

September 5, 2018



Arch Therapeutics Reports Topline Results from Skin Sensitization Study of AC5

Study finds no evidence of irritation or allergic reaction in any enrolled subject

FRAMINGHAM, Mass., Sept. 05, 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 topline data for its irritation/sensitization patch test study of AC5™ Topical Gel (AC5)¹. The study was designed to address a request by the Food and Drug Administration (FDA or "the Agency").

These topline results indicate that AC5 is neither an irritant nor a sensitizer. Additionally, no immunogenic response and no serious or other adverse events attributable to the device were reported in any of the enrolled subjects.

The objective of this Study ("Cumulative Irritancy Assay with Delayed Challenge for Allergic Contact Dermatitis Potential of AC5™ Topical Gel (AC5) in Healthy Volunteers") was to assess irritation and sensitization potential (development of allergic contact dermatitis) of AC5 after repeat applications and then a delayed challenge application of the product to the skin. Products can be studied in this way to determine if a reaction develops immediately upon initial exposure to the skin, in the case of irritation, or when the skin is 'challenged' or exposed again at a point in the future, in the case of allergic contact dermatitis.

Terrence W. Norchi, MD, President and CEO of Arch, said, "We are pleased that these topline results provide favorable support for the safety profile of AC5, and we are eager to provide the full report to the FDA. As previously indicated, this study is intended to strengthen and enhance the Company's 510(k) notification for AC5 Topical Gel, which we expect to file during this third quarter of calendar 2018, as previously disclosed."

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 and 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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¹ AC5 is currently an investigational device and is limited by federal law to investigational use.



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