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Arch Therapeutics Receives 510(k) Clearance from the US FDA for AC5™ Topical Gel

AC5™ provides a new option for the treatment of topical wounds

FRAMINGHAM, Mass., Dec. 17, 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 510(k) premarket notification for AC5™ Topical Gel has been reviewed and cleared by the U.S. Food and Drug Administration (FDA), allowing for the product to be marketed. AC5 Topical Gel is a topical dressing indicated for use in the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

Chief Executive Officer, Terrence W. Norchi, MD, said, "We are pleased to have received 510(k) clearance for AC5 Topical Gel, having obtained important feedback from the FDA throughout the process."

Marketing clearance, which requires the provision of necessary documentation and data to the FDA, is an essential milestone to the path to commercialization.

Norchi added, "We believe that AC5 can add an important option to healthcare providers' tool kits for the treatment of wounds. We continue to develop our commercialization plans and look forward to expanding the AC5 product family both in the US and abroad, where we have filed our first application for a CE mark in Europe."

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 AC5™ Topical Gel, AC5™ Topical Hemostat¹ and AC5™ Surgical Hemostat¹.

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 Topical Hemostat and AC5 Surgical Hemostat are currently investigational devices and are limited by federal law to investigational use.



Source: Arch Therapeutics, Inc.