ForPatients
by Roche

Pancreatic CancerBladder CancerCancer

A Study to Determine Best Tumor Response With Trastuzumab Emtansine in Human Epidermal Growth Factor Receptor 2 (HER2) Overexpressing Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT02999672 2015-001377-40 MO29694

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:

Phase II, Exploratory, Multicenter, Non Randomized, Single Agent Cohort Study to Determine Best Tumor Response With Trastuzumab Emtansine in HER2 Overexpressing Solid Tumors

Trial Summary:

This multicenter, non-randomized, Phase II study will assess the efficacy, safety, and pharmacokinetics of trastuzumab emtansine in participants with HER2 overexpressing locally advanced (unresectable and not treatable with curative intent) or metastatic urothelial bladder cancer (UBC), locally advanced (unresectable and not treatable with curative intent) or metastatic pancreatic cancer/cholangiocarcinoma with advanced disease where cure is no longer possible and where no other treatment options are available anymore. Participants will receive intravenous (IV) infusion of trastuzumab emtansine as Regimen A (2.4 milligrams per kilogram [mg/kg], weekly [qw]) or Regimen B (3.6 mg/kg, every 3 weeks [q3w]) until unacceptable toxicity, withdrawal of consent, disease progression (PD), or death, whichever occurs first. Based on tolerability and safety aspects, steering committee and Independent Data Monitoring Committee (iDMC) will decide on expansion of the study to include more participants with other carcinoma types.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT02999672 2015-001377-40 MO29694
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	# 18 Years	No

Inclusion Criteria:

- Histologically centrally confirmed HER2-positive (immunohistochemistry [IHC]3+ in greater than or equal to [>/=] 30 percent [%] of tumor cells): locally advanced (unresectable and not treatable with curative intent), or metastatic UBC or locally advanced (unresectable and not treatable with curative intent) or metastatic pancreatic cancer/cholangiocarcinoma
- There must be no standard treatment options available for participants with the above HER2 overexpressing tumors and they must have undergone at least one prior platinum-based treatment for locally advanced (unresectable and not treatable with curative intent) or metastatic tumor (Note: for pancreatic cancer/cholangiocarcinoma, prior treatments are not required to be platinum-based.)
- Participant's lesion should be measurable according to RECIST V1.1 on diagnostic computed tomography (CT) scan/magnetic resonance imaging (MRI); Target lesion(s) should not have been previously irradiated
- At least one formalin-fixed paraffin-embedded (FFPE) biopsy of the primary tumor and/or from a metastatic site is required
- Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0-2
- No significant cardiac history and a current left ventricular ejection fraction (LVEF) >/=50%
- Adequate organ function
- Life expectancy of at least 12 weeks

Exclusion Criteria:

- Participants with previous exposure to HER2-targeted therapies in any setting
- Participants showing histologically confirmed focal HER2-expression, that is, less than (<) 30% of positively stained tumor cells
- Participants with brain metastasis as the sole site of metastatic disease and/or are symptomatic or require therapy to control symptoms
- Current uncontrolled hypertension (systolic greater than [>] 150 millimeters of mercury [mmHg] and/or diastolic >100 mmHg)
- Current unstable angina pectoris
- History of symptomatic congestive heart failure (CHF) of any New York Heart Association (NYHA) criteria or ventricular arrhythmia that requires treatment
- History of myocardial infarction within the last 6 months
- Peripheral neuropathy, Grade >/=3
- Current dyspnea at rest due to complications of advanced malignancy, or other diseases that require continuous oxygen therapy
- Current severe, uncontrolled systemic disease
- History of other malignancy within the last 5 years
- Concurrent, serious, uncontrolled infections or current known infection with human immunodeficiency virus (HIV), active hepatitis B and/or hepatitis C
- Known prior severe hypersensitivity to trastuzumab and trastuzumab emtansine or the excipients of the investigational medicinal product (IMP)
- Clinically significant bleeding within 30 days before enrollment
- Major surgical procedure or significant traumatic injury within 28 days prior to randomization or anticipation of the need for major surgery during the course of study treatment
- Concurrent participation in any other therapeutic clinical trial