

FOR IMMEDIATE RELEASE

**Media Contact:**

Beth Mueller, (224) 948-5353  
[media@baxter.com](mailto:media@baxter.com)

**Investor Contact:**

Clare Trachtman, (224) 948-3085

**BAXTER ANNOUNCES AGREEMENT TO BROADEN PORTFOLIO  
OF INNOVATIVE SURGICAL PRODUCTS**

- *Proposed acquisition includes two pioneering hemostat and sealant products, including the first and only stand-alone recombinant thrombin and a surgical sealant*
- *Products expand Baxter's portfolio of surgical solutions to address intraoperative bleeding and increase surgeons' options*

**DEERFIELD, Ill., JANUARY 8, 2018** – Baxter International Inc. (NYSE: BAX), a global medical products company, is committed to advancing surgical innovation and today announced an agreement to acquire two hemostat and sealant products from Mallinckrodt plc: RECOTHROM Thrombin topical (Recombinant), the first and only stand-alone recombinant thrombin, and PREVELEAK Surgical Sealant, which is used in vascular reconstruction.

“Uncontrolled intraoperative bleeding can lead to a wide variety of clinical and economic complications for patients and hospitals. As a leading provider of advanced hemostats and sealants, Baxter is focused on continually identifying solutions to help meet surgeons’ varying needs,” said Wil Boren, president of Baxter’s Advanced Surgery business. “We are excited about the addition of RECOTHROM to help surgeons

address less severe intraoperative bleeding and PREVELEAK to complement Baxter's existing portfolio of sealants for cardiovascular and other surgical specialties.”

Thrombin is a proven blood coagulation agent – used on its own or in combination with other hemostats – that has been estimated to be used in more than one million patients per year in the United States to help surgeons address intraoperative bleeding<sup>1</sup>. RECOTHROM is a thrombin-based product indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age. As the only topical hemostat from recombinant DNA origin approved in the United States and Canada, RECOTHROM can be used in pediatric and adult patients with or without antibodies to bovine-derived thrombin.

The acquisition also includes PREVELEAK, a surgical sealant designed to seal suture holes formed during surgical repair of the circulatory system and to reinforce sutured connections between blood vessels. PREVELEAK augments Baxter's portfolio of complementary hemostats, sealants and tissue products used in cardiovascular and other surgeries, offering surgeons additional clinically differentiated products to address patients' varying needs. PREVELEAK is approved in the United States and European Union.

Sales of the proposed acquired products totaled approximately \$56 million in the twelve months preceding September 29, 2017. Upon closing, the deal is expected to be modestly accretive to Baxter's 2018 adjusted earnings and increasingly accretive

thereafter. Under the terms of the agreement, Baxter will acquire RECOTHROM and PREVELEAK for an upfront payment of approximately \$153 million and potential contingent payments in the future.

The transaction is expected to close in the first half of 2018, subject to the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions.

### **About Baxter's Surgery Portfolio**

Baxter is committed to advancing surgical innovation with a variety of products and delivery devices used for hemostasis (addressing bleeding), tissue sealing, and hard tissue regeneration, as well as soft tissue repair and microsurgery. With products available in nearly 60 countries, Baxter is at the forefront of providing surgeons and hospitals with innovative products that improve patient outcomes, are convenient to use and are cost-effective. Baxter's surgical portfolio includes FLOSEAL Hemostatic Matrix, TISSEEL Fibrin Sealant, COSEAL Surgical Sealant and VASCU-GUARD Patch among others.

### **About Baxter**

Baxter International Inc. provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; surgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the

critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

## **IMPORTANT SAFETY INFORMATION**

### **RECOTHROM Thrombin topical (Recombinant) Indication**

RECOTHROM Thrombin topical (Recombinant) is a topical thrombin indicated to aid hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age.

RECOTHROM may be used in conjunction with an absorbable gelatin sponge, USP.

## **IMPORTANT RISK INFORMATION**

### **Contraindications**

- Do not inject directly into the circulatory system.
- Do not use for the treatment of massive or brisk arterial bleeding.
- Do not administer to patients with a history of hypersensitivity to RECOTHROM or any components of RECOTHROM.
- Do not use in patients with known hypersensitivity to hamster proteins.

