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JNJ-90301900 (NBTXR3) activated by radiotherapy with or without cetuximab in LA-HNSCC

Submission date 15/05/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/02/2026	**Overall study status** Ongoing	
Last Edited 26/10/2026	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04892173

Clinical Trials Information System (CTIS)
2024-530386-31

Integrated Research Application System (IRAS)
1011758

Central Portfolio Management System (CPMS)
49832

Protocol serial number
NANORAY-312: Phase 3

Study information

Scientific Title
A Phase 3 Study of NBTXR3 Activated by Investigator's Choice of Radiotherapy Alone or Radiotherapy in Combination With Cetuximab for Platinum-based Chemotherapy-Ineligible Elderly Patients With LA-HNSCC

Study objectives
-

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/08/2025, East Midlands - Nottingham 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8065; nottingham2.rec@hra.nhs.uk), ref: 25/WM/0107

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Locally advanced head & neck squamous cell carcinoma

Interventions
Participants will undergo a screening assessment over a period of less than or equal to (<=) 28 days to determine eligibility.

Eligible participants will be treated by the Investigator's choice of RT alone or RT in combination with cetuximab. Following theInvestigator's choice, participants will be randomized in a 1:1 ratio:

Arm A: JNJ-90301900 (NBTXR3), as an intratumoral/intranodal injection, activated by investigator's choice of RT alone or RT incombination with cetuximab
Arm B: Investigator's choice of RT alone or RT in combination with cetuximab

All participants (Arm A and Arm B) will receive 70 Gy in 35 fractions over a 7 week period.

An EOT visit will be performed 4 weeks after the completion of RT. Follow-up visits will start at 12 weeks post-RT completion, and willcontinue every 12 weeks for 2 years, and then every 24 weeks thereafter until death; the participant is determined to be lost to follow up;withdrawal of consent; or the end of the study, whichever occurs first. Participants who have received further anti-cancer therapy for thestudy disease and/or have had disease progression/recurrence will be followed only for survival information

Experimental: Arm A
-JNJ-90301900 (NBTXR3), as an intratumoral/intranodal injection, activated by investigator's choice of RT alone or RT in combination with cetuximab. JNJ-90301900 (NBTXR3) is given as a dose of 33%of the Gross Tumor Volume.

- Drug: JNJ-90301900 (NBTXR3)
- Suspension of inert, crystalline hafnium oxide particles, designed to generate oxygen free radicals to destroy cancer cells after activation by ionizing radiation.

- Other Names:
-- Functionalized hafnium oxide nanoparticles
-- NBTXR3

- Drug: Cetuximab
- Solution for infusion

- Other Names:
-- Erbitux

- Radiation: Radiation Therapy
- Intensity-modulated radiation therapy (IMRT): 70Gray in 35 fractions over a 7-week period.

Active Comparator: Arm B
- Investigator's choice of RT alone or RT in combination with cetuximab.

- Drug: Cetuximab
- Solution for infusion

- Other Names:
-- Erbitux

- Radiation: Radiation Therapy
- Intensity-modulated radiation therapy (IMRT): 70Gray in 35 fractions over a 7-week period.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cetuximab, JNJ-90301900 [Hafnium Oxide]

Primary outcome(s)
Progression-free Survival (PFS).Time from randomization to local-regional recurrence, local-regional progression, distant progression, or death from any cause, whichever occurs first measured using patient records up to 30 months following first randomized participant

Key secondary outcome(s)
1. Overall Survival (OS). Time from randomization to death from any cause measured using patient records up to 48 months following first randomized participant
2. Local-regional control. Time to local regional progression: time from Randomization to local-regional progression or death, whichever occurs first measured using patient records up to 48 months following first randomized participant
3. Distant control. Time to distant progression: time from Randomization to distant progression or death, whichever occurs first measured using patient records up to 48 months following first randomized participant
4. Objective Response Rate (ORR). Rate of complete response (CR)+partial response (PR) [RESIST 1.1] measured using patient records up to 48 months following first randomized participant
5. Duration of Overall Response. Time from CR or PR to progression of disease, unequivocal clinical progression, or death, whichever occurs first measured using patient records up to 48 months following first randomized participant
6. Quality of Life over time - QLQ H&N35. Change from baseline over time in symptoms, function, and health related QOL using the European Organisation for Research and Treatment of Cancer (EORTC) questionnaire-Head and Neck Cancer Module (QLQ H&N35) up to 48 months following first randomized participant
7. Quality of Life over time - EQ 5D 5L. Change from baseline over time in symptoms, function, and health related QOL using the 5 level EuroQol 5 dimension (EQ 5D5L) instrument up to 48 months following first randomized participant
8. Safety across duration of study. Adverse events (AEs) measured using patient records up to 48 months following first randomized participant

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Age greater than or equal to (>=) 60 years old
2. Squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or supraglottic larynx and a candidate for definitive radiation therapy with or without cetuximab
3. Clinical stage T3-4 NX or T2 N2-3 disease according to the 8th edition of AJCC
4. One primary tumor lesion amendable for intratumoral injection
5. Ineligible to receive platinum-based chemotherapy with radiation (at least one of the following):
- Estimated creatinine clearance >= 30 and less than (<) 50 milliliters/minute (mL/min) (per

Cockcroft-Gault equation),Grade >= 2 hearing loss or tinnitus, Grade >= 2 peripheral neuropathy, Eastern Cooperative Oncology Group (ECOG)Performance Status 2 or New York Heart Association Class 3
- Age 70-74 years old with Geriatric 8 (G8) score less than or equal to (<=) 14
- Age >= 75 years old

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Carcinoma of the nasopharynx, paranasal sinus(es), salivary gland, thyroid gland, or unknown primary
2. Non-squamous cell histology
3. Clinical stage T1-2 N0, T2 N1, or M1 disease according to the 8th edition of AJCC
4. Loco-regionally recurrent head & neck cancer that has been previously treated with surgery, radiation therapy, and/or chemotherapy
5. Prior or concurrent primary malignancy (including second synchronous head & neck cancer) within the last 2 years of informed consent and whose natural history has the potential to interfere with the safety and efficacy assessment of the investigational agent
6. Ongoing or active infection requiring treatment with antimicrobial therapy within 2 weeks of randomization

Date of first enrolment
05/01/2022

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

Austria

Belgium

Brazil

Bulgaria

Canada

China

Croatia

Czech Republic

Finland

France

Georgia

Germany

Greece

Hungary

India

Israel

Japan

Korea, South

Philippines

Portugal

Romania

Serbia

Spain

Sweden

Taiwan

United States of America

Study participating centre

-
-
-
England
-

Sponsor information

Organisation
Johnson And Johnson Enterprise Innovation Inc.

Funder(s)

Funder type
Industry

Funder Name
Johnson And Johnson Enterprise Innovation Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at www.janssen.com/clinical- trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request