For Immediate Release

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NEW ANTIVENOM FOR RATTLESNAKE BITES
INTRODUCED BY RARE DISEASE THERAPEUTICS, INC.

ANAVIP® [Crotalidae Immune F(ab')$_2$ (Equine)]
Reduces late effects of venom

<Franklin, TN; October 8, 2018> Rare Disease Therapeutics, Inc. (RDT) announced today the launch of ANAVIP® [Crotalidae Immune F(ab')$_2$ (Equine)] an equine-derived antivenin indicated for the management of adult and pediatric patients with North American rattlesnake envenomation.

About Rattlesnake Envenomation

Rattlesnakes are found throughout the United States[1]. The CDC estimates that the US incidence of venomous snake bites is 7,000-8,000 per year[1]. Because people seek--and receive--rapid medical intervention, the number of deaths from snake bites is low (about 5 per year)[1]. However, coagulopathies (blood clotting disorders) can be major complications of a venomous rattlesnake bite, and one of the goals of treatment is to limit the potential incidence of latent (delayed) coagulopathy[2]. Because this new antivenom lasts longer in the body, it eliminates the need for scheduled maintenance doses.

ANAVIP® was specifically engineered with a long half-life in order to minimize the likelihood of re-emergent venom effects (such as a drop in platelets, prolonged bleeding times, and other abnormal blood clotting tests) that commonly require additional doses of a shorter-acting antivenom.

“To make this advance possible, RDT partnered with a world-leader in antivenoms, Instituto Bioclon, S.A. de C.V. (Bioclon) / Laboratorios Silanes, S.A. de C.V.(Silanes)” stated Mr. Milton Ellis, founder and CEO of RDT. “We are pleased to add ANAVIP® to our expanding antivenom line, which includes the scorpion antivenom, ANASCORP® [Centruroides (Scorpion) Immune F(ab')$_2$ (Equine) Injection], and a black widow spider antivenom which is now in development.”

Responding to Mr. Ellis, Mr. Jaime Silanes, CEO of Bioclon/Silanes, commented “We are proud of our development collaboration with RDT, and we’re equally proud to be manufacturing ANAVIP® in our FDA-approved, state-of-the-art facility. We’ve worked closely with the FDA in order to bring this world-class facility on-stream to satisfy the high anticipated demand for ANAVIP® in the United States.”

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A prominent clinical researcher who studied ANAVIP® is Richard Clark, MD, Director of Medical Toxicology at UCSD Medical Center and Medical Director of the San Diego Division of the California Poison Control System. “From our experience as participants in the clinical trials for ANAVIP®, it appears that this new antivenom works very well to reverse the symptoms associated with acute rattlesnake bite, and may have less issues with symptom recurrence than the presently approved antivenom” he commented. "I am enthusiastic about putting ANAVIP® into our practice of managing snakebites, and I look forward to the opportunity to improve the care of these patients in the future.”

See package insert for important safety information and full prescribing information about ANAVIP® [Crotalidae Immune $F(ab')_2$ (Equine)] http://www.anavip-us.com

ADVERSE REACTIONS

The most common adverse reactions (> 2%) in the clinical studies were: pruritus, nausea, rash, arthralgia, peripheral edema, myalgias, headache, pain in extremity, vomiting, and erythema.

WARNINGS AND PRECAUTIONS

Hypersensitivity

Anavip may cause allergic reactions.

- Patients with known allergies to horse protein are particularly at risk for an anaphylactic reaction. If signs or symptoms of anaphylaxis or hypersensitivity reactions (including urticaria, rash, tightness of the chest, wheezing, hypotension) occur, discontinue immediately and institute appropriate treatment.
- Monitor patients with follow-up visits for signs and symptoms of delayed allergic reactions or serum sickness (rash, fever, myalgia, arthralgia, pruritus, urticarial rash) and treat appropriately if necessary.

Transmissible Infectious Agents

Anavip is made from equine (horse) plasma and may therefore carry a risk of transmitting infectious agents, e.g., viruses.

Reactions to Cresol

Localized reactions and generalized myalgias have been reported with the use of cresol as an injectable excipient.

MORE ABOUT RARE DISEASE THERAPEUTICS, INC.

Rare Disease Therapeutics, Inc. (RDT) located in Franklin, Tennessee, specializes in the development and marketing of drugs for rare disorders. Founded in 1991, RDT was America’s first company to focus solely on the development of orphan drugs. RDT 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.

Please visit us at www.raretx.com

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MORE ABOUT INSTITUTO BIOCLON

Instituto Bioclon, member of the Silanes group, is a biopharmaceutical company located in Mexico. Founded 75 years ago, Bioclon-Silanes is the leader in the development, manufacturing, and marketing of antivenom for snakes, scorpions, and spider envenomation on three continents aligned with our corporate vision of making life a healthy story by making available better treatments to reduce the complications of envenomation and saving lives.

To report suspected adverse reactions, contact 1-877-851-1902 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References**:**

1. CDC website (https://www.cdc.gov/niosh/topics/snakes) Sept. 2018

2. Boyer, et al. Subacute coagulopathy in a randomized comparative trial of Fab and F(ab')$_2$ antivenoms. *Toxicon* 2013; 74:101-108 (November, 2013). https://www.sciencedirect.com/science/article/pii/S0041010113002675

SOURCE: Rare Disease Therapeutics, Inc.

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