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BAXTER ANNOUNCES ACQUISITION OF PERCLOT POLYSACCHARIDE HEMOSTATIC SYSTEM TO EXPAND ADVANCED SURGERY PORTFOLIO

Marks Baxter's entry into the attractive global hemostatic powder segment, broadening its portfolio offering to include a wider range of active and passive solutions

DEERFIELD, Ill., JULY 29, 2021 – Baxter International Inc. (NYSE:BAX), a leading global medical products company, announced its Baxter Healthcare Corporation subsidiary has completed the acquisition of certain assets related to PerClot Polysaccharide Hemostatic System from CryoLife, Inc (NYSE:CRY) for up to $60.8 million, including $25 million paid upfront. The remainder will be paid out upon achievement of certain select milestones. The transaction reinforces Baxter's strategy of acquiring products and technologies that both complement and augment the company's leading portfolio across the hospital, including in the operating room. PerClot has a global commercial presence with sales in more than 35 countries worldwide. It is not currently cleared for sale in the United States.

"The addition of PerClot further enhances our ability to optimize patient care by addressing a broad range of intraoperative bleeding with both active and passive hemostatic solutions, helping surgeons to use the right product for the right bleed," said Wil Boren, president of Baxter's Advanced Surgery business. "PerClot launches Baxter into the attractive hemostatic powder segment, while expanding our surgical offerings and complementing our recent acquisition of Seprafilm Adhesion Barrier."

Addressing intraoperative bleeding is important in preventing blood transfusions and major complications for patients, as well as reducing the total cost of care. A blood management strategy that includes effective hemostasis is especially critical in today's environment, given current

worldwide shortages of blood donations and products due to the ongoing COVID-19 pandemic. A recent retrospective analysis found that implementing a framework that incorporates patient factors and a bleeding severity tool, such as Baxter's Validated Intraoperative Bleeding Scale (**VIBe SCALE**), can support optimal hemostatic product selection.[1]

A polysaccharide hemostatic powder can be used as an adjunctive hemostat to facilitate control of bleeding from capillary, venous or arteriolar vessels to address low-grade intraoperative bleeding.[2] **PerClot** is composed of plant starch that is modified to create an adhesive hemostatic powder. It is used as an adjunctive hemostatic device to control bleeding during multiple open and laparoscopic surgical procedures, including gynecologic, general, cardiovascular and urology. **PerClot** rapidly absorbs water from blood to produce a gelled matrix that adheres to and forms a mechanical barrier with the bleeding tissue.

CryoLife recently completed a multicenter, randomized controlled clinical trial of more than 300 patients intended to support an application for U.S. Food and Drug Administration (FDA) clearance. The trial evaluated the safety and efficacy of **PerClot** in achieving intraoperative hemostasis compared to the control (a similar marketed hemostatic powder).

Important Safety Information for PerClot in the European Union (EU)

Indications: PerClot Polysaccharide Hemostatic System (PHS) is indicated for use in surgical procedures (except neurological and ophthalmic) or injuries as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

Contraindications: Do not apply **PerClot** PHS into blood vessels as potential for embolization and death may exist. **PerClot** PHS is contraindicated in patients who are sensitive to starch or starch-derived materials.

Warnings: PerClot PHS is not intended as a substitute for good surgical practice, and in particular, the proper use of conventional procedures (such as ligature) for hemostasis.

PerClot PHS is not recommended when an infection is suspected. **PerClot** PHS should be used with caution in contaminated areas. If signs of an infection develop in the site where **PerClot** PHS has been used, surgery may be necessary to allow adequate drainage.

Combined use of **PerClot** PHS with other topical hemostatic agents has not been studied in controlled clinical trials.

Remove excess absorbable modified polymer (**AMP**) particles once hemostasis is achieved. This removal of excess particles is particularly important in and around the spinal cord, areas of bone confine, the optic nerve/chiasm, and foramina of bone because unsaturated particles may swell and compress the surrounding tissues.

PerClot PHS should not be mixed with methylmethacrylate or other acrylic adhesives as it may reduce the adhesive strength and compromise the attachment of prosthetic devices to bone tissue. Excess particles should be fully removed from bony surfaces by irrigation prior to the use of adhesives.

