Denosumab

Targets (1)

IDENTIFICATION

Name

Denosumab

Accession Number

DB06643

Type

Biotech

Groups

Approved

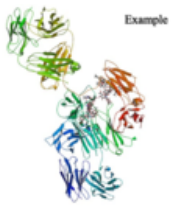
Biologic Classification

Protein Based Therapies
Monoclonal antibody (mAb)

Description

Denosumab is a novel, fully human IgG2 monoclonal antibody specific to receptor activator of nuclear factor kappa-B ligand (RANKL), suppresses bone resorption markers in patients with a variety of metastatic tumors and is being investigated in multiple clinical trials for the prevention and treatment of bone metastases. Chemically, it consists of 2 heavy and 2 light chains. Each light chain consists of 215 amino acids. Each heavy chain consists of 448 amino acids with 4 intramolecular disulfides. FDA approved on June 1, 2010.

Protein structure



Protein chemical formula

$C_{6404}H_{9912}N_{1724}O_{2004}S_{50}$

Protein average weight

144700.0 Da

Sequences

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> Denosumab αOPGL-1 heavy chain sequence
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SSGLYSLSSVVTVPSSSLGTQTYICNVNHKPSNTKVDKKVEPKSCDKTHTCPPCPAPELL
GGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPEVKFNWYVDGVEVHNAKTKPREEQ
YNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPREPQVYTLPPSR
DELTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFFLYSKLTVDKS
RWQQGNVFSCSVMHEALHNHYTQKSLSLSPGK
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> Denosumab αOPGL-1 light chain sequence
EIVLTQSPGTLSLSPGERATLSCRASQSVRGRYLAWYQQKPGQAPRLLIYGASSRATGIP
DRFSGSGSGTDFTLTISRLEPEDFAVFYCQQYGSSPRTFGQGTKVEIKRTVAAPSVFIFP
PSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSTYSLSSTL
TLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC
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Synonyms

Not Available

External IDs

AMG-162

Prescription Products

Search

NAME	DOSAGE	STRENGTH	ROUTE	LABELLER	MARKETING START	MARKETING END		
Prolia	Solution	60 mg	Subcutaneous	Amgen	2010-08-12	Not applicable		
Prolia	Injection	60 mg/mL	Subcutaneous	Amgen	2010-06-05	Not applicable		
Prolia	Solution	60 mg	Subcutaneous	Amgen	Not applicable	Not applicable		
Xgeva	Injection, solution	120 mg	Subcutaneous	Amgen Europe B.V.	2011-07-13	Not applicable		
Xgeva	Injection	120 mg/1.7mL	Subcutaneous	Amgen	2010-11-18	Not applicable		
Xgeva	Injection, solution	120 mg	Subcutaneous	Amgen Europe B.V.	2011-07-13	Not applicable		
Xgeva	Solution	120 mg	Subcutaneous	Amgen	2011-06-06	Not applicable		
Xgeva	Injection, solution	120 mg	Subcutaneous	Amgen Europe B.V.	2011-07-13	Not applicable		

Showing 1 to 8 of 8 entries

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International/Other Brands

Ranmark (Daiichi Sankyo)

Categories

Amino Acids, Peptides, and Proteins

Antibodies

Antibodies, Monoclonal

Blood Proteins

Bone Density Conservation Agents

Drugs Affecting Bone Structure and Mineralization

Drugs for Treatment of Bone Diseases

Globulins

Immunoglobulins

Immunoproteins

Musculo-Skeletal System

Proteins

RANK Ligand Inhibitor

Serum Globulins

UNII

4EQZ6YO2HI

CAS number

615258-40-7

PHARMACOLOGY

Indication

Prolia is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. It reduces the incidence of vertebral, nonvertebral, and hip fractures. Prolia is also indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. It can also be used in men with osteoporosis at high risk for fracture or in men receiving androgen deprivation therapy for nonmetastatic prostate cancer to increase bone mass. Xgeva is indicated for the prevention of skeletal-related events in patients with bone metastases from solid tumors.

