A Phase 1/2, Open-Label, Dose-Escalation and Expansion Study of Entrectinib (RXDX-101) in Pediatrics with Locally Advanced or Metastatic Solid or Primary CNS Tumors and/or Who Have no Satisfactory Treatment Options PROTOCOL NUMBER: CO40778 (RXDX-101-03)

Status: Terminated

Eligibility Criteria

Inclusion Criteria:

1. Disease status:
   • Phase 1 portion (closed): Participants must have measurable or evaluable disease, as defined by RECIST v1.1
   • Phase 2 portion:
     • Part B: Participants must have measurable or evaluable disease, as defined by RANO
     • Part C (closed): Participants must have measurable or evaluable disease, as defined by RECIST v1.1 Â± Curie Scale
     • Part D: Participants must have measurable or evaluable disease, as defined by RECIST v1.1
     • Part E (closed): Participants must have measurable or evaluable disease, as defined by RECIST v1.1 Â± Curie Scale or RANO 2. Tumor type:
   • Phase 1 portion: * Part A: Relapsed or refractory extracranial solid tumors
   • Phase 2 portion:
     • Part B: Primary brain tumors with NTRK1/2/3 or ROS1 gene fusions; gene fusions are defined as those predicted to translate into a fusion protein with a functional TRKA/B/C or ROS1 kinase domain, without a concomitant second oncogene as determined by a nucleic acid-based diagnostic testing method
     • Part D: Extracranial solid tumors (including NB) with NTRK1/2/3 or ROS1 gene fusions; gene fusions are defined as those predicted to translate into a fusion protein with a functional TRKA/B/C or ROS1 kinase domain, without a concomitant second oncogene as determined by a nucleic acid-based diagnostic testing method
     • Part E: Participants must have measurable or evaluable disease, as defined by RECIST v1.1 Â± Curie Scale or RANO 3. Tumor type: * Part A: Relapsed or refractory extracranial solid tumors

Exclusion Criteria:

1. Receiving other experimental therapy 2. Known congenital long QT syndrome 3. History of recent (3 months) symptomatic congestive heart failure or ejection fraction ≤50% at screening 4. Known active infections 5. Familial or personal history of congenital bone disorders, bone metabolism alterations or osteopenia 6. Receiving Enzyme Inducing Antiepileptic Drugs (EIAEDs) within 14 days of first dose 7. Prior treatment with approved or investigational TRK or ROS1 inhibitors 8. Known hypersensitivity to entrectinib or any of the other excipients of the investigational medicinal product 9. Females of childbearing potential must have a negative serum pregnancy test during screening and be neither breastfeeding nor intending to become pregnant during study participation. Agreement to remain abstinent or use use combined contraceptive methods prior to study entry, for the duration of study participation and in the following 90 days after discontinuation of study treatment. 10. For male participants with a female partner of childbearing potential or a pregnant female partner: Agreement to remain abstinent or use a condom during the treatment period and for at least 3 months after the last dose of study drug

Conditions & Interventions

Interventions:
Drug: Entrectinib

Conditions:
Solid Tumors, CNS Tumors

Keywords:
TRK, Tyrosine kinase, NTRK, NTRK1, NTRK2, NTRK3, ROS1, ALK, Pediatric, Relapsed, Refractory, Solid Tumor, Metastatic Cancer, Gene rearrangement, Neuroblastoma, Infantile fibrosarcoma, Secretory breast cancer, Congenital mesoblastic nephroma, Pontine glioma, Brain tumors, CNS tumors, Sarcoma, Ewing sarcoma, Glioblastoma, Salivary Gland Cancer (MASC), Papillary thyroid cancer, Medulloblastoma, Wilms tumor (anaplastic)

More Information

Description: This is a Phase 1/2 multicenter, open-label dose escalation study in pediatric patients (<18 years) with relapsed or refractory extracranial solid tumors (Phase 1; Part A), with additional expansion cohorts (Phase 2) in patients with primary brain tumors harboring NTRK1/2/3 or ROS1 gene fusions (Part B), and extracranial solid tumors harboring NTRK1/2/3 or ROS1 gene fusions (Part D).

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System ID: NCT02650401

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