Thrombozone® is a pharmaceutical derivative of human platelets being developed as a hematologic product for treatment of certain vascular-related disorders and short conditions associated with life-threatening bleeding. Historical and recent data from human clinical studies and the fact that >90% of fatalities caused by hemorrhage on the battlefield could be prevented with recombinant hemostatic agents. Thrombozone® is produced by a proprietary process that includes thrombocytes, other coagulation factors, and tissue factor that results in a product that is structurally similar to human platelets. Thrombozone® maintains certain platelet functions such as aggregation, adhesion, and release of growth factors. In a series of studies conducted over a background of tissue factor triggered coagulation cascade (TF-TRPC), Thrombozone® demonstrated significant reduction in blood loss and in the median length of treatment time compared to historical controls. Furthermore, Thrombozone® has been subjected to safety studies in two species (raccoon and canine) where no less adverse events (AEs) or severe adverse events (SAEs) have been observed during one or after 2 and 14 days of observation. Histopathological studies of necropsy also resulted in negative findings. Thrombozone® provides a unique hemostatic profile, which when combined with a long-term shelf-life, enables storage conditions, and viability, in extreme conditions, could meet a critical medical need and avoid early treatment of life-threatening bleeding conditions in diverse circumstances and especially during military operations where fresh plasma and thrombin are not available.

MATERIALS AND METHODS

Rabbits were made thrombocytopenic following the method of Knittel and Florence (1984, Bl. 64-27). The bleeding study was performed on the ears of a healthy rabbit. An ear artery catheter was placed in an ear for withdrawal of blood for thrombocytopenia. Balloon bleeding of RBC using an automated laboratory RBC was used to inject blood into the circulating system. The animals were sacrificed at 1, 3, and 5 minutes after injection of Thrombozone®-treated RBC. The Thrombozone®-treated group was found to have a greater percentage of reticulated RBC (RBC) than the control group. The results demonstrated that Thrombozone® significantly reduced blood loss and in the median length of treatment time compared to historical controls. Furthermore, Thrombozone® has been subjected to safety studies in two species (raccoon and canine) where no less adverse events (AEs) or severe adverse events (SAEs) have been observed during one or after 2 and 14 days of observation. Histopathological studies of necropsy also resulted in negative findings. Thrombozone® provides a unique hemostatic profile, which when combined with a long-term shelf-life, enables storage conditions, and viability, in extreme conditions, could meet a critical medical need and avoid early treatment of life-threatening bleeding conditions in diverse circumstances and especially during military operations where fresh plasma and thrombin are not available.

CONCLUSIONS

The studies regarding the in vivo safety and efficacy of Thrombozone® suggest the following:

- Thrombozone® demonstrates significant efficacy on uncontrolled lethal hemorrhage and provides survival rates (100% vs. 0% for a placebo group).
- The study results indicate that Thrombozone® is not associated with any adverse events or side effects in rabbits and dogs. The data support the conclusion that Thrombozone® is safe and effective in reducing bleeding and improving survival rates in rabbits and dogs.

These findings are consistent with the results observed in previous studies on the use of Thrombozone® in military and civilian settings, which have shown significant reductions in blood loss and improvements in survival rates compared to historical controls.