Structured Indications

Bone Loss

Bone pain

Fracture Bone

Spinal Cord Compression

Bone destruction

Giant cell tumor of the bone

High risk of fracture Osteoporosis

Refractory Hypercalcemia of malignancy

Pharmacodynamics

In clinical studies, treatment with 60 mg of Prolia resulted in reduction in the bone resorption marker serum type 1 C-telopeptide (CTX) by approximately 85% by 3 days. Consistent with the physiological coupling of bone formation and resorption in skeletal remodeling, subsequent

Mechanism of action

Denosumab is designed to target RANKL (RANK ligand), a protein that acts as the primary signal

to promote bone removal/resorption. In many bone loss conditions, RANKL overwhelms the body's natural defense against bone destruction. Denosumab prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone.

(A)	Tumor necrosis factor ligand superfamily member 11
	antibody
	Human

Absorption

When 60 mg of denosumab was subcutaneously administered to healthy subjects after fasting for 12 hours, the pharmacokinetic parameters are as follows: Cmax = 6.75 mcg/mL; Tmax= 10 days (range of 3 to 21 days); AUC (0-16 weeks) = 316 mcg•day/mL. Denosumab does not accumulate following multiple doses once every 6 months. The pharmacokinetics of denosumab were not affected by the formation of antibodies.

Volume of distribution

Not Available

Protein binding

Not Available

Metabolism

Not Available

Route of elimination

Not Available

Half life

25.4 days

Clearance

Not Available

Toxicity

In patients with postmenopausal osteoporosis, the most common adverse reactions (> 5% and more common than placebo) were: back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis. Pancreatitis has been reported in clinical trials. In male patients with osteoporosis, the most common adverse reactions (> 5% and more common than placebo) were: back pain, arthralgia, and nasopharyngitis. In patients experiencing bone loss due to hormone ablation for cancer, the most common adverse reactions (≥ 10% and more common than placebo) were: arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials

Affected organisms

Pathways

Not Available

Pharmacogenomic Effects/ADRs

Not Available

INTERACTIONS

Drug Interactions

Search

DRUG	INTERACTION	DRUG GROUP
2-Methoxyethanol	The risk or severity of adverse effects can be increased when Denosumab is combined with 2-Methoxyethanol.	Experimental
Abatacept	The risk or severity of adverse effects can be increased when Denosumab is combined with Abatacept.	Approved
Abetimus	The risk or severity of adverse effects can be increased when Denosumab is combined with Abetimus.	Investigational
Acteoside	The risk or severity of adverse effects can be increased when Denosumab is combined with Acteoside.	Investigational
Adalimumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Adalimumab.	Approved
Adefovir	The risk or severity of adverse effects can be increased when Denosumab is combined with Adefovir.	Investigational
Afelimomab	The risk or severity of adverse effects can be increased when Denosumab is combined with Afelimomab.	Investigational
Alefacept	The risk or severity of adverse effects can be increased when Denosumab is combined with Alefacept.	Approved, Investigational, Withdrawn
Alemtuzumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Alemtuzumab.	Approved, Investigational
Alicaforsen	The risk or severity of adverse effects can be increased when Denosumab is combined with Alicaforsen.	Investigational
Altretamine	The risk or severity of adverse effects can be increased when Denosumab is combined with Altretamine.	Approved
Amsacrine	The risk or severity of adverse effects can be increased when Denosumab is combined with Amsacrine.	Approved, Investigational
Anakinra	The risk or severity of adverse effects can be increased when Denosumab is combined with Anakinra.	Approved
Anthrax immune globulin human	The therapeutic efficacy of Anthrax immune globulin human can be decreased when used in combination with Denosumab.	Approved
Antilymphocyte immunoglobulin (horse)	The risk or severity of adverse effects can be increased when Denosumab is combined with Antilymphocyte immunoglobulin (horse).	Approved, Investigational
Antithymocyte immunoglobulin (rabbit)	The risk or severity of adverse effects can be increased when Denosumab is combined with Antithymocyte immunoglobulin (rabbit).	Approved
Apremilast	The risk or severity of adverse effects can be increased when Denosumab is combined with Apremilast.	Approved, Investigational
Azacitidine	The risk or severity of adverse effects can be increased when Denosumab is combined with Azacitidine.	Approved, Investigational

