

February 5, 2018



# Dermatologic Surgery Publishes Clinical Data on Arch Therapeutics' AC5™ in a Topical Application

## Peer-Reviewed Paper Concludes That AC5™ Provided Safe and Effective Hemostasis Regardless of Whether Patients Were Taking or Not Taking Antiplatelet Therapy

FRAMINGHAM, Mass., Feb. 05, 2018 (GLOBE NEWSWIRE) -- Positive data from a clinical study of patients undergoing dermatologic surgery and treated with the AC5™ was published in the peer-reviewed journal *Dermatologic Surgery*, the official journal of the American Society for Dermatologic Surgery. The study was sponsored by Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company") and conducted by an independent research organization in Ireland. The results in the manuscript, titled "First Safety and Performance Evaluation of T45K, a Self-Assembling Peptide Barrier Hemostatic Device After Skin Lesion Excision" by Rahmani et al. show that AC5™ was safe and rapidly achieved hemostasis agnostic to the presence of antiplatelet medication. SAPB-T45K is a development name for AC5. The paper has been published as Open Access, and can be accessed online at the [journal website](#).

The authors report that in this single-blind study, wounds were randomized to receive AC5 or control treatment after sequential shave excision of two lesions in the same patient. This design allowed patients to serve as their own controls. Patients and clinical assessors were blind to treatment allocation. Safety was assessed at treatment, Day 7 and Day 30. Performance was evaluated using time to hemostasis (TTH) and a published wound scoring system, with a subgroup analysis for patients with or without antiplatelet therapy (aspirin). A total of 46 patients (10 of which, or 22% of the study group, received antiplatelet therapy) received randomized AC5 or control treatment for their two wounds. Safety assessments were similar for AC5 and the control treatment, and wound scores reflected normal healing in both wound groups. AC5 demonstrated significantly faster median TTH (24.5 [range, 7–165] seconds) compared with the control treatment (44 [10–387] seconds), for a 41% median TTH reduction (18 [95% confidence interval, 7–35] seconds, and this result was statistically significant ( $p < 0.001$ , Wilcoxon signed rank test). AC5 use resulted in an identical median TTH of 24 seconds in the group of patients taking antiplatelet therapy and the group not taking antiplatelet therapy. In contrast, the median TTH for the control treatment was 90 and 40 seconds for the groups of patients taking or not taking antiplatelet therapy, respectively.

Safety assessments in the study included a full battery of laboratory blood tests, assessment of wound healing scores and observation for any systemic reactions. Terrence W. Norchi, MD, President and CEO of Arch Therapeutics, said, "This report represents the first clinical

study of both the safety and performance of AC5. The primary purpose of the study was to assess safety. The safety profile of a topical agent is important, and AC5's safety profile was similar to that of saline and consistent with a normal healing pattern."

The senior author of the paper and Principle Investigator of the study, Professor Jack Kelly MB MD FRCS(Plast), is a Consultant Plastic Surgeon and Professor of Plastic Surgery at Galway University Hospital, Galway Ireland. Professor Kelly said, "According to a 2015 report, almost half of the patients undergoing elective surgery are taking anticoagulant or antiplatelet medications to prevent potentially life-threatening problems, such as strokes, heart attacks and pulmonary emboli. When these patients require surgery or even a minor procedure, the surgeon often decides to discontinue the drug, weighing the risk of bleeding against the risk of stroke or other event for which the medication was prescribed. The consistent performance of AC5 regardless of the patient's antiplatelet medication support the potential of AC5 as an important option to control bleeding without having to stop the medication." In animal studies, AC5 has also demonstrated this consistent performance in the presence of various anticoagulant and antiplatelet medications.

Topline results of the study were previously reported in a press release issued by the Company on August 15, 2016, which can be accessed at the company's [website](#).

Dr. Norchi further commented, "We continue to develop our exciting technology for wound care and biosurgical applications. As our priority, we are committed to continued collaboration with the FDA and plan to submit a new 510(k) notice for AC5 Topical Gel as soon as possible following further discussion with the agency. We will provide a more detailed update when the plan is finalized."

#### **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](http://www.sec.gov).

Source: Arch Therapeutics, Inc.

**Contact**

ARTH Investor Relations

Toll Free: +1-855-340-ARTH (2784) (US and Canada)

Email: [investors@archtherapeutics.com](mailto:investors@archtherapeutics.com)

Website: [www.archtherapeutics.com](http://www.archtherapeutics.com)

or

Richard Davis

Chief Financial Officer

Arch Therapeutics, Inc.

Phone: 617-431-2308

Email: [rdavis@archtherapeutics.com](mailto:rdavis@archtherapeutics.com)

Website: [www.archtherapeutics.com](http://www.archtherapeutics.com)



Source: Arch Therapeutics, Inc.