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PTO/SB/16 (11-08)
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Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1 Remove

Given Name	Middle Name	Family Name	City	State	Country i
Herriot		Tabuteau	New York	NY	US

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Title of Invention	USE OF PAMIDRONATE AND RELATED COMPOUNDS FOR THE TREATMENT OF COMPLEX REGIONAL PAIN SYNDROME
Attorney Docket Number (if applicable)	

Correspondence Address

Direct all correspondence to (select one):

◯ The address corresponding to Customer Number	◉ Firm or Individual Name
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

◉ No.

◯ Yes, the name of the U.S. Government agency and the Government contract number are:

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Entity Status

Applicant claims small entity status under 37 CFR 1.27

- (•) Yes, applicant qualifies for small entity status under 37 CFR 1.27
- ( ) No

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Signature	/Herriot Tabuteau/			Date (YYYY-MM-DD)	2012-05-14
First Name	Herriot	Last Name	Tabuteau	Registration Number (If appropriate)	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Utility Patent Application (Provisional)

USE OF PAMIDRONATE AND RELATED COMPOUNDS FOR THE TREATMENT OF COMPLEX REGIONAL PAIN SYNDROME

Inventor: **Herriot Tabuteau**

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BACKGROUND OF THE INVENTION

Complex regional pain syndrome type I (CRPS-I), also known as reflex sympathetic dystrophy (RSD), and complex regional pain syndrome type II (CRPS-II), also known as causalgia, are debilitating pain syndromes. They are characterized by severe pain in a limb accompanied by allodynia, hyperalgesia, edema, changes in skin blood flow and abnormal sudomotor activity.

These disorders are often difficult to treat and there exists a need for additional therapeutic options.

DESCRIPTION OF THE INVENTION

Disclosed are pharmaceutical compositions and methods for the treatment of complex regional pain syndrome type I and type II (CRPS-I and CRPS-II).

One embodiment is a pharmaceutical composition comprising pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound for the treatment of CRPS-I and CRPS-II.

The terms pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate, or another bisphosphonate compound, as used in this application refer to these compounds or their pharmaceutically acceptable salts, and any of their polymorphic forms.

Other names for pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, and zoledronate may include but are not limited to pamidronic acid, neridronic acid, olpadronic acid, alendronic acid, ibandronic acid, risedronic acid, and zoledronic acid, respectively.

Another embodiment is a method for the treatment of treatment of CRPS-I and CRPS-II comprising administering to an individual pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound.

Any suitable route of administration may be employed for providing an individual with an effective dosage of the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound. For example, oral, rectal, parenteral, transdermal, sublingual, subcutaneous, intrathecal, intramuscular and the like may be employed as appropriate.

Dosage forms for the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate , zoledronate or another bisphosphonate compound in the present embodiments include

but are not limited to tablets, coated tablets, cachets, capsules, caplets, troches, dispersions, sustained release formulations, suspensions, solutions, patches and the like.

In addition to the common dosage forms set forth above, the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound may also be administered by controlled release or sustained release means and/or delivery devices.

The effective amount of pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate , zoledronate or another bisphosphonate compound in the treatment of CRPS-I and CRPS-II will vary depending on various factors known to the treating physicians, such as the severity of the condition to be treated, route of administration, formulation and dosage forms, physical characters of the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate , zoledronate or another bisphosphonate compound used, and age, weight and response of the individual patients.

In some embodiments the daily oral dose of pamidronate is about 10 mg to about 1,000 mg, about 50 mg to about 500 mg, about 100 mg to about 500 mg, or about 150 mg to about 300 mg. In some embodiments the parenteral dose of pamidronate is about 5 mg to about 500 mg, about 5 mg to about 200 mg, or about 10 mg to about 150 mg.

In some embodiments the daily oral dose of neridronate is about 10 mg to about 1,000 mg, about 50 mg to about 500 mg, about 100 mg to about 500 mg, or about 150 mg to about 300 mg. In some embodiments the parenteral dose of neridronate is about 5 mg to about 500 mg, about 5 mg to about 200 mg, or about 10 mg to about 150 mg.

In some embodiments the daily oral dose of alendronate is about 0.5 mg to about 200 mg, about 1 mg to about 100 mg, about 5 mg to about 100 mg, or about 2 mg to about 50 mg. In some embodiments the parenteral dose of alendronate is about 1 mg to about 100 mg, about 1 mg to about 40 mg, or about 2 mg to about 30 mg.

In some embodiments the daily oral dose of olpadronate is about 0.5 mg to about 200 mg, about 1 mg to about 100 mg, about 5 mg to about 100 mg, or about 2 mg to about 50 mg. In some embodiments the parenteral dose of olpadronate is about 1 mg to about 100 mg, about 1 mg to about 40 mg, or about 2 mg to about 30 mg.

In some embodiments the daily oral dose of ibandronate is about 0.25 mg to about 100 mg, about 0.5 mg to about 50 mg, about 2.5 mg to about 50 mg, or about 1 mg to about 25 mg. In some embodiments the parenteral dose of ibandronate is about 0.5 mg to about 50 mg, about 0.5 mg to about 20 mg, or about 1 mg to about 15 mg.

In some embodiments the daily oral dose of risedronate is about 0.25 mg to about 100 mg, about 0.5 mg to about 50 mg, about 2.5 mg to about 50 mg, or about 1 mg to about 25 mg. In some embodiments the parenteral dose of risedronate is about 0.25 mg to about 25 mg, about 0.25 mg to about 10 mg, or about 0.5 mg to about 7.5 mg.

In some embodiments the daily oral dose of zoledronate is about 0.005 mg to about 20 mg, about 0.1 mg to about 10 mg, about 0.5 mg to about 10 mg, or about 0.2 mg to about 5 mg. In some embodiments the parenteral dose of zoledronate is about 0.25 mg to about 25 mg, about 0.25 mg to about 10 mg, or about 0.5 mg to about 7.5 mg.

The dose of pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound may be administered in a single or divided dose.

CLAIMS

1. A pharmaceutical composition comprising either pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound for the treatment of CRPS-I or CRPS-II.

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