Rare Disease Therapeutics, Inc. Announces New Expanded FDA Approved Indication for Antivenom ANAVIP® for Treatment of North American Pit Viper Envenomation

ANAVIP Now Indicated for Management of Adult and Pediatric Patients with All North American Pit Viper Envenomation, Including Rattlesnake, Copperhead, and Cottonmouth/Water Moccasin Bites

FRANKLIN, Tenn., Apr. 5, 2021 /BusinessWire/ -- Rare Disease Therapeutics, Inc. (RDT) today announced that the United States (US) Food & Drug Administration (FDA) approved a new expanded indication for ANAVIP® (crotalidae immune F(ab')$_2$ (equine)), an equine-derived antivenin, for the management of adult and pediatric patients with North American Pit Viper envenomation. This new expanded indication now includes Rattlesnake, Copperhead, and Cottonmouth/Water Moccasin envenomations. ANAVIP was previously indicated for the management of adult and pediatric patients with North American rattlesnake envenomation. RDT exclusively markets ANAVIP in the US in partnership with manufacturer Laboratorios Silanes, S.A. de C.V., a worldwide leader in antivenom technologies.

ANAVIP was specifically engineered with a long half-life 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. ANAVIP controlled local, systemic, and hematologic symptoms for all Pit Viper envenomation patients studied[1,2]. No patients in clinical trials required retreatment with ANAVIP for late venom effects[1,2].

"This new expanded indication demonstrates not only the remarkable scientific value of ANAVIP, but also the significant unmet need for treatment options that has existed for North American Pit Viper envenomated patients in the US," said Milton Ellis, Founder and Chief Executive Officer of RDT. "After decades of focus on this overlooked patient need, we are pleased to provide the thousands of North American Pit Viper envenomated patients in the US with a new treatment option, furthering RDT's mission of bringing necessary treatments for rare conditions to market."

7,000–8,000 people per year are bitten by venomous snakes in the US annually[3]. North American Pit Vipers include Rattlesnakes, Copperheads, and Water Moccasins (also known as Cottonmouths). Because people seek – and receive – rapid medical intervention, the number of deaths from snakebites is low (about 5 per year)[3]. However, coagulopathies (blood clotting disorders) can be major complications of a venomous Pit Viper snakebite, and one of the goals of treatment is to limit the potential incidence of late coagulopathies[2].

"After serving as RDT's Medical Science Liaison for roughly a decade and leading as President during the launch of ANAVIP in 2019, I'm very pleased to see the science behind ANAVIP now being applied successfully to the treatment of a broader set of snakebites," said Jude McNally, President of RDT. "ANAVIP, with its ease of dosing and reduction of late coagulopathies, is now a vital treatment option for not only Rattlesnake envenomated patients, but for all patients with any North American Pit Viper envenomation – a group that prior to this approval, has had very limited treatment options."

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

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: Trace amounts of cresol from the manufacturing process are contained in ANAVIP. Localized reactions and generalized myalgias have been reported with the use of cresol as an injectable excipient.

ADVERSE REACTIONS

The most common adverse reactions observed in more than 2 percent (2%) of patients in the clinical trials for ANAVIP were: pruritus, nausea, rash, arthralgia, peripheral edema, erythema, headache, myalgia, pain in extremity, and vomiting.

To report suspected adverse reactions, contact Rare Disease Therapeutics at 1-844-4RareTx (1-844-472-7389) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. To contact the Poison Control Center, call 1-800-222-1222.

For additional product information, including full prescribing information, please visit ANAVIP.com.

ABOUT RARE DISEASE THERAPEUTICS (RDT)

Founded in 1991, Rare Disease Therapeutics, Inc. (RDT) is America's first company to focus solely on orphan drugs. Based in Franklin, Tennessee, RDT specializes in the development, registration, marketing, and distribution of drugs for rare disorders. RDT conducts business in the Americas as a privately held entity, and globally through a consortium of similarly focused companies. To learn more, visit: RARETX.com.

ABOUT LABORATORIOS SILANES, S.A. de C.V.
Laboratorios Silanes is a biopharmaceutical company located in Mexico. Founded 77 years ago, Laboratorios Silanes is the leader in developing, manufacturing, and marketing antivenoms for snake,

scorpion, and spider envenomation on three continents. Silanes's purpose is to make life a healthy story by creating better treatments to reduce the complications of envenomation and to save lives.

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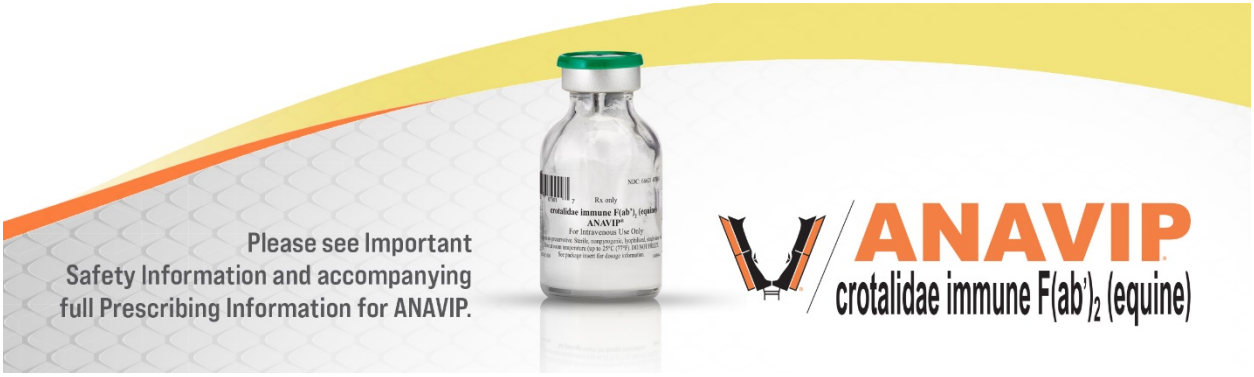

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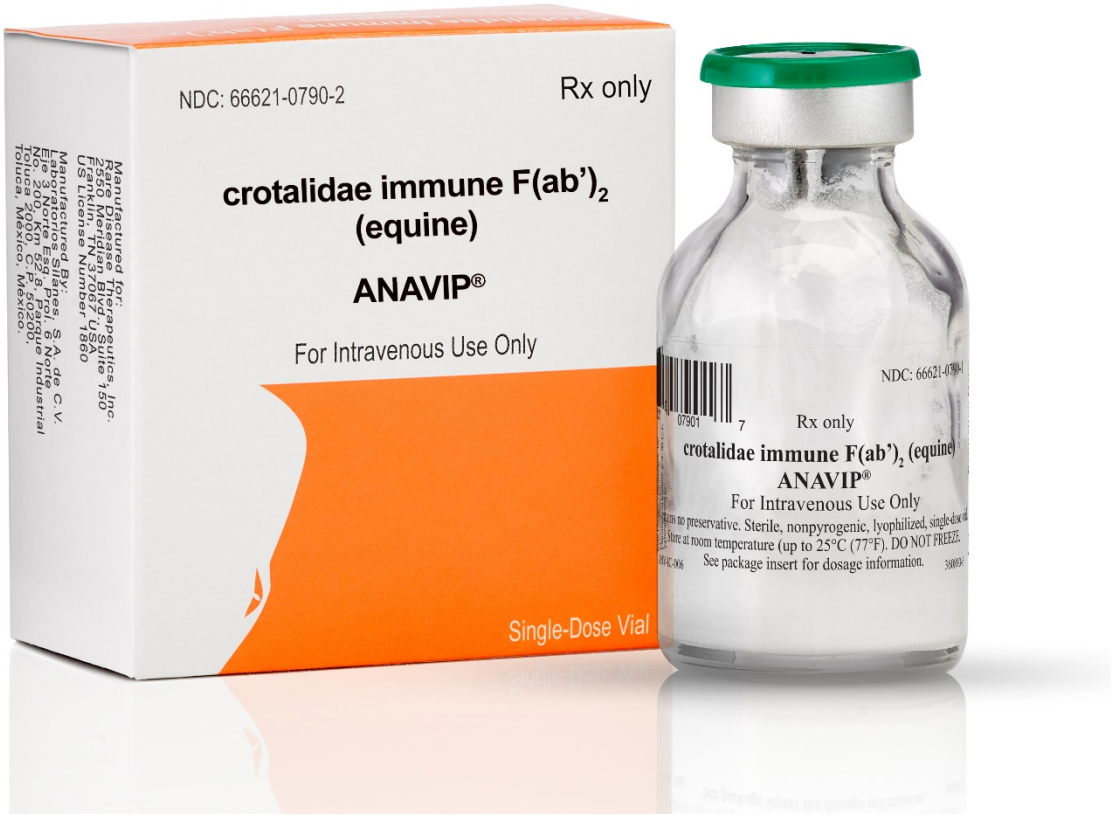
NDC: 66621-0790-2
Rx only
crotalidae immune F(ab')2 (equine)
ANAVIP®
For Intravenous Use Only
Single-Dose Vial
Manufactured for:
Rare Disease Therapeutics, Inc.
2550 Meridian Blvd Suite 150
Franklin, TN 37067 USA
US License Number 1860
Manufactured By:
Laboratorios Silanes, S.A. de C.V.
Km 52.8 Paseo Industrial
Toluca, 2000, C.P. 50200.
Toluca, Mexico.
NDC: 66621-0790-1
Rx only
crotalidae immune F(ab')2 (equine)
ANAVIP®
For Intravenous Use Only
See package insert for dosage information.

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