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BAXTER COMPLETES ACQUISITION OF SEPRAFILM ADHESION BARRIER

- *Acquired product line is strong complement to the company's leading Advanced Surgery portfolio*
- *Global integration process begins immediately to manage successful transition with customers and distributors*

DEERFIELD, Ill., FEBRUARY 18, 2020 – Baxter International Inc. (NYSE:BAX), a leading global medical products company, has completed its previously announced acquisition of **Seprafilm** Adhesion Barrier and related assets from Sanofi for $350 million. The **Seprafilm** product family, which is used as an adjunct to reduce the incidence, extent and severity of adhesions in certain pelvic and abdominal surgeries, currently has a global commercial presence in the U.S., Japan, China, South Korea and France, among other countries.

"We are excited to bring **Seprafilm** products, alongside our leading hemostat and sealant portfolio, to our surgeon and hospital customers around the world," said Wil Boren, general manager, Baxter's Advanced Surgery business. "As we begin the integration process, our dedicated surgery commercial team is focused on working with customers and distributors to ensure a smooth transition."

Seprafilm has been more extensively evaluated than any other adhesion barrier and has been found to significantly reduce the incidence, extent, and severity of adhesions following abdominopelvic surgery.[1,2] Numerous prospective, randomized, controlled, clinical studies have demonstrated the efficacy of **Seprafilm.**[1,2,3]

- **Abdominal surgeries:** In a randomized, prospective, masked, multicenter clinical study involving 183 patients [175 evaluable] with ulcerative colitis and familiar polyposis

undergoing two-stage intestinal resection, 51% of patients treated with **Seprafilm** were adhesion-free at 12 weeks compared to 6% of untreated patients.[1]

- **Pelvic surgeries:** In a prospective, masked, blinded, multicenter clinical study involving 127 patients undergoing gynecologic surgery, **Seprafilm** reduced the mean number of sites adherent to the uterine surface following myomectomy (a surgical procedure to remove uterine fibroids) compared with untreated patients. **Seprafilm** also significantly reduced the extent and severity of adhesions in patients undergoing uterine myomectomy compared with untreated patients.[2]

Adhesion prevention products, hemostats and sealants are important tools surgeons use to manage intraoperative bleeding and reduce adhesions. Adhesions can occur in any surgery[4] when scar tissue develops and binds to nearby tissue. Adhesions can be a source of major post-surgical complications and often require revision, or a second surgery to remove the adhesions. Up to 93% of patients have been shown to develop adhesions following laparotomy,[1] large, surgical incision into the abdominal cavity. Approximately 20% of abdominal surgery patients return for adhesion-related complications, with annual surgical costs of more than $2 billion in the U.S. alone.[5]

Important Safety Information

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

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). **Seprafilm** Adhesion Barrier must be used according to the instructions for use. **Seprafilm** Adhesion Barrier is for single use only, supplied sterile and must not be re-sterilized. Every opened and unused **Seprafilm** pouch must be discarded. Do not use product if pouch is damaged or opened. 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. The safety and effectiveness of **Seprafilm** Adhesion Barrier in combination with other adhesion prevention products and/or in other surgical procedures not within the abdominopelvic cavity have not been established in clinical studies. The safe and effective use of **Seprafilm** Adhesion Barrier in pregnancy and Cesarean section has not been evaluated. No clinical studies have been conducted in pregnant women or women who have become pregnant within the first month after exposure to **Seprafilm** Adhesion Barrier. Therefore, this product is not recommended for use during pregnancy and avoidance of conception should be considered during the first complete menstrual cycle after use of **Seprafilm** Adhesion Barrier Long term clinical outcomes such as chronic pain and infertility have not been determined in clinical studies.

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 more than 85 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 Baxter acquisition of ***Seprafilm*** *Adhesion Barrier from Sanofi, 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 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; 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.

Baxter and **Seprafilm** are registered trademarks of Baxter International Inc.

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[1] Becker JM, Dayton MT, Fazio VW, et al. Prevention of postoperative abdominal adhesions by a sodium hyaluronate-based bioresorbable membrane: a prospective, randomized, double-blind multicenter study. *J Am Coll Surg*. 1996;183(4):297-306.

[2] Diamond MP. **Seprafilm** Adhesion Study Group. Reduction of adhesions after uterine myomectomy by **Seprafilm** membrane (HAL-F): a blinded, prospective, randomized, multicenter clinical study. Fertil Steril. 1996;66(6):904-910.

[3] Beck DE, Cohen Z, Fleshman JW, Kaufman HS, van Goor H, Wolff BG. Adhesion Study Group Steering Committee; A prospective, randomized, multicenter, controlled study of the safety of **Seprafilm** adhesion barrier in abdominopelvic surgery of the intestine. Dis Colon Rectum. 2003 Oct;46(10):1310-9. Fazio VW, Cohen Z, Fleshman JW, et al. Reduction in adhesive small-bowel obstruction by **Seprafilm** adhesion barrier after intestinal resection. Dis Colon Rectum. 2006 Jan;49(1):1-11.

[4] DeWilde R, Trew G. Postoperative abdominal adhesions and their prevention in gynaecological surgery. Expert consensus position. Part 2-steps to reduce adhesions. Gynecological Surgery. 2007;4(243-253).

[5] Sikirica V, Bapat B, Candrilli SD, Davis KL, Wilson M, Johns A. The inpatient burden of abdominal and gynecological adhesiolysis in the US. *BMC Surg*. 2011; 11:13.