Safety and effectiveness of **PerClot** PHS have not been clinically evaluated in children and pregnant women.

When **PerClot** PHS is used in the nasal cavity and laryngopharyngeal, **PerClot** PHS should be used with caution to avoid the dry particles being drawn into the trachea or bronchi, which may form a gel that blocks the trachea and bronchi.

PerClot PHS is a single use product. Do not use **PerClot** PHS in more than a single surgical procedure.

PerClot PHS should not be used for controlling post-partum bleeding or menorrhagia.

Safety and effectiveness in neurological and ophthalmic procedures has not been studied in controlled clinical trials.

Important Safety Information for Seprafilm in the U.S.

Seprafilm Adhesion Barrier is indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder.

Important Risk Information for Seprafilm in the U.S.

Seprafilm Adhesion Barrier is contraindicated in patients with a history of hypersensitivity to **Seprafilm** and/or to any component of **Seprafilm**. **Seprafilm** Adhesion Barrier is contraindicated for use wrapped directly around a fresh anastomotic suture or staple line; as such use increases the risk of anastomotic leak and related events (fistula, abscess, leak, sepsis, peritonitis). The number of sheets used should be just adequate to cover the under surface of the abdominal wall or uterine incision in a single layer. In patients who have ovarian, primary peritoneal or fallopian tube malignancies, **Seprafilm** use has been reported to have an increased risk of intra-abdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required. The safety and effectiveness of **Seprafilm** Adhesion Barrier has not been evaluated in clinical studies for the following: Patients with frank infections in the abdominopelvic cavity; patients with abdominopelvic malignancy; device placement in locations other than directly beneath an abdominal wall incision following laparotomy, or directly on the uterus following open myomectomy (not laparoscopic); patients with ongoing local and/or systemic inflammatory cell responses; device use in the presence of other implants, e.g. surgical mesh; patients requiring re-operation within four weeks of **Seprafilm** placement – during anticipated time of peak adhesion formation. Foreign body reactions have occurred with **Seprafilm** Adhesion Barrier.

Important Safety Information for Seprafilm in the EU

Seprafilm is intended as an adjunct in abdominal and pelvic surgery for reducing the incidence, extent and severity of postoperative adhesions at the site of placement, and to reduce adhesive small bowel obstruction when placed in the abdomen.

Important Risk Information for Seprafilm in the EU

Seprafilm is contraindicated in patients with a history of hypersensitivity to **Seprafilm** and/or to any component of **Seprafilm.**

Seprafilm must be used according to the instructions for use. Read instructions prior to use. **Seprafilm** is supplied sterile and should not be resterilised. The membrane is for single use only. Every opened and unused **Seprafilm** pouch must be discarded.

Seprafilm is not recommended to be wrapped directly around a fresh anastomotic suture or staple line of the intestine. Clinical trial data on **Seprafilm** indicate that such use may result in an increased risk of anastomotic leak-related events (fistula, abscess, leak, sepsis and peritonitis). The incidence of these events was not affected when **Seprafilm** was placed elsewhere in the abdomen.

In patients undergoing surgery for ovarian, primary peritoneal or fallopian tube malignancies, **Seprafilm** use has been reported as having an increased risk of intraabdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

*This release includes forward-looking statements concerning a definitive agreement entered into by Baxter to acquire **PerClot** Polysaccharide Hemostatic System from CryoLife, including expectations regarding the financial impact and other benefits of such acquisition for Baxter. 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: Baxter's ability to successfully integrate the product and realize the benefits of the acquisition, including with respect to potential expansion activities; continued strength in Baxter's financial position, including cash flows; demand for and market acceptance of existing products; the ability of Baxter to develop, manufacture and commercialize, as applicable, new and existing products; product quality or patient safety concerns; actions of regulatory bodies and other governmental authorities (including potential FDA clearance of **PerClot**); 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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[1] Iannitti, et al. Impact of an active hemostatic product treatment approach on bleeding-related complications and hospital costs among inpatient surgeries in the United States. Journal of Medical Economics, 24:1, 514-523, DOI:10.1080/13696998.2021.1916751

[2] PerClot® Polysaccharide Hemostatic System Instructions for Use