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The Centers for Medicare & Medicaid Services Makes Preliminary Recommendation to Establish New HCPCS Billing Code Dedicated to Arch Therapeutics' AC5® Advanced Wound System

A dedicated code would represent a key milestone for commercialization of AC5 Advanced Wound System in doctors' offices and other outpatient settings

FRAMINGHAM, Mass., Dec. 05, 2022 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), a marketer and developer of novel self-assembling wound care and biosurgical products, today announced that the Centers for Medicare and Medicaid Services ("CMS") has made a preliminary recommendation to establish a dedicated Healthcare Common Procedure Coding System ("HCPCS") Level II billing code specific to AC5® Advanced Wound System ("AC5"). The preliminary recommendation was discussed at CMS' First Biannual 2022 HCPCS Public Meeting, which was held on November 30, 2022. The HCPCS code would better enable providers to bill third party payors for AC5 that is used in doctors' offices. Currently, providers report AC5 on claims using A4100 (Skin substitute, FDA-cleared as a device, not otherwise specified).

AC5 was cleared as a device by the Food and Drug Administration ("FDA") for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds. AC5 is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. Case studies demonstrating that AC5 can lead to improved outcomes, including limb salvage, even for patients who have not responded to alternative modalities, are available for review on the Company's website here: https://www.archtherapeutics.com/technology/clinical-data.

"An AC5-specific HCPCS billing code would represent an important milestone in our commercialization efforts by opening a new vertical beyond government channels and hospital operating rooms. Although the establishment of a dedicated HCPCS code for AC5 does not guarantee coverage or reimbursement, a HCPCS code specific to AC5 would enhance our ability to work directly with payors as we expand access in outpatient settings and continue to advocate for clinically appropriate usage of our technology for patients in need," stated Dan Yrigoyen, Vice President of Sales of Arch Therapeutics.

About Arch Therapeutics, Inc.
Arch Therapeutics, Inc. is a biotechnology company with a novel approach to stop bleeding (hemostasis), control leaking (sealant) and manage wounds during surgery, trauma, and interventional care. Arch is developing wound care and biosurgical products based on an innovative self-assembling peptide technology platform with the goal of improving healing outcomes for patients. Arch has received regulatory clearance to market AC5® Advanced Wound System in the United States and AC5® Topical Hemostat in Europe. Arch's development stage product pipeline includes AC5-G™ for endoscopic resection of gastrointestinal tumors, AC5-V® for hemostasis during vascular surgery and AC5 Surgical Hemostat™ for general surgical hemostasis, among others.[1,2]

Notice Regarding Forward-Looking Statements
This news release contains "forward-looking statements" as that term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements and include any statements regarding beliefs, plans, expectations, or intentions regarding the future. Such forward-looking statements include, among other things, references to novel technologies and methods, our ability to recruit additional field sales representatives and their effectiveness, our business and product development plans and projections, or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the inherent uncertainties associated with developing new products or technologies and operating as a development stage company, our ability to retain important members of our management team and attract other qualified personnel, our ability to raise the additional funding we will need to satisfy our existing obligations and continue to pursue our business and product development plans, our ability to obtain required regulatory approvals, our ability to produce commercial quantities of our products within projected timeframes, our ability to obtain the inclusion of our AC5® Advanced Wound System on targeted federal supply schedules, our ability to develop and commercialize products based on our technology platform, and market conditions, and our ability to establish additional commercialization partnerships and build a critical mass of field sales representatives. These forward-looking statements are made as of the date of this news release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Although we believe that any beliefs, plans, expectations, and intentions contained in this press release are reasonable, there can be no assurance that any such beliefs, plans, expectations, or intentions will prove to be accurate. Investors should consult all of the information set forth herein and should also refer to the risk factors disclosure outlined in the reports and other documents we file with the SEC, available at www.sec.gov.

[1] AC5-G, AC5-V, and AC5 Surgical Hemostat are currently investigational devices limited by law to investigational use.
[2] AC5, AC5-G, AC5-V and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and/or its subsidiaries.

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