Azathioprine	The risk or severity of adverse effects can be increased when Denosumab is combined with Azathioprine.	Approved
Bacillus calmette-guerin substrain connaught live antigen	The therapeutic efficacy of Bacillus calmette-guerin substrain connaught live antigen can be decreased when used in combination with Denosumab.	Approved, Investigational
Bacillus calmette-guerin substrain tice live antigen	The therapeutic efficacy of Bacillus calmette-guerin substrain tice live antigen can be decreased when used in combination with Denosumab.	Approved
Basiliximab	The risk or severity of adverse effects can be increased when Denosumab is combined with Basiliximab.	Approved, Investigational
BCG vaccine	The therapeutic efficacy of BCG vaccine can be decreased when used in combination with Denosumab.	Investigational
Begelomab	The risk or severity of adverse effects can be increased when Denosumab is combined with Begelomab.	Experimental, Investigational
Belatacept	The risk or severity of adverse effects can be increased when Denosumab is combined with Belatacept.	Approved, Investigational
Belimumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Belimumab.	Approved
Benznidazole	The risk or severity of adverse effects can be increased when Denosumab is combined with Benznidazole.	Approved, Investigational
Betamethasone	The risk or severity of adverse effects can be increased when Denosumab is combined with Betamethasone.	Approved, Vet Approved
Bleomycin	The risk or severity of adverse effects can be increased when Denosumab is combined with Bleomycin.	Approved, Investigational
Blinatumomab	The risk or severity of adverse effects can be increased when Denosumab is combined with Blinatumomab.	Approved, Investigational
Brentuximab vedotin	The risk or severity of adverse effects can be increased when Denosumab is combined with Brentuximab vedotin.	Approved
Briakinumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Briakinumab.	Investigational
Brodalumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Brodalumab.	Approved, Investigational
Budesonide	The risk or severity of adverse effects can be increased when Denosumab is combined with Budesonide.	Approved
Busulfan	The risk or severity of adverse effects can be increased when Denosumab is combined with Busulfan.	Approved, Investigational
Cabazitaxel	The risk or severity of adverse effects can be increased when Denosumab is combined with Cabazitaxel.	Approved
Canakinumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Canakinumab.	Approved, Investigational
Capecitabine	The risk or severity of adverse effects can be increased when Denosumab is combined with Capecitabine.	Approved, Investigational
Carboplatin	The risk or severity of adverse effects can be increased when Denosumab is combined with Carboplatin.	Approved
Carmustine	The risk or severity of adverse effects can be increased when Denosumab is combined with Carmustine.	Approved, Investigational
Castanospermine	The risk or severity of adverse effects can be increased when Denosumab is combined with Castanospermine.	Experimental
Certolizumab pegol	The risk or severity of adverse effects can be increased when Denosumab is combined with Certolizumab pegol.	Approved
Chlorambucil	The risk or severity of adverse effects can be increased when Denosumab is combined with Chlorambucil.	Approved

