NOVARTIS

Phase I Study of [177Lu]Lu-NNS309 in Patients With Pancreatic, Lung, Breast and Colorectal Cancers

Last Update: Apr 27, 2025

Phase I Open-label, Multi-center Study to Evaluate the Safety, Tolerability, Dosimetry, and Preliminary Activity of [177Lu]Lu-NNS309 in Patients With Pancreatic, Lung, Breast and Colorectal Cancers

ClinicalTrials.gov Identifier:

NCT06562192

Novartis Reference Number:CFXX489A12101

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate the safety, tolerability, dosimetry and preliminary efficacy of \[177Lu\]Lu-NNS309 and the safety and imaging properties of \[68Ga\]Ga-NNS309 in patients aged ≥ 18 years with locally advanced or metastatic pancreatic ductal adenocarcinoma (PDAC), non-small cell lung cancer (NSCLC), HR+/HER2- ductal and lobular breast cancer (BC), triple negative breast cancer (TNBC) and colorectal cancer (CRC). The study will be done in two parts. The first part is called "escalation" and the second part is called "expansion". In both parts of the study, patients will initially be imaged with a \[68Ga\]Ga-NNS309 positron emission tomography (PET)/ computed tomography (CT) or PET/magnetic resonance imaging (MRI) scan and will be evaluated for eligibility for \[177Lu\]Lu-NNS309 treatment. In the escalation part, different doses of \[177Lu\]Lu-NNS309 will then be tested to identify recommended dose(s) (RD(s)) for further evaluation. The expansion part of the study will examine the safety and preliminary efficacy of \[177Lu\]Lu-NNS309 at the RD(s) determined during the escalation part. The end of study will occur when all patients per disease group in the expansion part have completed the follow-up for disease progression or discontinued from the study for any reason, and all patients have completed treatment and the 36-month long-term follow-up period.

Condition

Pancreatic Ductal Adenocarcinoma, Non-small Cell Lung Cancer, HR+/HER2- Ductal and Lobular Breast Cancer, Triple Negative Breast Cancer, Colorectal Cancer

Phase

Phase1

Overall Status

Recruiting

Number of Participants

124

Start Date

Oct 15, 2024

Completion Date
Jun 26, 2030
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

[177Lu]Lu-NNS309

Radioligand therapy
Drug

[68Ga]Ga-NNS309

Radioligand imaging agent

Eligibility Criteria

Inclusion Criteria:

* Age ≥ 18 years old
* Patients with one of the following indications:
* Locally advanced unresectable or metastatic PDAC with disease progression following, or intolerance to cytotoxic chemotherapy, unless patient was ineligible to receive such therapy
* Locally advanced unresectable or metastatic NSCLC without any actionable genomic alterations with disease progression following, or intolerance to chemotherapy and immunotherapy, unless patient was ineligible to receive such therapy, or locally advanced unresectable or metastatic NSCLC with an actionable genomic alteration with disease progression following, or intolerance to targeted therapy, unless patient was ineligible to receive such therapy
* Locally advanced unresectable or metastatic HR+/HER2- ductal or lobular BC with disease progression following, or intolerance to, at least 2 lines of therapy, unless patient was ineligible to receive such therapy
* Locally advanced unresectable or metastatic TNBC with disease progression following, or intolerance to, at least 2 lines of therapy, unless patient was ineligible to receive such therapy
* (Dose escalation part only) Locally advanced or metastatic unresectable CRC with disease progression following, or intolerance to cytotoxic chemotherapy, unless patient was ineligible to receive such therapy. Patients with known microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) status must also have had disease progression following, or intolerance to immune checkpoint inhibitor therapy, unless patient was ineligible to receive such therapy
* Patients must have lesions showing 68Ga-NNS309 uptake

Exclusion Criteria:

* Absolute neutrophil count (ANC) \< 1.5 x 109/L, hemoglobin \< 9 g/dL, or platelet count \< 100 x 109/L
* QT interval corrected by Fridericia's formula (QTcF) ≥ 470 msec
* Creatinine clearance \< 60 mL/min

* Unmanageable urinary tract obstruction or urinary incontinence
* Radiation therapy within 4 weeks prior to the first dose of \[177Lu\]Lu-NNS309

Other protocol-defined inclusion/exclusion criteria may apply.

Canada

Novartis Investigative Site

Recruiting

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Novartis Investigative Site

Recruiting

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06562192*

List of links present in page

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