### **Warnings and Precautions**

- **For topical use only. DO NOT INJECT.**
- RECOTHROM may cause thrombosis if it enters the circulatory system.

- Hypersensitivity reactions, including anaphylaxis, may occur. RECOTHROM is produced in a genetically modified Chinese Hamster Ovary (CHO) cell line and may contain hamster or snake proteins.

**Adverse Reactions**

- Thromboembolic adverse reactions were reported in 6% of surgical patients treated with RECOTHROM in all completed clinical trials.
- Antibody formation to RECOTHROM occurred in <1% of patients. None of the antibodies detected neutralized native human thrombin.

**Use in Specific Populations**

- Pregnancy Category C. RECOTHROM should be given to a pregnant woman only if clearly needed.
- Pediatric Use: Safety and efficacy have not been established in neonates.
- Geriatric Use: Of 644 patients in clinical studies of RECOTHROM, 36% (n=232/644) were ≥65 years old and 15% (n=95/644) were ≥75 years old. No differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Please see additional important risk information and [Full Prescribing Information](#).

**PREVELEAK Surgical Sealant Indications**

PREVELEAK Surgical Sealant is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

**IMPORTANT RISK INFORMATION****Contraindications**

Not for use in patients with known allergies to materials of bovine or shellfish origin.

- Not for intravascular use.
- Not for cerebrovascular repair or cerebrospinal leak repair.

### **Warnings and Precautions**

- Do not use as a substitute for sutures or staples.
  - Avoid exposure to nerves.
  - Do not use in the presence of obvious infection and use with caution in contaminated areas of the body.
  - Do not allow either the uncured or polymerized form to contact circulating blood.
  - PREVELEAK contains a material of animal origin that may be capable of transmitting infectious agents.
  - Repeated use of PREVELEAK in subsequent surgeries has not been studied.
  - Hypersensitivity reactions were not seen using PREVELEAK, but hypersensitivity of BSA has been reported.
  - Avoid contact with skin or other tissue not intended for application.
  - Safety and effectiveness of PREVELEAK in minimally invasive procedures or coronary artery bypass grafting (CABG) have not been established.
  - Do not use blood saving devices when suctioning excess PREVELEAK.
  - PREVELEAK syringe and delivery tips are for single patient use only. Do not resterilize.
  - Do not use if packages have been opened or damaged.
  - Take care not to spill contents of syringe. Avoid tissue contact with material expelled from delivery tip during priming.
  - Avoid pausing more than 10-15 seconds between priming and application to prevent polymerization within the delivery tip.
  - Minimize use in patients with abnormal calcium metabolism (e.g. chronic renal failure, hyperparathyroidism).
- Polyaldehyde treated tissue can have an enhanced propensity for mineralization.
- Evidence of cytotoxicity was observed during cell culturebased laboratory assays and is believed to be due to the polyaldehyde component of the product. No evidence of

cytotoxicity was observed in animal or clinical studies.

### **Adverse Reactions**

- Potential adverse effects associated with the use of this class of surgical sealants include application of the sealant to tissue not targeted for the procedure, failure of the sealant to adhere to the tissue, hypersensitivity reaction such as swelling or edema at the application site, possible transmission of infectious agents from materials of animal origin, thrombosis and thromboembolism.
- Serious adverse events that occurred in clinical studies included death, hypotension, thrombosis/ thromboembolism, ischemia, respiratory failure/dysfunction, steal syndrome, and myocardial infarction.

### **Use in Specific Populations**

- Use of PREVELEAK in pediatric or pregnant patients has not been studied.

*This release includes forward-looking statements concerning a definitive agreement entered into by the company to acquire two hemostat and sealant products from Mallinckrodt plc. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: the ability of the company and Mallinckrodt plc to obtain required regulatory approvals and satisfy closing conditions; the company's ability to close the transaction, successfully integrate the products into its hemostat and sealant portfolio and realize the anticipated benefits of the acquisition; demand for and market acceptance of risks for new and existing products, and the impact of those products on quality or patient safety concerns; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on its website. Baxter does not undertake to update its forward-looking statements.*

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<sup>1</sup> Lawson JH. The clinical use and immunologic impact of thrombin in surgery. *Semin Thromb Hemost.* 2006;32(Suppl 1):98–110. <https://www.ncbi.nlm.nih.gov/pubmed/16673271>

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