Cisplatin	The risk or severity of adverse effects can be increased when Denosumab is combined with Cisplatin.	Approved
Cladribine	The risk or severity of adverse effects can be increased when Denosumab is combined with Cladribine.	Approved, Investigational
Clofarabine	The risk or severity of adverse effects can be increased when Denosumab is combined with Clofarabine.	Approved, Investigational
Clostridium tetani toxoid antigen (formaldehyde inactivated)	The therapeutic efficacy of Clostridium tetani toxoid antigen (formaldehyde inactivated) can be decreased when used in combination with Denosumab.	Approved
Corticotropin	The risk or severity of adverse effects can be increased when Denosumab is combined with Corticotropin.	Approved, Investigational, Vet Approved
Cortisone acetate	The risk or severity of adverse effects can be increased when Denosumab is combined with Cortisone acetate.	Approved, Investigational
Corynebacterium diphtheriae toxoid antigen (formaldehyde inactivated)	The therapeutic efficacy of Corynebacterium diphtheriae toxoid antigen (formaldehyde inactivated) can be decreased when used in combination with Denosumab.	Approved
Cyclophosphamide	The risk or severity of adverse effects can be increased when Denosumab is combined with Cyclophosphamide.	Approved, Investigational
Cyclosporine	The risk or severity of adverse effects can be increased when Denosumab is combined with Cyclosporine.	Approved, Investigational, Vet Approved
Cytarabine	The risk or severity of adverse effects can be increased when Denosumab is combined with Cytarabine.	Approved, Investigational
Dacarbazine	The risk or severity of adverse effects can be increased when Denosumab is combined with Dacarbazine.	Approved, Investigational
Daclizumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Daclizumab.	Approved, Investigational
Dactinomycin	The risk or severity of adverse effects can be increased when Denosumab is combined with Dactinomycin.	Approved, Investigational
Dasatinib	The risk or severity of adverse effects can be increased when Denosumab is combined with Dasatinib.	Approved, Investigational
Daunorubicin	The risk or severity of adverse effects can be increased when Denosumab is combined with Daunorubicin.	Approved
Deflazacort	The risk or severity of adverse effects can be increased when Denosumab is combined with Deflazacort.	Approved, Investigational
Deoxyspergualin	The risk or severity of adverse effects can be increased when Denosumab is combined with Deoxyspergualin.	Investigational
Dexamethasone	The risk or severity of adverse effects can be increased when Denosumab is combined with Dexamethasone.	Approved, Investigational, Vet Approved
Dimethyl fumarate	The risk or severity of adverse effects can be increased when Denosumab is combined with Dimethyl fumarate.	Approved, Investigational
Dinutuximab	The risk or severity of adverse effects can be increased when Denosumab is combined with Dinutuximab.	Approved, Investigational
Docetaxel	The risk or severity of adverse effects can be increased when Denosumab is combined with Docetaxel.	Approved, Investigational
Doxifluridine	The risk or severity of adverse effects can be increased when Denosumab is combined with Doxifluridine.	Investigational
Doxorubicin	The risk or severity of adverse effects can be increased when Denosumab is combined with Doxorubicin.	Approved, Investigational

Eculizumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Eculizumab.	Approved, Investigational
Efalizumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Efalizumab.	Approved, Investigational
Epirubicin	The risk or severity of adverse effects can be increased when Denosumab is combined with Epirubicin.	Approved
Estramustine	The risk or severity of adverse effects can be increased when Denosumab is combined with Estramustine.	Approved, Investigational
Etanercept	The risk or severity of adverse effects can be increased when Denosumab is combined with Etanercept.	Approved, Investigational
Etoposide	The risk or severity of adverse effects can be increased when Denosumab is combined with Etoposide.	Approved
Everolimus	The risk or severity of adverse effects can be increased when Denosumab is combined with Everolimus.	Approved
Fingolimod	The risk or severity of adverse effects can be increased when Denosumab is combined with Fingolimod.	Approved, Investigational
Floxuridine	The risk or severity of adverse effects can be increased when Denosumab is combined with Floxuridine.	Approved
Fludarabine	The risk or severity of adverse effects can be increased when Denosumab is combined with Fludarabine.	Approved
Fludrocortisone	The risk or severity of adverse effects can be increased when Denosumab is combined with Fludrocortisone.	Approved, Investigational
Fluorouracil	The risk or severity of adverse effects can be increased when Denosumab is combined with Fluorouracil.	Approved
G17DT	The therapeutic efficacy of G17DT can be decreased when used in combination with Denosumab.	Investigational
Gallium nitrate	The risk or severity of adverse effects can be increased when Denosumab is combined with Gallium nitrate.	Approved, Investigational
Gemcitabine	The risk or severity of adverse effects can be increased when Denosumab is combined with Gemcitabine.	Approved
Gemtuzumab ozogamicin	The risk or severity of adverse effects can be increased when Denosumab is combined with Gemtuzumab ozogamicin.	Approved, Investigational
GI-5005	The therapeutic efficacy of GI-5005 can be decreased when used in combination with Denosumab.	Investigational
Glatiramer Acetate	The risk or severity of adverse effects can be increased when Denosumab is combined with Glatiramer Acetate.	Approved, Investigational
Glimepiride	The risk or severity of adverse effects can be increased when Denosumab is combined with Glimepiride.	Approved
Golimumab	The risk or severity of adverse effects can be increased when Denosumab is combined with Golimumab.	Approved
GS 0573	The risk or severity of adverse effects can be increased when Denosumab is combined with GS 0573.	Investigational
Gusperimus	The risk or severity of adverse effects can be increased when Denosumab is combined with Gusperimus.	Investigational
Hepatitis A Vaccine	The therapeutic efficacy of Hepatitis A Vaccine can be decreased when used in combination with Denosumab.	Approved
Hepatitis B Vaccine (Recombinant)	The therapeutic efficacy of Hepatitis B Vaccine (Recombinant) can be decreased when used in combination with Denosumab.	Approved, Withdrawn
Human C1-esterase inhibitor	The risk or severity of adverse effects can be increased when Denosumab is combined with Human C1-esterase inhibitor.	Approved

