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### **Biotech Firm Entegriion Receives FDA 510(k) Approval for Wound Dressing that Stops Blood Loss**

*Research Triangle Park, N.C.*, – Entegriion, Inc., a privately owned life sciences product development company specializing in technologies for hemorrhage control, resuscitation, and tissue repair, announced that it has received 510(k) market approval from the U. S. Food and Drug Administration (FDA) for its hemostatic medical textile technology. The first application of the technology is Stasilon™|FR – hemostatic wound dressings for first responders. This market includes EMS workers, police officers, emergency personnel and fire fighters. The Stasilon™|FR – hemostatic wound dressing was approved by the FDA for use by medical professionals under prescription and “over-the-counter” by consumers to control bleeding resulting from “minor cuts and abrasions” as well as “lacerations, punctures and incisions.” Pending acceptance of an amendment to the FDA approval, a second version of the technology will be implemented as Stasilon™|OR – hemostatic surgical pads.

“This is a remarkable technology. It’s so powerful in controlling problem bleeding that it was approved by the FDA for use by medical professionals, yet so easy to use that it’s also approved for Dr. Mom,” said Stan Eskridge, Entegriion’s President and CEO. “This

is a cost effective North Carolina medical textile technology, and it's a first-in-class product that is demonstrating effectiveness in everything from skinned knees and nose bleeds to management of bleeding in severe burns and trauma.”

Developed by Dr. Thomas Fischer, Chief Science Officer at Entegriion and Scientific Director of the Francis Owen Blood Research Laboratory at the University of North Carolina at Chapel Hill, the Stasilon™|FR bandage provides hemorrhage control by rapidly activating the body's hemostatic systems. It is woven from a mixture of glass (silica dioxide) and bamboo (cellulosic rayon) fibers specifically selected for their ability to activate both blood platelets and coagulation proteins, constrict blood vessels, and rapidly wick fluids out of wounded tissues. The result is a uniquely engineered textile that effectively controls blood loss by mobilizing the body's natural mechanisms for hemorrhage control. Because of Stasilon's™ strong vaso-constrictive effect, it activates clotting mechanisms within the damaged blood vessels resulting in minimal incidences of rebleeding upon removal, a major factor in reduction of blood loss after surgery or trauma.

Entegriion invented the Stasilon™ technology in consultation with the Office of Naval Research. The technology addresses the military's critical need for effective, but low-cost, hemostatic wound dressings, as severe blood loss accounts for 50% of all battlefield deaths. Severe blood loss is also a contributing factor in 50,000 civilian deaths each year.

“While examining the military's medical case studies from Iraq and Afghanistan on excessive bleeding through gauze wrappings, I became determined to design a common textile that could work with our hemostatic system to stop blood loss,” said Dr. Thomas Fisher, Entegriion's chief science officer.

Entegriion is working with Southeastern Emergency Medical Distributors to distribute Stasilon™|FR to EMS organizations, fire departments, and other first responders in order to build experience with clinical applications of this remarkable new technology.

Additional distribution relationships are being established and plans are being finalized to allow consumers the opportunity to directly purchase Stasilon™ products via the Internet.

### **About Entegriion**

Entegriion is a life sciences company that selectively integrates synergistic technologies with those in its patent portfolio for development of novel devices and drugs for hemorrhage control, resuscitation, and associated tissue repair. The company is based in North Carolina's Research Triangle Park, and is the inventor of Stasilon™ – the FDA approved hemostatic medical textile technology approved for use by prescription and also by consumers – from which multiple hemorrhage control products are being made. Building upon technologies licensed from the University of North Carolina, Entegriion's portfolio includes platelet-derived platform technologies that are being developed as topical gels and sprays for tissue repair, infusible hemostatic agents for the control of internal hemorrhage, and novel vehicles for delivery of drugs to targeted tumors and other sites of internal bleeding. For more information, visit [www.entegriion.com](http://www.entegriion.com).

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