Nimotuzumab- Head and neck cancer

---------- Public Title:
Nimotuzumab- Head and neck cancer
---------- Scientific Title:
Using the monoclonal antibody Nimotuzumab in treating patients with squamous cell carcinoma of head and neck in advanced stages.
---------- Secondary Identifying Numbers:
IIC RD-EC0113
---------- Issuing Authority of the Secondary Identifying Numbers:
Center of Molecular Immunology(CIM)
---------- Primary Sponsor:
Center of Molecular Immunology(CIM)
---------- Secondary Sponsor(s):
No proceed
---------- Source(s) of Monetary or Material Support:
Goverment found
---------- Regulatory authority to approve the initiation to the study:
Center for State Control of the Quality of Medicines (CECMED),Notification,24-081-08-B
---------- Authorization Date:
26/12/2008 00:00
---------- Reference Number:
24-081-08-B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Holguín
---------- Principal Clinical Site:
“Vladimir Ilich Lenin” Hospital
---------- Principal Investigator:
MD.María de los Angeles Reynaldo González.Second degree specialist in Otorrinolaringologia.
---------- Other Clinical Sites:
Havana City,“Hermanos Ameijeiras” Hospital,MD.Tamara Correa Pablos.First degree specialist in Radiologia.
Havana City,Research Center for Medical-Surgical(CIMEQ),MD.Ilsa Garcia Estrada.First degree specialist in Otorrinolaringologia.
Havana City,National Institute of Oncology and Radiobiology(INOR),MD.Miguel Arredondo López.First degree specialist in Oncology.
Havana City,“Enrique Cabrera” Hospital,MD.Vladimir Tomás Pérez Báez.First degree specialist in Otorrinolaringologia.
Villa Clara,“Celestino Hernandez Robau” Hospital,MD.Julio Hernández Cruz.First degree specialist in Oncology.
Camaguey,“María Curie” Hospital,MD.Lisandro Vila Martínez.First degree specialist in Otorrinolaringologia.
Santiago de Cuba,“Conrado Benítez” Hospital,MD.Justo Despaigne Delisle.Second degree specialist in Surgery.
---------- Research Ethics Committees:
Havana City,“Hermanos Ameijeiras” Hospital,December 8,2008.
Havana City,Research Center for Medical-Surgical(CIMEQ),May 14,2009.
Havana City,National Institute of Oncology and Radiobiology(INOR),June 22,2009.
Havana City,“Enrique Cabrera” Hospital,October 17 de,2008.
Villa Clara,“Celestino Hernandez Robau” Hospital,July 28,2008.
Camaguey,“María Curie” Hospital,0ctober 13,2008.

Holguin,“Vladimir Ilich Lenin” Hospital,25 de Agosto de 2008.
Santiago de Cuba,“Conrado Benítez” Hospital,July 21,2008.
---------- Recruitment Status:
2. Active
---------- Date of First Enrollment:
06/01/2009 00:00
---------- Health Condition(s) or Problem(s) Studied.:
Squamous cell carcinoma of head and neck in advanced stages.
---------- Intervention(s):
Treatment schemes:
1.Schedule A:Nimotuzumab + RT
2.Schedule B:Nimotuzumab + RT + CT,concurrent
3.Schedule C:Nimotuzumab + RT + CT,sequential
4.Scheme D:Monotherapy with Nimotuzumab
5.Scheme E: Nimotuzumab + CT
Nimotuzumab Indication: 200 mg intravenous infusion (IV),(30-60 minutes,diluted in 250 ml 0.9% NaCl)
Induction phase:,1 time/week for 6 weeks.
Maintenance phase: every 21 days until discontinuation of treatment (IT) for at least one of the causes provided in the protocol.
Indication of radiotherapy(RT): Dose:66 Gy
Scheme may involve Co60, linear accelerator or fractionated 2 Gy/day,1-5 days a week (Monday-Friday) until doses indicated.
Indication of Chemotherapy(CT):Cisplatin 100 mg/m2 intravenous(EV) + 5-FU 1000 mg/m2.
Frequency and Duration of Treatment:
Concurrent treatment: days 1, 22 and 43
Sequential treatment:Cisplatin days 1, 5-FU days 1-4 (Monday-Thursday) every 3 to 4 weeks for 3 cycles.
---------- Primary Outcome(s):
Incidence of Adverse Events (AE) relating to the administration of Nimotuzumab (AE with causal relationship probable or very likely). Measuring time: every three months until to complete 2 years of treatment.
---------- Key Secondary Outcomes:
Clinical Response (Objective response and Antitumor Clinical Response). Measuring Time: every 3 months until to complete 2 years of treatment.
- Objective response (Measurable disease and No measurable disease)
- Measurable disease (Complete Response,Partial Response,No change,Progression),
- No measurable disease (Complete Response, Partial Response, Stabilization, Progression)
- Antitumor Clinical Response(Complete Response, Partial Response, Progressive Disease, Stable disease)
Progression-free survival (PFS). Time in months from inclusion date until it objectively documented progressive disease or death. Measuring time: 2 years of treatment or progression date or death date.
Global Survival. Time in months from the inclusion date until death or last date you have news. Measurement time: 2 years of treatment or death.
Quality of Life (Quality of Life Questionnaire EORTC QLQ-C30 (version 3) and QLQ-H&N35 (version 3)). Measuring Time: every 3 months until to complete 2 years of treatment.
Adverse events (AE). Measuring Time: 2 years of treatment.
- Type of AE (name of the adverse event)
- Time between the time of administration and the occurrence of AE (hours and minutes or days)
- Duration of AE (Difference between of start date and the end date of the AE. May be in days, hours or minutes)
- Serious AE (Severe/Serious, not serious/not serious)
- Intensity of AE (Grade 1:Slight, Grade 2:Moderate, Grade 3:Severe, Grade 4:Danger to life, Grade 5:Death)