Human rabies virus immune globulin	The therapeutic efficacy of Human rabies virus immune globulin can be decreased when used in combination with Denosumab.	Approved
Hydrocortisone	The risk or severity of adverse effects can be increased when Denosumab is combined with Hydrocortisone.	Approved, Vet Approved
Hydroxyurea	The risk or severity of adverse effects can be increased when Denosumab is combined with Hydroxyurea.	Approved
Hypericin	The risk or severity of adverse effects can be increased when Denosumab is combined with Hypericin.	Investigational
Ibritumomab tiuxetan	The risk or severity of adverse effects can be increased when Denosumab is combined with Ibritumomab tiuxetan.	Approved, Investigational
Ibrutinib	The risk or severity of adverse effects can be increased when Denosumab is combined with Ibrutinib.	Approved
Icatibant	The risk or severity of adverse effects can be increased when Denosumab is combined with Icatibant.	Approved, Investigational
Idarubicin	The risk or severity of adverse effects can be increased when Denosumab is combined with Idarubicin.	Approved
Idelalisib	The risk or severity of adverse effects can be increased when Denosumab is combined with Idelalisib.	Approved

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Food Interactions

Not Available

REFERENCES

General References

1. Malan J, Ettinger K, Naumann E, Beirne OR: The relationship of denosumab pharmacology and osteonecrosis of the jaws. Oral Surg Oral Med Oral Pathol Oral Radiol. 2012 Dec;114(6):671-6. doi: 10.1016/j.oooo.2012.08.439. [PubMed:23159111]
2. Link [Link]
3. Link [Link]

External Links

KEGG Drug

D03684

PubChem Substance

347910354

ChEMBL

CHEMBL1237023

PharmGKB

PA166048634

RxList

RxList Drug Page

Drugs.com

Drugs.com Drug Page

Denosumab

ATC Codes

M05BX04 — Denosumab

- M05BX — Other drugs affecting bone structure and mineralization
- M05B — DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION
- M05 — DRUGS FOR TREATMENT OF BONE DISEASES
- M — MUSCULO-SKELETAL SYSTEM

AHFS Codes

92:24.00 — Bone Resorption Inhibitors

FDA label

Download (226 KB)

MSDS

Download (97.5 KB)

CLINICAL TRIALS

Clinical Trials

Search

PHASE	STATUS	PURPOSE	CONDITIONS	COUNT
0	Completed	Basic Science	Aging / Bone Loss	1
0	Not Yet Recruiting	Prevention	BRCA1 Gene Mutation / Brca2 Gene Mutation / Fallopian Tube Carcinoma / Ovarian Carcinoma / Premenopausal	1
0	Recruiting	Treatment	Anorexia Nervosa (AN) / Atypical Anorexia Nervosa / Bone Density / Bone Loss / Eating Disorder	1
0	Recruiting	Treatment	Cancer, Breast	1
1	Completed	Not Available	Healthy Volunteers	1
1	Completed	Basic Science	Healthy Volunteer, Female, Breast	1
1	Completed	Basic Science	Hypersensitivity, Delayed / Immune Tolerance/Drug Effects / Immunosuppression / Ultraviolet Rays	1
1	Completed	Treatment	Healthy Volunteers	1
1	Completed	Treatment	Impaired Renal Function	1
1	Completed	Treatment	Postmenopausal Osteoporosis (PMO)	1
1	Completed	Treatment	Bone destruction	1
1	Not Yet Recruiting	Prevention	Disorder Related to Bone Marrow Transplantation	1
1	Recruiting	Prevention	Arthroplasty, Replacement, Hip	1
1	Recruiting	Treatment	Advanced Cancers	1
1	Terminated	Treatment	Bone destruction / One to five years postmenopausal / Osteopenia / Rheumatoid Arthritis	1

