ForPatients
by Roche

Solid Tumors

A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Preliminary Efficacy of Atezolizumab (Anti-Programmed Death-Ligand 1 [PD-L1] Antibody) in Pediatric and Young Adult Participants With Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Terminated	11 Countries	NCT02541604 2014-004697-41 GO29664

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Early-Phase, Multicenter, Open-Label Study of the Safety and Pharmacokinetics of Atezolizumab (MPDL3280A) In Pediatric and Young Adult Patients With Previously Treated Solid Tumors

Trial Summary:

This early phase, multicenter, open-label, single-arm study evaluated the safety, tolerability, pharmacokinetics, immunogenicity, and preliminary efficacy of atezolizumab in pediatric and young adult participants with solid tumors for which prior treatment was proven to be ineffective.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT02541604 2014-004697-41 GO29664
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 30 Years	No

Inclusion Criteria:

- Pediatric solid tumor (including Hodgkin's and Non-Hodgkin's lymphoma), for which prior treatment had proven to be ineffective (that is, relapsed or refractory) or intolerable

- Disease that is measurable as defined by RECIST v1.1, mINRC, Revised Response Criteria for Malignant Lymphoma, RANO criteria (as appropriate) or evaluable by nuclear medicine techniques, immunocytochemistry techniques, tumor markers, or other reliable measures
- Archival tumor tissue block or 15 freshly cut, unstained, serial slides available for submission, or willingness to undergo a core or excisional biopsy prior to enrollment (fine-needle aspiration, brush biopsy, and lavage samples are not acceptable).

Participants with fewer than 15 slides available may be eligible for study entry following discussion with Medical Monitor

- Lansky Performance Status (participants less than [<] 16 years old) or Karnofsky Performance Status (participants greater than or equal to [>=] 16 years old) >=50
- Life expectancy >=3 months, in the investigator's judgment
- Adequate hematologic and end organ function, confirmed by laboratory results obtained within 28 days prior to initiation of study drug

Exclusion Criteria:

- Known primary central nervous system (CNS) malignancy or symptomatic CNS metastases, except ATRT
- Treatment with high-dose chemotherapy and hematopoietic stem-cell rescue within 3 months prior to initiation of study drug
- Prior allogeneic hematopoietic stem-cell transplantation or prior solid-organ transplantation
- Treatment with chemotherapy (other than high-dose chemotherapy as described above) or differentiation therapy (such as retinoic acid) or immunotherapy (such as anti-GD2 antibody treatment) within 3 weeks prior to initiation of study drug or, if treatment included nitrosoureas, within 6 weeks prior to initiation of study drug
- Treatment with thoracic or mediastinal radiotherapy within 3 weeks prior to initiation of study drug
- Treatment with hormonal therapy (except hormone replacement therapy or oral contraceptives) or biologic therapy within 4 weeks or 5 half-lives, whichever is shorter, prior to initiation of study drug. This requirement may be waived at the investigator's request if the participant has recovered from therapeutic toxicity to the degree specified in the protocol, with approval of the Medical Monitor
- Treatment with a long-acting hematopoietic growth factor within 2 weeks prior to initiation of study drug or a short-acting hematopoietic growth factor within 1 week prior to initiation of study drug
- Treatment with investigational therapy (with the exception of cancer therapies as described above) within 4 weeks prior to initiation of study drug
- Treatment with a live vaccine or a live, attenuated vaccine (e.g., nasal spray of live attenuated influenza vaccine or FluMist®) within 4 weeks prior to initiation of study drug or anticipation that such treatment will be required during the study or within 5 months after the final dose of study drug
- Treatment with herbal cancer therapy within 1 week prior to initiation of study drug
- Prior treatment with cluster of differentiation 137 (CD137) agonists or immune checkpoint blockade therapies, including anti-cytotoxic T-lymphocyte-associated protein 4 (anti-CTLA4), anti-programmed death-1 (PD-1), or anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents (including but not limited to interferons or interleukin 2 [IL-2]) within 6 weeks or five drug elimination half-lives prior to Day 1 of Cycle 1, whichever is longer
- Treatment with systemic corticosteroids or other systemic immunosuppressive medications (including but not limited to prednisone, dexamethasone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor [TNF] agents) at the time of initiation of study drug, or anticipated requirement for systemic immunosuppressive medications during the study
- Current treatment with therapeutic anticoagulants

- Any non-hematologic toxicity (excluding alopecia) from prior treatment that has not resolved to Grade less than or equal to (<=) 1 (per National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE] version 4.0) at screening
- Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation