New Data from Largest Prospective Study on CroFab® for Treatment of Copperhead Snake Envenomation

Results Demonstrate Reduced Disability for Patients Treated with CroFab®

London, UK, March 9, 2016: BTG plc (LSE: BTG) announced today the presentation of new data from the largest prospective study ever conducted in the treatment of copperhead snake envenomation. This study builds on the extensive body of evidence supporting the safety and efficacy of CroFab® Crotalidae Polyvalent Immune Fab (Ovine) in treating copperhead snake envenomation. The data were shared in a keynote presentation at the Venom Week V International Scientific Symposium (March 9-12) in Greenville, NC.

A randomized, double-blind, placebo-controlled study compared CroFab® versus placebo for the treatment of copperhead snake envenomation in 74 patients (45, CroFab®; 29, placebo).1 The primary study outcome was met, which was a comparison of scores on the Patient Specific Functional Scale (PSFS) – a measure of a patient’s ability to do activities he or she enjoys 14 days after treatment. Patients treated early with CroFab® were more fully recovered (day 14 least squares mean PSFS score difference +1.176, p=0.036). Other study measures, including limb-specific outcome tools, grip strength, physical function-related quality of life, and pain medication use, broadly supported the primary study outcome.

Principal investigator, Eric Lavonas, MD, FACEP, FACMT, of the Rocky Mountain Poison and Drug Center – Denver Health and the University of Colorado, commented: “Although highly purified antivenom has been available for 16 years, this is the first clinical trial to look at whether giving antivenom to patients whose snakebites were not life-threatening helps them recover more quickly. The results are clear. The patients who received antivenom got back to doing the activities they enjoy more quickly.”

The study also sought to determine if early administration of CroFab® reduced the likelihood or severity of long-term limb dysfunction in patients following envenomation.2 The results demonstrated that patients treated with CroFab® following copperhead envenomation tended to have better function in their limbs and increased ability to do activities they enjoy than patients treated with placebo.3

The most common adverse events experienced by >5% of patients overall or within treatment group included headache (11.1% in the CroFab® group vs 6.9% in the placebo group), pruritus (11.1% vs 3.4%), urticaria (11.1% vs 0%), nausea (8.9% vs 6.9%), dizziness (8.9% vs 3.4%), pyrexia (8.9% vs 0%), paraesthesia (6.7% vs 0%), rash (6.7% vs 0%), and pain in extremity (6.7% vs 0%).1
Press Release

CroFab® is the only U.S. Food and Drug Administration (FDA) approved treatment indicated for the management of patients with North American crotalid envenomation.¹ Crotalids, also known as pit viper snakes, include rattlesnakes, copperheads, and cottonmouths/water moccasins.

Selected Important Safety Information for CroFab® Crotalidae Polyvalent Immune Fab (Ovine)²

INDICATION

CroFab® Crotalidae Polyvalent Immune Fab (Ovine) is an antivenin indicated for the management of patients with North American crotalid envenomation. The term crotalid is used to describe the Crotalinae subfamily (formerly known as Crotalidae) of venomous snakes that includes rattlesnakes, copperheads, and cottonmouths/water moccasins. Early use of CroFab® (within 6 hours of snakebite) is advised to prevent clinical deterioration and the occurrence of systemic coagulation abnormalities.

IMPORTANT SAFETY INFORMATION

The most common adverse events reported in clinical studies were mild or moderate reactions involving the skin and appendages (primarily urticaria, rash, or pruritus), which occurred in 14 out of 42 patients. Three patients experienced a serious adverse event. Two patients had a severe allergic reaction (severe hives and a severe rash and pruritus) following treatment. One patient had a recurrent coagulopathy due to envenomation, which required rehospitalization and additional antivenin administration. In clinical trials, recurrent coagulopathy (the return of a coagulation abnormality after it has been successfully treated with antivenin), characterized by decreased fibrinogen, decreased platelets, and elevated prothrombin time, occurred in approximately half of the patients studied. Recurrent coagulopathy may persist for 1 to 2 weeks or more. One patient discontinued CroFab® therapy due to an allergic reaction. Patients with allergies to papain, chymopapain, other papaya extracts, or the pineapple enzyme bromelain may also be at risk for an allergic reaction to CroFab®.

Please see full Prescribing Information.
About CroFab®
CroFab® Crotalidae Polyvalent Immune Fab (Ovine) is an antivenin indicated for the management of patients with North American crotalid envenomation. The term crotalid is used to describe the Crotalinae subfamily (formerly known as Crotalidae) of venomous snakes that includes rattlesnakes, copperheads, and cottonmouths/water moccasins.

CroFab® has triple action to gain initial control regardless of snakebite severity. CroFab® has been demonstrated to: 1) halt the progression of local effects, such as edema and ecchymosis; 2) resolve systemic effects, such as nausea, vomiting, dizziness, or tachycardia; and 3) reduce coagulation abnormalities, such as thrombocytopenia and spontaneous bleeding. Early use of CroFab® (within six hours of snakebite) is advised to prevent clinical deterioration and the occurrence of systemic coagulation – or clotting – abnormalities.

CroFab® has been used to treat more than 40,000 patients in the past 10 years.

For more information please visit www.crofab.com.

About BTG
BTG is a growing international specialist healthcare company bringing to market innovative products in specialist areas of medicine to better serve doctors and their patients. We have a portfolio of Interventional Medicine products to advance the treatment of liver tumors, advanced emphysema, severe blood clots and varicose veins, and Specialty Pharmaceuticals that help patients overexposed to certain medications or toxins. Inspired by patient and physician needs, BTG is investing to expand its portfolio to address some of today’s most complex healthcare challenges. To learn more about BTG, please visit: www.btgplc.com.

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1 CroFab® [prescribing information]. BTG International Inc.; March 2012.