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## **FOR IMMEDIATE RELEASE**

### **Rare Disease Therapeutics, Inc. Obtains FDA Approval of Scorpion Sting Antivenom Anascorp®** *The First FDA Approved Scorpion Antivenom Treats Clinically Important Signs of Scorpion Stings*

TUCSON, Ariz. (August 3, 2011) – Rare Disease Therapeutics, Inc., today announced that the U.S. Food and Drug Administration (FDA) has approved Anascorp® (Centruroides (Scorpion) Immune F(ab')<sub>2</sub> (Equine) Injection), an equine-derived antivenom indicated for treatment of patients with clinical signs of scorpion stings. Anascorp is the first-ever FDA approved scorpion antivenom. Clinical studies have shown that this antivenom reverses clinically important signs of scorpion envenomation and significantly reduces time spent in hospitals.

Rare Disease Therapeutics, Inc. has partnered with Instituto Bioclon to market Anascorp in the United States. The FDA approval is the culmination of efforts by Rare Disease Therapeutics, Inc., Instituto Bioclon S.A. de C.V., the University of Arizona, Universidad Nacional Autónoma de México and hundreds of physicians, nurses and pharmacists to demonstrate the safety and efficacy of Anascorp.

“Our team and Instituto Bioclon are pleased to offer this breakthrough orphan drug, the first FDA approved antivenom to treat scorpion stings, in the United States,” said Milton Ellis, President and Chief Executive Officer of Rare Disease Therapeutics, Inc. “We anticipate that Anascorp will be available to physicians and patients within one month.”

Scorpion envenomation occurs throughout the southwestern United States. Poison control centers in the U.S. report more than 15,000 scorpion stings annually inflicted by over 60 different scorpion species. The only species in the U.S. that will cause clinically significant systemic symptoms is the *Centruroides sculpturatus*, or the bark scorpion. These scorpions are most commonly found in Arizona; however isolated colonies have been reported in Clark County, Nevada; Texas; Western New Mexico and California.

Severe symptoms, most commonly seen in young children, may include local pain and numbness progressively radiating from the sting site, increased heart rate, agitation, restlessness, abnormal eye movements, hypersalivation, increased blood pressure, difficulty swallowing, gastrointestinal complaints and pulmonary edema. Young children are particularly prone to develop more serious cardiovascular and neuromotor manifestations.

Clinical studies led by Dr. Leslie Boyer, a University of Arizona Medical Center physician and principal investigator, have shown that Anascorp treats the dangerous signs of scorpion envenomation and reduces time in a healthcare facility.

“Eighty-five percent of patients given a dose of Anascorp were able to be discharge from the emergency department within two hours,” said Dr. Walter Garcia Ubbelohde, Medical Director for Instituto Bioclon.

This antivenom is especially beneficial to individuals in remote areas. Frequently, a child stung by a bark scorpion requires immediate transportation to a major healthcare facility with a pediatric intensive care unit, and 16 to 24 hours of patient care in the hospital. With Anascorp now available to every hospital and clinic, patients in rural areas can receive an effective treatment quickly, avoiding costly transportation and hospitalization.

The most common adverse reactions observed in less than two percent of patients in the clinical studies for Anascorp were: vomiting, pyrexia, rash, nausea, and pruritus. Severe hypersensitivity reactions, including anaphylaxis, are possible with Anascorp. Delayed allergic reactions (serum sickness) may occur following treatment with Anascorp. Anascorp is made from equine plasma and may contain infectious agents, e.g. viruses. Localized reactions and generalized myalgias have been reported with the use of cresol as an injectable excipient.

Anascorp is available as a lyophilized powder in single-use vials, for intravenous infusion only, and must be reconstituted and diluted by a healthcare professional prior to administration.

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#### **ABOUT RARE DISEASE THERAPEUTICS, INC.**

Rare Disease Therapeutics, Inc. located in Franklin, Tennessee, specializes in the development and marketing of drugs for rare disorders. Founded in 1991, Rare Disease Therapeutics, Inc. was America's first company to focus solely on the development of orphan drugs. Orphan diseases are characterized as patient populations in the United States of less than 200,000 patients. Rare Disease Therapeutics, Inc. is an established biopharmaceutical company focused on development, registration, and distribution of orphan products in the Americas as well as globally through a consortium of similarly focused companies.

#### **ABOUT INSTITUTO BIOCLON**

Instituto Bioclon, member of the Silanes group, is a pharmaceutical company located in Mexico City. Founded in 1990, Bioclon has been a world leader in the development and marketing of antivenom for snakes, scorpions and spider envenomation on three continents.

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