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# Arch Therapeutics Obtains Additional Positive Safety Data for AC5 Surgical Hemostatic Device(TM) in Preclinical Toxicity Test of Sensitization

## Test Result Further Supports the AC5™ Biocompatibility Profile

FRAMINGHAM, MA -- (Marketwired) -- 09/08/15 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of the AC5 Surgical Hemostatic Device™ ("AC5™"), obtained favorable data from a preclinical toxicology test for AC5™ showing that the device did not cause sensitizing reactions in animals and is considered a "non-sensitizer." The test, called the Maximization Test, is a standardized test of contact sensitization and is performed in animals as a major component of the biocompatibility test panel that a medical device must typically complete successfully prior to use in humans. Testing was conducted under the guidelines provided by the International Organization for Standardization (ISO) and the study also complied with Good Laboratory Practice (GLP), a Federal regulation (21 CFR part 58) governing the conduct of nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration (FDA). AC5 is a development-stage hemostasis product being evaluated to control bleeding, mitigate fluid loss, and create an environment permissive to normal healing in order to provide more efficient surgical and interventional care.

In this standard *in vivo* study, designed to provide general information on the health hazards likely to arise from acute exposure to clinically relevant quantities of AC5, AC5 was well tolerated when using standardized success criteria based upon comparison with control materials. As a result, AC5 was classified as a non-sensitizer with no evidence of causing delayed contact sensitization. Results from this biocompatibility safety study indicate that AC5's peptide structure and mechanism of action, which is based on the formation of a local physical-mechanical barrier at the wound site, does not promote sensitization to the overall biological system following application of standardized AC5 extract solutions in animals. The results of this study provide further evidence of the absence of toxicity for AC5, and represent a critical step toward demonstrating biocompatibility of this medical device.

Arch Therapeutics President and CEO Terrence Norchi, MD, stated, "We remain pleased with the safety data generated for AC5, and we hope and anticipate that the safety profile of our products will represent an important distinguishing feature. This sensitization test adds to the portfolio of solid results. Tests such as this are important for us to be able to initiate our first clinical trial, which we intend to commence after we receive the go-ahead from the relevant bodies."

**About Arch Therapeutics, Inc.**

Arch Therapeutics, Inc. is a medical device company developing a novel approach to stop bleeding (hemostasis) and control leaking (sealant) during surgery and trauma care. Arch is developing products based on an innovative self-assembling peptide technology platform to make surgery and interventional care faster and safer for patients. Arch's flagship development stage product candidate, known as the AC5 Surgical Hemostatic Device, is being designed to achieve hemostasis in minimally invasive and open surgical procedures.

Find out more at [www.archtherapeutics.com](http://www.archtherapeutics.com).

**Notice Regarding Forward-Looking Statements**

This news release contains "forward-looking statements" as that term is defined in Section 27(a) of the Securities Act of 1933, as amended, and Section 21(e) 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 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).

On Behalf of the Board,  
Terrence W. Norchi, MD  
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)

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