

Trial record 1 of 1 for: Bay 16996

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Radium-223 Dichloride Long-term Follow-up Program

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified July 2015 by Bayer

Sponsor:

Bayer

Information provided by (Responsible Party):

Bayer

ClinicalTrials.gov Identifier:

NCT02312960

First received: December 5, 2014

Last updated: July 9, 2015

Last verified: July 2015

[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

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Purpose

Patients will be followed up in this study after prior treatment with **BAY 88-8223** / Radium-223 dichloride / Xofigo

Condition	Intervention	Phase
Neoplasm Metastasis / Bone and Bones	Other: Data Collection	Phase 4

Study Type: Interventional

Study Design: Allocation: Non-Randomized

Endpoint Classification: Safety Study

Intervention Model: Single Group Assignment

Masking: Open Label

Official Title: A Phase 4 Long-term Follow-up Study to Define the Safety Profile of Radium-223 Dichloride

Resource links provided by NLM:

[Drug Information](#) available for: [Succinylcholine chloride](#) [Radium Ra 223 dichloride](#)

[U.S. FDA Resources](#)

Further study details as provided by Bayer:

Primary Outcome Measures:

- Incidence of radium 223 dichloride related Adverse Events (AEs) [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Severity of radium 223 dichloride related Adverse events (AEs) [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
Severity will be measured as per guidelines by Common Terminology Criteria for Adverse Events; Version 4.03 (CTCAE)
- Incidence of radium 223 dichloride related Serious Adverse Events (SAEs) [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Incidence of leukemia [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Incidence of myelodysplastic syndrome [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Incidence of aplastic anemia [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Incidence of primary bone cancer [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Incidence of any other new primary malignancy [Time Frame: Up to 7 years] [Designated as safety issue: Yes]
- Incidence of febrile neutropenia in subjects who receive cytotoxic chemotherapy [Time Frame: Up to 7 years]

[Designated as safety issue: Yes]

- Incidence of hemorrhage in subjects who receive cytotoxic chemotherapy [Time Frame: Up to 7 years]
[Designated as safety issue: Yes]

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: Up to 7 years] [Designated as safety issue: No]

OS defined as the time in days from the subject's applicable feeder trial start date to the date of death due to any cause

Estimated Enrollment: 800
Study Start Date: December 2014
Estimated Study Completion Date: September 2025
Estimated Primary Completion Date: September 2025 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Arm 1 The subjects previously enrolled in a selected radium-223 dichloride feeder trial will be contacted in 6-month intervals for follow up and query	Other: Data Collection No study treatment will be provided in this long term follow up study

Detailed Description:

This long-term follow up study will enroll subjects who will be transferred from selected interventional, company sponsored trials with radium-223 dichloride (feeder trials).

The primary objectives are to define the long term safety profile of radium-223 dichloride (for up to 7 years after the last dose of radium-223 dichloride); to assess the incidence of leukemia, myelodysplastic syndrome, aplastic anemia, and primary bone cancer or any other new primary malignancy; and, in subjects who receive cytotoxic chemotherapy, to assess the incidence of febrile neutropenia and hemorrhage during their chemotherapy treatment and for up to 6 months thereafter at a frequency based on local clinical practice.

The secondary objective is to evaluate overall survival (OS).

▶ Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Subject was previously enrolled in a selected company sponsored feeder trial, and has received at least 1 dose of radium 223 dichloride or placebo in the feeder trial

Exclusion Criteria:

- Not applicable to this follow up study

▶ Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02312960

Contacts

Contact: Bayer Clinical Trials Contact clinical-trials-contact@bayerhealthcare.com

Locations

Germany

Not yet recruiting

Freiburg im Breisgau, Baden-Württemberg, Germany, 79106

Not yet recruiting

Tübingen, Baden-Württemberg, Germany, 72076

Not yet recruiting

Ulm, Baden-Württemberg, Germany, 89091

Not yet recruiting

Erlangen, Bayern, Germany, 91054

Not yet recruiting

München, Bayern, Germany, 81377

Recruiting

Rostock, Mecklenburg-Vorpommern, Germany, 18107

Not yet recruiting

Aachen, Nordrhein-Westfalen, Germany, 52074

Not yet recruiting

Mainz, Rheinland-Pfalz, Germany, 55131

Not yet recruiting

Dresden, Sachsen, Germany, 01307

Recruiting

Jena, Thüringen, Germany, 07740

Recruiting

Berlin, Germany, 10719

Not yet recruiting

Berlin, Germany, 12200

Recruiting

Bremen, Germany, 28277

Not yet recruiting

Hamburg, Germany, 20246

Not yet recruiting

Magdeburg, Germany, 39120

Russian Federation

Not yet recruiting

Moscow, Russian Federation, 115478

Not yet recruiting

Obninsk, Russian Federation, 249036

Sponsors and Collaborators

Bayer

Investigators

Study Director: Bayer Study Director Bayer

 **More Information**

Additional Information:

[Click here and search for drug information provided by the FDA.](#) 

[Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product.](#) 

No publications provided

Responsible Party: Bayer
ClinicalTrials.gov Identifier: [NCT02312960](#) [History of Changes](#)
Other Study ID Numbers: [16996](#), 2014-002407-25
Study First Received: December 5, 2014
Last Updated: July 9, 2015
Health Authority: Australia: Department of Health and Ageing Therapeutic Goods Administration
Belgium: Federal Agency for Medicinal Products and Health Products
Brazil: National Sanitary Vigilance Agency (ANVISA)
Canada: Health Canada

Chile: Instituto de Salud Pública de Chile
Czech Republic: State Institute for Drug Control
Finland: Finnish Medicines Agency
France: Agence française de sécurité sanitaire des produits de santé (Afssaps)
Germany: Federal Institute for Drugs and Medical Devices
Israel: Ministry of Health
Italy: Agenzia Italiana del Farmaco
Japan: Pharmaceuticals and Medical Devices Agency
South Korea: Korea Food and Drug Administration (KFDA)
Norway: Norwegian Medicines Agency
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Russia: Ministry of Health of Russian Federation
Singapore: Health Sciences Authority
Spain: Agencia Española de Medicamentos y Productos Sanitarios
Sweden: Medical Products Agency
Taiwan: Department of Health
Netherlands: College ter Beoordeling van Geneesmiddelen Medicines Evaluation Board
United Kingdom: Medicines and Healthcare Products Regulatory Agency
United States: Food and Drug Administration

Additional relevant MeSH terms:

Neoplasm Metastasis
Neoplasms
Neoplastic Processes
Pathologic Processes
Radium Ra 223 dichloride
Succinylcholine
Antineoplastic Agents

Neuromuscular Agents
Neuromuscular Blocking Agents
Neuromuscular Depolarizing Agents
Peripheral Nervous System Agents
Pharmacologic Actions
Physiological Effects of Drugs
Therapeutic Uses

ClinicalTrials.gov processed this record on July 12, 2015