December 18, 2017

Arch Therapeutics Withdraws 510(k) with Plans to Resubmit After Further Discussions with FDA

FRAMINGHAM, Mass., Dec. 18, 2017 (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developer of novel liquid, gel and solid hemostatic and wound care devices, today announced that the Company has withdrawn its 510(k) notification for its medical device AC5 Topical Gel, from the Food and Drug Administration (FDA) with plans to submit a new 510(k) as soon as possible following further discussion with the FDA.

Arch voluntarily withdrew the application on December 18, 2017 after receiving questions from the FDA for which an adequately comprehensive response could not be provided within the FDA's congressionally-mandated 90-day review period. Arch is committed to collaborating with the FDA to gain a better understanding of the FDA's issues, which the company plans to address in a subsequent 510(k) submission.

Terrence Norchi, MD, President & Chief Executive Officer of Arch, commented, "We have been involved in productive and positive interactions with the FDA, and the agency has been very engaging. Unfortunately, the FDA requested certain additional information that was not feasible to provide within the congressionally mandated MDUFA deadlines, and so we withdrew our application to provide additional opportunities to resolve the issues raised by the FDA. We remain confident in the data package that we submitted, and that after working further with the FDA, we will be able to submit another 510(k) that is supportive of clearance for AC5 Topical Gel."

While Arch still anticipates obtaining marketing clearance in 2018, commercialization of AC5 Topical Gel is expected to be delayed by approximately one to two quarters until the first half of 2019 based on the information currently available to the Company. The 510(k) submission for AC5 Topical Gel is the first step in a more comprehensive regulatory strategy for this product and the AC5 platform, including internal surgical applications. Plans for additional submissions continue in line with expanding commercial potential.

Dr. Norchi concluded, "Arch remains focused on manufacturing scale-up, clinical regulatory strategy, and developing commercial partnerships, and execution of operating plans. We are still awaiting further interactions with the FDA, and expect to provide additional updates as we learn more."

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.

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