- Causal relationship (Remote, possible, probable, very likely) accordint to FDA criteria
- Possible causal treatment (name of treatment that provo, if one considers that the AE is due to the administration Nimotuzumab or the QT and/or RT or other concomitant treatment)
- Attitude from study treatment (unchanged, dose modification, temporary discontinuation of study treatment, permanent discontinuation of study treatment)
- Result of AE (recovered, improved, persist, sequelae)

---------- Gender:
3. Both
---------- Minimun Age:
18 years
---------- Maximun Age:
none
---------- Inclusion Criteria:
1.Age greater than or equal to 18 years.
2.Life expectancy of at least 12 weeks.
3.General status ECOG 0-2.
4.Patients give their consent to participate in the study in writing.
---------- Exclusión criteria:
1.Patient at the time of inclusion is receiving another investigational drug.
2.Pregnancy,postpartum or breastfeeding.
3.History of hypersensitivity to any of the components of the pharmaceutical formulation of Nimotuzumab.
4.Presence of a second primary tumor, except basal or squamous cell carcinoma of the skin and neck carcinoma in situ treated.
---------- Type of Participant:
2. Patients
---------- Type of study:
1. Interventional
---------- Allocation:
3. N/A: single arm study.
---------- Masking:
1. Open.
---------- Control Group:
3. Uncontrolled
---------- Study Design:
1. Single Group
---------- Other Design:
---------- Purpose:
1. Treatment
---------- Phase:
8. Phase IV
---------- Target Sample Size:
Inclusion of 2 years.
---------- First Name (Contact for Public Queries):
Patricia MD.
---------- Middle Name (Contact for Public Queries):
---------- Last Name (Contact for Public Queries):
Piedra
---------- Affiliation (Contact for Public Queries):
CIMAB SA.
---------- Postal Address (Contact for Public Queries):
206 No.1926 e/ 19 and 21 Atabey,Playa
---------- City (Contact for Public Queries):
Havana City

---------- Country (Contact for Public Queries):
Cuba
---------- Zip Code (Contact for Public Queries):
11600
---------- Telephone (Contact for Public Queries):
(537)271-50-57 Etx.111
---------- Email Address (Contact for Public Queries):
patrip@cim.sld.cu
---------- First Name (Contact for Scientific Queries):
Patricia MD.
---------- Middle Name (Contact for Scientific Queries):
---------- Last Name (Contact for Scientific Queries):
Piedra
---------- Affiliation (Contact for Scientific Queries):
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Cuba
---------- Zip Code (Contact for Scientific Queries):
11600
---------- Telephone (Contact for Scientific Queries):
(537)271-50-57 Ext.111
---------- Email Address (Contact for Scientific Queries):
patrip@cim.sld.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000089
---------- Date of Registration in Primary Register:
22/10/2009 20:00
---------- Record Verification Date:
27/08/2009 20:00

Agregar un Comentario