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Arch Therapeutics Submits Application to Centers for Medicare and Medicaid Services for AC5® Advanced Wound System

HCPSC Code May Support Product Differentiation and Enhance Existing Sales Opportunities Under New CMS 2022 Billing and Reimbursement Pathway for Synthetic Skin Substitutes

FRAMINGHAM, Mass., Sept. 01, 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 it recently submitted an application to the Centers for Medicare & Medicaid Services (“CMS”) for a unique HCPSC billing code (the “HCPSC Code”) for its AC5® Advanced Wound System (“AC5”). If approved, the HCPSC Code will enable providers to bill AC5 with specificity in doctors’ offices, wound care clinics, hospital outpatient departments and ambulatory surgical centers.

The Company intends to engage with payors to advocate for clinically appropriate AC5 coverage and payment policies. If successful, these activities would promote appropriate patient access to AC5 and build on the continued progress within the Company’s current distribution network, supported by Lovell Government Services and Centurion Therapeutics. In the interim, while there is no guarantee of coverage or payment, the 2022 CMS rule establishing principles for billing synthetic skin substitutes in physician office settings may facilitate near term sales opportunities for the Company’s AC5® Advanced Wound System.

“The Company believes that the new CMS guidance provides additional clarity to health care providers that may favorably impact the overall market for advanced wound care products and, in particular, the adoption, acceptance and growth of AC5. The continued execution of our commercialization plan is expected to support both near and long-term revenue growth, which is consistent with our vision to become the preeminent leader in the treatment of challenging wounds,” 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}

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.

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 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.

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