



Artivion Announces FDA PMA Approval of PerClot and Transfer of PMA to Baxter

May 23, 2023

Artivion to Receive \$18.75 Million Milestone Payment Under Previously Announced Agreement

Artivion to Begin Supplying Product to Baxter Under Transitional Manufacturing and Supply Agreement

ATLANTA, May 23, 2023 /PRNewswire/ -- **Artivion, Inc. (NYSE: AORT)**, a leading cardiac and vascular surgery company focused on aortic disease, today announced that the U.S. Food and Drug Administration (FDA) granted premarket application (PMA) approval of PERCLOT Absorbable Hemostatic System ("PerClot") for use to control bleeding in certain open and laparoscopic surgical procedures. Artivion sold the PerClot product line to Baxter International Inc. ("Baxter"), (NYSE: BAX), in July 2021. Pursuant to the terms of its previously announced agreements with Baxter, Artivion will transfer ownership of the PMA to Baxter following approval. Shipment of PerClot product to Baxter will commence upon receipt of a milestone payment of \$18.75 million in cash, \$4.5 million of which will be paid to Artivion's former partner Starch Medical, Inc. ("SMI").

Under the terms of its agreements with Baxter, Artivion will supply Baxter with PerClot for a minimum of twenty-one (21) months, until manufacturing operations are transferred in full to Baxter or its designee.

"We are excited to receive FDA approval of PerClot, which represents a significant step forward in optimizing patient care by addressing intraoperative bleeding" said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "We continue to see Baxter as the perfect partner to commercialize PerClot due to its expertise in blood management and its strong hemostat portfolio, with corresponding customer relationships. The sale of PerClot to Baxter and the recent FDA approval mark the culmination of years of hard work and collaboration across many dedicated teams, and we are proud to have played a part in bringing this product to market."

Steve Wallace, President of Baxter's Advanced Surgery business added, "I would like to thank the team at Artivion for their partnership throughout the FDA review and approval process. The addition of PerClot to Baxter's portfolio further enhances our ability to optimize patient care by addressing a broad range of intraoperative bleeding with both active and passive hemostatic solutions."

With this latest milestone payment following FDA PMA approval for PerClot, Baxter will have paid approximately \$44 million in cash to Artivion, of which \$10.5 million was paid to SMI. Under the agreements, Baxter may make future payments as outlined below:

- Up to \$10 million upon Baxter's achievement of certain cumulative worldwide net sales of PerClot prior to December 31, 2026, and December 31, 2027, of which up to \$3 million is payable to SMI; and
- Approximately \$800,000 upon transfer to Baxter of Artivion's PerClot manufacturing equipment at the conclusion of Artivion's manufacturing and supply services for Baxter.

Artivion intends to use the net proceeds from the transaction for general corporate purposes, contingent consideration obligations, and potential debt repayment.

About Artivion, Inc.

Headquartered in suburban Atlanta, Georgia, Artivion, Inc. is a medical device company focused on developing simple, elegant solutions that address cardiac and vascular surgeons' most difficult challenges in treating patients with aortic diseases. Artivion's four major groups of products include: aortic stent grafts, surgical sealants, On-X mechanical heart valves, and implantable cardiac and vascular human tissues. Artivion markets and sells products in more than 100 countries worldwide. For additional information about Artivion, visit our website, www.artivion.com.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions 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](#).

Statements made in this press release that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made. These statements include our beliefs that FDA approval of PerClot represents a significant step forward in optimizing patient care by addressing intraoperative bleeding and that we continue to see Baxter as the perfect partner to commercialize PerClot due to its expertise in blood management and its strong hemostat portfolio, with corresponding customer relationships. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2022 and our subsequent filings with the SEC. Artivion assumes no obligation, and expressly disclaims any duty, to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

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