



OptMed Receives FDA Marketing Clearance For Its Topical Surgical Skin Adhesive, BondEase®

**Large Clinical Study Demonstrates First-in-Class Chemistry Affords
Effective Wound Closure Rates, Cosmetic Appearance**

NEW YORK, January 12, 2016 — OptMed Inc., medical device manufacturer, announced today that the Company received 510(k) marketing clearance from the US Food and Drug Administration (FDA) for its BondEase® product, a topical skin adhesive intended for the closure of surgical incisions and lacerations as an alternative to sutures and staples. BondEase is a biocompatible, topical skin adhesive that combines a novel polymer technology with a user-friendly delivery device.

Steven B. Sands, Co-Chairman of OptMed noted: "This milestone represents several years of hard work by the OptMed team and our clinical support staff. The FDA's clearance of BondEase builds on Sands Brothers' prior success in the early-stage financing and continued support towards the development of Dermabond, which was acquired by Johnson & Johnson's Ethicon division. This success resulted in substantial commercialization and creation of value for stakeholders; I am confident that BondEase will yield similar results."

OptMed anticipates that its product will be made available to medical professionals in late 2016.

"The approval was the result of a rigorous product development and clinical trial program in combination with a good working relationship with the FDA," said Dr. James Quinn, Professor of Emergency Medicine at Stanford University. "BondEase presents an excellent alternative for surgeons and patients seeking an effective, safe technology for treating surgical incisions and lacerations."

BondEase, is the first and only tissue adhesive for the topical approximation of skin adhesive that is not based on cyanoacrylate chemistry. The product is also the first topical surgical adhesive cleared via the 510(k) process, based on randomized controlled clinical trials. The randomized open label trials, which enrolled 162 patients in six surgical centers in the United States, compared BondEase with conventional sutures, staples, and adhesive strips. The trial endpoints were the incidence of 100% wound closure at 10 days as the primary endpoint, and optimal cosmetic outcome at 28 days and the incidence of >50% wound closure at 10 days as the secondary endpoints.

BondEase's clinical trials revealed no signs of infection. All adverse results were mild and appeared to have no impact on the cosmetic outcome. Signs of inflammation at the wound sites were minimal and comparable between treatment groups.

BondEase is applied directly to the wound with a patented delivery system that affords ease of use and rapid drying times. The solution is odor-free and has key product advantages in busy surgical settings and emergency room environments and has no contraindication for sensitivity to formaldehyde.

"FDA clearance of BondEase represents a significant advance for OptMed and its ability to move innovative medical products through clinical development and the regulatory process. We believe, the news provides an excellent foundation for the continued development of BondEase for additional medical indications and global markets," said Dr. Ervin Braun, Chief Executive Officer of OptMed.

OptMed is also developing its adhesive technology for several additional indications, including the treatment of acute wounds in other indications that include skin tears of the elderly, as well as chronic wound treatment. The Company believes these represent substantially underserved, medical and commercial opportunities in a number of global markets.

Biosurgical adhesives are rapidly emerging as important alternatives to sutures and staples to achieve rapid wound closure, reduce surgical treatment time and costs, protect from infections, and improve cosmetic results. These products are used widely in the emergency and operating room settings. The global market for high-strength medical adhesives is forecasted to show strong double-digit growth over the next several years, growing from roughly \$713 million in 2011 to \$1.72 billion by 2017 (MedMarket Diligence, September 2013).

OptMed's Board of Directors, congratulates Dr. Braun, CEO, and Mr. Klapholz, COO, for their tenacity and continued support in bringing BondEase's science and technology through the approval process.

OptMed is a medical device company developing surgical, biocompatible adhesives headquartered in New York.

SOURCE: OptMed, Inc.

###