October 1, 2018

Arch Therapeutics Announces 510(k) Submission to the U.S. FDA for AC5™ Topical Gel

FRAMINGHAM, Mass., Oct. 01, 2018 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB: ARTH) (“Arch” or the “Company”), developer of novel liquid, gel and solid hemostatic and wound care devices, today announced that the Company submitted a 510(k) notification to the U.S. Food and Drug Administration (FDA or “the Agency”) for its AC5ä Topical Gel (AC5)[1] and has received acknowledgement from the Agency that the submission has been received.

The purpose of the 510(k) notification is to allow for commercial use of AC5 on external wounds for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

Terrence W. Norchi, MD, President and CEO of Arch, said, “We are happy to have initiated and completed the necessary steps required to file this submission during the third calendar quarter. As previously disclosed, these steps included developing a required study protocol and submitting it to the Agency in a pre-submission letter in the first calendar quarter, completing the pre-submission process and initiating the study in the second calendar quarter, and completing the study and filing the 510(k) during the third and most recent calendar quarter.”

As previously disclosed, the Company plans to file a CE Mark for external use of AC5 this calendar year, to subsequently seek regulatory approval for expanded indications, and to pursue internal use commercial opportunities for other AC5-related products through the premarket authorization process. Arch continues to evaluate commercialization options and will provide updates when appropriate.

About Arch Therapeutics, Inc.
Arch Therapeutics, Inc. is a biotechnology company developing a novel approach to stop bleeding (hemostasis), control leaking (sealant) and manage wounds during surgery, trauma and interventional care. Arch is developing products based on an innovative self-assembling barrier technology platform with the goal of making care faster and safer for patients. Arch's development stage product candidates include the AC5™ Topical Gel and the AC5™ Surgical Hemostatic Device.

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 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 develop and commercialize products based on our technology platform, and market conditions. 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.

Source: Arch Therapeutics, Inc.

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1. AC5 is currently an investigational device and is limited by federal law to investigational use.

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