March 12, 2018

Arch Therapeutics Provides Update on 510(k)

Company files pre-submission with FDA for feedback on proposed plan to address FDA comments before next medical device submission; Expecting to file 510(k) during Q3

FRAMINGHAM, Mass., March 12, 2018 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB:ARTH) ("Arch" or the "Company"), developer of liquid, gel and solid hemostatic and wound care devices, today announced that it has utilized the Food and Drug Administration's (FDA, "the agency") pre-submission process to submit a proposed development strategy to the FDA to address the agency's comments on its previous 510(k) submission for its AC5 Topical Gel product.

As previously reported, Arch voluntarily withdrew its 510(k) notification for its medical device AC5 Topical Gel from the FDA after receiving comments from the FDA late in the review process for which a complete response could not be provided within the FDA's statutorily-mandated 90-day review period. We are proceeding with our disclosed intent to gain a better understanding of the agency's comments and submit a new 510(k) as soon as possible, which would follow appropriate discussion, agreement and completion of a plan.

The 510(k) package previously submitted by Arch included a comprehensive battery of tests. The agency requested further evidence that the product does not cause sensitization in humans. While we respectfully disagree that further evidence should be necessary, we are working with the agency to address their outstanding comments, and we have determined that the most expeditious path involves providing additional data.

In order to provide a comprehensive response to the agency and minimize further delay, we consulted with several medical experts and developed a strategy to perform a small, three-month long, non-invasive human study to provide the additional data to the FDA. The Company has presented this proposal to the FDA via the pre-submission process with the intention of ensuring that the strategy will address their questions. Based on the body of scientific data that the Company has generated, including favorable results in a prior animal test for sensitization, we anticipate supportive findings in a human sensitization test.

Terrence Norchi, MD, President & Chief Executive Officer of Arch, commented, "We determined it most prudent to submit a pre-submission filing to provide the agency adequate time for full review of both the information we presented and our proposal. We expect this phase of the review process by the agency to last roughly two months, after which we would expect to initiate the proposed study at a cost of approximately $100,000."

Assuming that the FDA agrees with the Company's proposed development plan and the

additional testing is completed when expected, Arch expects to submit the 510(k) later in the third quarter of 2018. Arch also expects to file a CE mark in Europe for AC5 in the second half of 2018.

Dr. Norchi added, “This puts us on target to submit the 510(k) later in the third calendar quarter of 2018 and for us to hear back by the end of 2018 with possible commercialization mid-2019. We believe that the additional testing will answer the agency’s questions and be helpful in future regulatory submissions.”

Arch remains focused on manufacturing scale-up, clinical regulatory strategy, developing commercial partnerships, advancing intellectual property and expanding its pipeline of products.

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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