1, 2	Completed	Treatment	Bone Cyst Aneurysmal / Pathological Fractures / Recurrent Disease / Refractory Tumors	1
1, 2	Not Yet Recruiting	Treatment	Bone destruction / Dermatomyositis / Glucocorticoid-induced Osteoporosis / Polyarthritis / Rheumatoid Arthritis, Juvenile / Systemic Lupus Erythematosus (SLE) / Vasculitis	1
1, 2	Recruiting	Treatment	Crohn's Disease (CD)	1
1, 2	Recruiting	Treatment	Melanoma / Melanoma Stage Iii / Melanoma Stage Iv	1
2	Active Not Recruiting	Treatment	Benign GCT / Cancers / GCT / Giant Cell Tumors of Bone	1
2	Active Not Recruiting	Treatment	Cancer, Breast	2
2	Active Not Recruiting	Treatment	Early Stage Breast Cancer	1
2	Active Not Recruiting	Treatment	Infertilities / Sperm / Testis	1
2	Active Not Recruiting	Treatment	Neoplasms, Breast	1
2	Active Not Recruiting	Treatment	Bone destruction / Thalassemia Major (TM)	1
2	Active Not Recruiting	Treatment	Bone destruction	1
2	Completed	Prevention	Ambulation Difficulty / Osteoarthritis, Hip	1
2	Completed	Supportive Care	Bone Metastases in Subjects With Advanced Breast Cancer / Cancer, Breast / Metastases	1
2	Completed	Treatment	Cancer, Breast / Endocrine Cancer / Head and Neck Carcinoma / Hypercalcemia of Malignancy / Lung Cancer Non-Small Cell Cancer (NSCLC) / Lung Cancers / Lymphoma, Hodgkins / Malignant Lymphomas / Malignant Neoplasm of Colon / Metastatic Cancers / Multiple Myeloma (MM) / Non-Hodgkin's Lymphoma (NHL) / Parathyroid Neoplasms / Renal Cancers / Thyroid Cancers	1
2	Completed	Treatment	GCT / Giant Cell Tumors of Bone	1
2	Completed	Treatment	Low Bone Mineral Density	1
2	Completed	Treatment	Low Bone Mineral Density / Postmenopausal Osteoporosis (PMO)	1
2	Completed	Treatment	Lung Cancer Non-Small Cell Cancer (NSCLC)	1
2	Completed	Treatment	Osteogenesis Imperfecta	1
2	Completed	Treatment	Postmenopausal Osteoporosis (PMO)	1
2	Completed	Treatment	Relapsed or Plateau-Phase Multiple Myeloma	1
2	Completed	Treatment	Rheumatoid Arthritis	1
2	Recruiting	Prevention	Adult Idiopathic Generalized Osteoporosis	1
2	Recruiting	Prevention	Osteolysis	1
2	Recruiting	Treatment	Breast Carcinoma Metastatic in the Bone / Circulating Tumor Cell Count / Estrogen Receptor Positive / HER2/Neu Negative / Progesterone Receptor Positive / Stage IV Breast Cancer	1
2	Recruiting	Treatment	Calcific Aortic Stenosis	1
2	Recruiting	Treatment	Cancer, Breast	1
2	Recruiting	Treatment	Childhood Osteosarcoma / Metastatic Osteosarcoma / Recurrent Osteosarcoma	1
2	Recruiting	Treatment	Gout Acute	1

