at Late Stage | Drug: mesenchymal stem cell Other: saline | Cell Energy Life Sciences Group Co. LTD Beijing 302 Hospital Shenzhen Third People's Hospital Fifth Hospital of Shijiazhuang City Beijing YouAn Hospital | Phase 1 Phase 2 | |
| NCT06157827 | A Clinical Trial of LBL-024 Combined With Etoposide and Platinum in Patients With Advanced Neuroendocrine Carcinoma | Drug: LBL-024 for Injection Drug: Etoposide Injection Drug: Cisplatin for Injection Drug: Carboplatin Injection | Nanjing Leads Biolabs Co.,Ltd | Phase 1 Phase 2 | |
| NCT06155396 | A Study of RC48-ADC Combination With Zimberelimab Injection Therapies at Least First-line Platinum-containing Standard Therapy Failed With Recurrent or Metastatic Cervical Cancer | Drug: Disitamab Vedotin Drug: Zimberelimab | RemeGen Co., Ltd. | Phase 2 | |
| NCT06079281 | Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants With HPP Who Have Not Previously Been Treated With Asfotase Alfa | Drug: ALXN1850 Drug: Placebo | Alexion Pharmaceuticals, Inc. | Phase 3 | |

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| NCT06079281 | Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants With HPP Who Have Not Previously Been Treated With Asfotase Alfa | Drug: ALXN1850 Drug: Placebo | Alexion Pharmaceuticals, Inc. | Phase 3 | |