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Arch Therapeutics Provides Update on Reimbursement Strategy in Additional Selling Channel

Initial A4100 code being deployed and application for specific HCPCS product code to be submitted in the second calendar quarter

FRAMINGHAM, Mass., June 22, 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 provided an update regarding its reimbursement strategy for the use of AC5[®] Advanced Wound System (“AC5”), specifically regarding its use in doctor’s offices and wound clinics. This segment represents its third targeted selling channel and is expected to expand upon the Company’s first two selling channels: government facilities and non-government hospital operating rooms, which are currently supported by Lovell Government Services and Centurion Therapeutics, respectively.

Specific action items related to the Company’s reimbursement initiative in doctor’s offices and wound clinics include the following:

- *Sunsetting the Pilot Program.* The previously announced Pilot Program (the “Pilot”) delivered on its objectives and is set to begin a natural wind-down process as the company transitions to its next stage of the reimbursement life cycle. The Pilot yielded patient data and payor responses across a wide array of healthcare systems, expanded access to multiple providers, generated clinical data, and tested various coding options that, together, helped guide the development of the Company’s HCPCS application to request a category specific code for AC5.
- *Leveraging New Temporary Code for Synthetic Skin Substitutes.* Effective April 1, 2022, CMS authorized the use of A4100 as a temporary code to facilitate the reimbursement of doctor’s offices and wound clinics for the use of synthetic skin substitutes. The Company has begun the process of advising providers to submit claims under this new code as the Company pursues a permanent HCPCS code, as described below.
- *Filing a HCPCS Application.* The Company expects to submit its HCPCS application for specific coding to Centers for Medicare and Medicaid Services (“CMS”) in the coming weeks. HCPCS is a collection of standardized codes for medical procedures, products and services that facilitate the submission and processing of insurance claims for Medicare and other health insurers.

- *Launching a Multi-Site Clinical Study.* Building on the progress of the Pilot program, clinical outcomes (including published case studies), and observations from key opinion leaders, the Company is planning to launch a multi-site clinical study in the third calendar quarter of 2022. The study is expected to enroll and treat up to approximately 60 patients at six sites, with the primary end point of wound closure. This study is intended to accelerate payor adoption as well as differentiate and highlight the key benefits of AC5 in treating hard to heal wounds.

“Reimbursement remains a key strategic initiative for Arch Therapeutics and is expected to drive sales in the Company’s non-government and non-operating room verticals. To that end, filing the application with CMS and launching the multi-site clinical study are important targets for us and exciting milestones for our ongoing commercialization efforts,” stated Dan Yrigoyen, Vice President of Sales of Arch Therapeutics. “Positive and differentiated patient outcomes from the Pilot have generated enthusiasm among doctors who have expressed interest in being investigators in the planned clinical study as well as supporting the product’s use in government channels,” concluded Mr. Yrigoyen.

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 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.

Contact:

ARTH Investor Relations

Toll Free: +1.855.340.ARTH (2784) (US and Canada)

Email: investors@archtherapeutics.com

Website: www.archtherapeutics.com

or

Michael Abrams

Chief Financial Officer

Arch Therapeutics, Inc.

Phone: 617.431.2333

Email: mabrams@archtherapeutics.com



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