2	Recruiting	Treatment	HER2 Positive Breast Cancers / Inflammatory carcinoma of the breast / Invasive Ductal Breast Carcinoma / Malignant Neoplasm of Female Breast / Mucinous Breast Cancer Stage II / Tubular Breast Cancer Stage II / Tubular Breast Cancer Stage III	1
2	Recruiting	Treatment	Hands Osteoarthritis	1
2	Recruiting	Treatment	Langerhans Cell Histiocytosis (LCH)	1
2	Recruiting	Treatment	Male Infertility	1
2	Recruiting	Treatment	Metastatic Kidney Cancer / Renal Cell Carcinoma, Clear Cell	1
2	Recruiting	Treatment	Multiple Myeloma (MM)	1
2	Recruiting	Treatment	Revision Surgery of Total Hip Arthroplasty	1
2	Recruiting	Treatment	Rheumatoid Arthritis	1
2	Recruiting	Treatment	Bone destruction / Spinal Cord Injuries (SCI)	1
2	Recruiting	Treatment	Bone destruction	1
3	Active Not Recruiting	Supportive Care	Bone Metastases / Cancers / Malignancies, Hematologic / Multiple Myeloma (MM) / Multiple Myeloma Bone Lesions / Oncology	1
3	Active Not Recruiting	Supportive Care	Cancer, Breast	1
3	Active Not Recruiting	Treatment	Bone Metastases in Men With Hormone-Refractory Prostate Cancer / Bone Metastases in Subjects With Advanced Breast Cancer	1
3	Active Not Recruiting	Treatment	Cancer, Breast	1
3	Active Not Recruiting	Treatment	Lung Cancer Non-small Cell Stage IV	1
3	Completed	Prevention	Hormone Refractory Prostate Cancer	1
3	Completed	Supportive Care	Bone Metastases	3
3	Completed	Supportive Care	Bone destruction / Cancers / Cataracts / Low Bone Mineral Density / Osteopenia / Prostate Cancer	1
3	Completed	Supportive Care	Bone destruction / Low Bone Mass / Low Bone Mineral Density / Postmenopausal Osteoporosis (PMO)	1
3	Completed	Treatment	Cancers / Carcinoma NOS / Castrate-resistant Prostate Cancer (CRPC) / Prostate Cancer / Tumors	1
3	Completed	Treatment	Castrate-resistant Prostate Cancer (CRPC)	1
3	Completed	Treatment	Bone destruction / Chronic Kidney Disease (CKD)	1
3	Completed	Treatment	Fractures, Bone	1
3	Completed	Treatment	Bone destruction / Low Bone Mass / Low Bone Mineral Density / Males With Osteoporosis / Osteopenia	1
3	Completed	Treatment	Bone destruction / Low Bone Mineral Density / Osteopenia	1
3	Completed	Treatment	Bone destruction / Osteopenia	2
3	Completed	Treatment	Postmenopausal Osteoporosis (PMO)	7
3	Completed	Treatment	Bone destruction	4
3	Enrolling by Invitation	Treatment	Parathyroid Adenomas / Parathyroid Hyperplasia / Primary Hyperparathyroidism	1
3	Not Yet Recruiting	Supportive Care	Metastatic Renal Cell Carcinoma	1
3	Not Yet Recruiting	Treatment	Evaluate the Safety and Efficacy of Denosumab in Pediatric Subjects With / Glucocorticoid-induced Osteoporosis	1

