A Phase I, Dose-Escalation and Dose-Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Antitumor Activities of CS5001, an Anti-ROR1 Antibody Drug Conjugate, in Patients With Advanced Solid Tumors and Lymphomas

Clinical summary

This is a dose escalation and dose expansion study to evaluate how safe and tolerable a drug called CS5001 is, as well as to determine its anti-cancer effect, in people with advanced solid cancers and lymphomas.
CS5001 is an antibody-drug conjugate (ADC) that targets the ROR1 which is a protein linked to various cancers. Once the drug binds to ROR1 on tumour cells, it the releases a toxin (pyrrolobenzodiazepine or PBD) which kills cancer cells while minimising harm to health tissue.
In both study stages, CS5001 will be administered every 3 weeks (21 days) by intravenous (IV) infusion.
The Dose Escalation stage will be recruiting people with either:

Advanced solid cancer that is unable to be removed with surgery (unresectable), that has progressed on or after at least 1 line of prior treatment with drugs (systemic therapy), or
Hodgkin or non-Hodgkin B-cell lymphoma that has progressed on or after at least 2 lines of prior systemic therapy.

The Dose Expansion stage will enrol people with either:

Mantle Cell Lymphoma (following at least 2 prior lines of systemic therapy including BTK inhibitors);
Diffuse large B Cell lymphoma (following at least 2 prior lines of systemic therapy); or
Triple Negative Breast Cancer (fllowing at least 2 lines of systemic therapy for advanced disease).

Conditions

This trial is treating patients with advanced solid cancers or lymphoma

Trial Acronym

Trial Identifiers
NCT05279300
CS5001-101

Cancer
Acute Lymphoblastic Lymphoma, Adrenocortical carcinoma, Anus, Astrocytoma, Basal cell carcinoma, B-Cell Non Hodgkin Lymphoma, Bile duct, Bladder, Bone, Brain, Brain stem, Breast, Cancer of Unknown Primary, Central Nervous System, Cervix, Chondrosarcoma, Colon, Colorectum, Cutaneous Squamous Cell Carcinoma (CSCC), Diffuse Large Cell Lymphoma, Endometrium, Ependymomas, Epithelial, Ewing's Sarcoma, Fallopian tube, Follicular Lymphoma, Gallbladder, Gastrointestinal stromal tumors (GISTs), Gastro-oesophageal junction , Germ cell and sex cord stromal cell, Germ cell tumour, Glioblastoma (GBM) , Glioma, Head and neck, Hodgkin's Disease (Hodgkin's Lymphoma), Kidney, Leiomyosarcoma, Liposarcoma, Liver, Lung, Lymphoma, Mantle Cell Lymphoma, Medullablastoma, Melanoma (Ocular), Melanoma (Skin), Meningioma, Merkel cell, Mouth (including tonsil, tongue, soft palate, cheeks, lips, gum), Neuroblastoma, Neuroendocrine tumours, Non-Small Cell Lung Cancer, Nose (nasopharynx), Oesophagus, Oral cavity, Oropharynx, Osteosarcoma, Ovary, Pancreas, Penis, Peritoneal, Prostate, Rectum, Renal cell carcinoma, Rhabdomyosarcoma, Salivary glands, Sarcoma, Skin Lymphoma, Small Cell Lung Cancer, Soft Tissue Sarcoma, Spinal Cord, Squamous cell carcinoma (Head and Neck), Squamous cell carcinoma (Skin), Stomach, Synovial Sarcoma, T-Cell Lymphoma, Testis, Throat (hypopharynx), Thyroid, Urinary tract, Urothelial, Uterus, Vagina, Voice box (larynx), Vulva, Wilm's tumour

Age: 18+
Phase: I

For full trial details, visit trials.cancervic.org.au/details/vctl_nct05279300