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Arch Therapeutics Completes Enrollment and Initiates Dosing in Skin Sensitization Study

Study completion and submission of 510(k) notification expected in Calendar Q3 2018

FRAMINGHAM, Mass., June 15, 2018 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB:ARTH) ("Arch" or the "Company"), developer of liquid, gel and solid hemostatic and wound care devices, announced today that it has completed enrollment for its human skin sensitization study and that applications of the Company's AC5™ Topical Gel are underway for all subjects. The study is anticipated to conclude during the third quarter.

Terrence W. Norchi, MD, President and CEO of Arch, said, "This study is an important component of our plans to address the request by the Food and Drug Administration (FDA or "the Agency"). The Agency had requested further evidence beyond that which was previously supplied to support that AC5 does not cause sensitization in humans. We are pleased that enrollment was completed within the expected timeframe and that the study volunteers have entered the repeat dosing phase."

The study protocol was designed with input from Arch's expert advisors and the Agency in order to support the Company's 510(k) submission for its AC5™ Topical Gel. As previously announced, the study is expected to cost approximately \$100,000 and take about three months. We anticipate filing a 510(k) notification by the end of the third quarter of calendar 2018.

Dr. Norchi added, "We expect the future anticipated 510(k) notification to contain both the information previously reviewed by the FDA, including the favorable results from a required animal test for sensitization, and the additional data from this human sensitization study. We believe that there are no other material items to address with the Agency."

As the study is conducted, Arch remains focused on manufacturing scale-up, clinical regulatory strategy, developing commercial partnerships, enhancing its intellectual property portfolio 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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