3	Not Yet Recruiting	Treatment	Bone destruction / Systemic Mastocytosis	1
3	Not Yet Recruiting	Treatment	Bone dest eta-Thalassemia Major)	1
3	Recruiting	Prevention	Cancer, Breast	1
3	Recruiting	Prevention	Giant Cell Tumors of Bone	1
3	Recruiting	Supportive Care	Bone Metastases / Metastatic Breast Cancer (MBC) / Metastatic Hormone Refractory Prostate Cancer	1
3	Recruiting	Treatment	Charcot Joint of Foot	1
3	Recruiting	Treatment	Osteogenesis Imperfecta	1
3	Recruiting	Treatment	Bone destruction	1
4	Active Not Recruiting	Treatment	Postmenopausal Osteoporosis (PMO)	2
4	Completed	Prevention	Bone Resorption	1
4	Completed	Treatment	Metabolic Bone Disease	1
4	Completed	Treatment	Post Menopausal Osteoporosis	1
4	Completed	Treatment	Postmenopausal Osteoporosis (PMO)	1
4	Completed	Treatment	Primary Hyperparathyroidism	1
4	Completed	Treatment	Rheumatoid Arthritis	1
4	Completed	Treatment	Bone destruction	2
4	Not Yet Recruiting	Treatment	Female With Osteoporosis and Chronic Kidney Disease	1
4	Not Yet Recruiting	Treatment	Secondary Osteoporosis / Spinal Cord Injuries (SCI)	1
4	Recruiting	Treatment	Cancer, Breast / Metastasis / Prostate Cancer	1
4	Recruiting	Treatment	Bone destruction / Osteoporotic Fractures / Postmenopausal Osteoporosis (PMO)	1
4	Recruiting	Treatment	Bone destruction	2
4	Suspended	Treatment	Bone Marrow Oedema Syndrome / High Turnover Bone Disease / Quality of Life	1
4	Unknown Status	Prevention	Osteoarthritis, Hip	1
4	Withdrawn	Not Available	Metastatic Bone Disease / Tumors, Solid	1
Not Available	Active Not Recruiting	Not Available	Post Menopausal Osteoperosis, Male Osteoperosis	1

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PHARMACOECONOMICS

Manufacturers

Not Available

Packagers

Not Available

Dosage forms

FORM	ROUTE	STRENGTH
Injection	Subcutaneous	60 mg/mL
Solution	Subcutaneous	60 mg
Injection	Subcutaneous	120 mg/1.7mL
Injection, solution	Subcutaneous	120 mg
Solution	Subcutaneous	120 mg

Showing 1 to 5 of 5 entries

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Prices

Not Available

Patents

Search

PATENT NUMBER	PEDIATRIC EXTENSION	APPROVED	EXPIRES (ESTIMATED)	
CA2257247	No	2012-09-11	2018-04-15	
CA2274987	No	2012-01-24	2017-12-22	
CA2285746	No	2010-09-28	2018-04-15	
CA2400929	No	2011-05-31	2021-02-23	
CA2328140	No	2012-03-13	2019-05-13	

Showing 1 to 5 of 5 entries

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PROPERTIES

State

Solid

Experimental Properties

Not Available

TAXONOMY

Description

Not Available

Kingdom

Organic Compounds

Super Class

Organic Acids

Carboxylic Acids and Derivatives

Sub Class

Amino Acids, Peptides, and Analogues

Direct Parent

Peptides

Alternative Parents

Not Available

Substituents

Not Available

Molecular Framework

Not Available

External Descriptors

Not Available

TARGETS

1. Tumor necrosis factor ligand superfamily member 11

Kind

Protein

Organism

Human

Pharmacological action

Yes

Actions

Antibody

General Function

Tumor necrosis factor receptor superfamily binding

Specific Function

Cytokine that binds to TNFRSF11B/OPG and to TNFRSF11A/RANK. Osteoclast differentiation and activation factor. Augments the ability of dendritic cells to stimulate naive T-cell proliferation. May be...

Gene Name

TNFSF11

Uniprot ID

O14788

Molecular Weight

35477.81 Da

References

1. Lipton A, Jun S: RANKL inhibition in the treatment of bone metastases. Curr Opin Support Palliat Care. 2008 Sep;2(3):197-203. doi: 10.1097/SPC.0b013e32830baac2. [PubMed:18685421]
2. Westenfeld R, Ketteler M, Brandenburg VM: Anti-RANKL therapy--implications for the bone-vascular-axis in CKD? Denosumab in post-menopausal women with low bone mineral density. Nephrol Dial Transplant. 2006 Aug;21(8):2075-7. Epub 2006 May 15. [PubMed:16702197]

Drug created on March 19, 2008 10:43 / Updated on February 21, 2018 17:22

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