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Arch Therapeutics Announces Submission of CE Mark File for AC5™ Topical Hemostat in Europe

Company anticipates review process could take up to six months

FRAMINGHAM, Mass., Nov. 28, 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 has submitted the required documents for AC5™ Topical Hemostat (AC5)[1] to its Notified Body as it seeks a CE mark, which is a next step on the path to commercialization in countries governed by the European Medical Devices Directive (MDD). This first such submission by Arch to a European regulatory body follows the recent submission of a 510(k) premarket notification to the US Food and Drug Administration.

Receipt of a CE mark would allow AC5 to be commercialized for use on external wounds, and in particular, for controlling bleeding by mechanically sealing areas of leakage and managing wounds in skin. The CE mark represents a company’s claim that a product meets the essential requirements of relevant European directives, and it is a legal prerequisite in order to place a device on the market in the European Union. AC5 will be assessed as a Class IIb device. We expect that the review process could take up to 6 months.

A Notified Body is an independent third-party selected by a Competent Authority to assess a medical device manufacturer’s compliance by conducting a conformity assessment under the MDD. Each country has one Competent Authority, which is a local government body responsible for, among other things, ensuring that the MDD requirements are placed into National Law.

Terrence W. Norchi, MD, President and CEO of Arch, said, “This is an important step in a busy quarter for Arch. Having filed the 510(k) notification in the third calendar quarter, we are happy to have also completed the work necessary to file this submission.”

As previously disclosed, Arch is seeking regulatory clearance in the U.S. and, following this initial clearance, potential clearance or approval for expanded indications. The company is also pursuing commercial opportunities for other AC5-related products, including use in open and laparoscopic surgical procedures. 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 AC5™ Topical Gel[1], AC5™ Topical Hemostat[1] and AC5™ Surgical Hemostat[1].

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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