May 8, 2018

Arch Therapeutics Provides Update on Study Initiation and 510(k)

Company intends to initiate confirmatory study in calendar H1, incorporating feedback received from FDA; 510(k) filing expected in calendar Q3, as planned

FRAMINGHAM, Mass., May 08, 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 will initiate the previously disclosed study designed to address the Food and Drug Administration's (FDA or "the agency") comments on Arch's previous 510(k) submission for its AC5™ Topical Gel. The agency has provided feedback via the pre-submission process and has indicated that the proposed study design is acceptable to support the Company's future marketing application. At present, the Company believes that there are no other material items to address with the agency.

Terrence Norchi, MD, President & Chief Executive Officer of Arch, commented, "We view the agency's comments as important, addressable, and straightforward. While this study on intact skin to test for sensitization still needs to be completed, the overall body of evidence to date, including results from a required animal test for sensitization, are favorable. Further, we believe that the testing will address the agency's questions and be helpful in future regulatory submissions."

Arch intends to initiate the study in the next few weeks incorporating FDA's comments and, assuming supportive study findings, expects to file the 510(k) notification in the third calendar quarter of 2018. That 510(k) notification would contain both the information previously reviewed by the FDA and the additional data discussed with the agency.

As previously disclosed, Arch voluntarily withdrew the 510(k) notification after receiving comments from the FDA late in the review process for which a complete response could not be provided within the time remaining in the agency's statutorily-mandated review period. The agency requested further evidence that the product does not cause sensitization in humans. While the Company respectfully disagreed that further evidence should have been necessary, after seeking feedback from the FDA, Arch decided it most expeditious to provide further documentation and perform a non-invasive human study designed with leading experts in the field. The Company requested agency feedback on the study design via the pre-submission process.

Dr. Norchi added, "We are very pleased with the input that the agency provided, which we deliberately sought before starting the trial. We still expect the trial to cost approximately $100,000 and take about three months."

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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