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Arch Therapeutics Reports Favorable Results for AC5 Surgical Hemostatic Device in Biocompatibility Testing Required for CE Mark

Company Completes Planned Series of ISO Safety Studies Required for Commercialization

FRAMINGHAM, MA -- (Marketwired) -- 03/14/16 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of the AC5 Surgical Hemostatic Device™ ("AC5™"), has obtained favorable results from a broad panel of preclinical biocompatibility tests that were performed on AC5, which is required prior to the planned filing of a CE Mark application and commercialization of AC5 in Europe. Results from these biocompatibility safety studies 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 toxicity to the overall biological system following exposure to AC5.

Arch Therapeutics President and CEO Terrence Norchi, MD, stated, "This testing of AC5, performed under International Organization for Standardization (ISO) and Good Laboratory Practice (GLP) protocols, represents another step in our progress toward commercialization. Outcomes of the biocompatibility tests can be meaningful predictors of human safety, which enhances our confidence as we continue with our first human trial. Further, they are an important component of a CE Mark application, which we expect to file this summer -- and obtaining a CE Mark is a required critical step for commercialization."

The standardized studies included tests to assess cytotoxicity, implantation, irritation, pyrogenicity, sensitization and systemic toxicity. The testing was conducted on AC5 samples that were produced and sterilized under the same Good Manufacturing Practice (GMP) protocols as used for the product being tested in the Company's human trial that is underway in Western Europe. Testing was conducted under the guidelines provided by the ISO. The studies also complied with 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 United States Food and Drug Administration (FDA).

In the cytotoxicity test, which is a three-day *in vitro* cell culture study, a product is assessed for toxicity to cells and is categorized as either non-cytotoxic or cytotoxic. AC5 was categorized as "non-cytotoxic."

In the implantation test, which is a 28-day *in vivo* study, each of several rabbits is injected

subcutaneously with AC5 and with a control product in multiple locations in order to assess biological tissue response. All animals survived and no adverse effects were observed for either AC5 or the control. When assessed at the end of the study, AC5 was no longer present in the injection sites and was not found in the draining lymph nodes.

In the irritation test, which is a three-day *in vivo* rabbit model study, intracutaneous tissue reactions to test and control materials are graded. AC5 was scored as a "non-irritant."

In the pyrogenicity test, an *in vitro* assay is used to test a product for the presence of pyrogens, also known as bacterial endotoxins, which are a type of toxin made by bacteria. A product that contained sufficient amounts of pyrogen or other cell toxins could trigger immune responses with the potential for tissue damage and significant harm to patients. AC5 was found to be non-pyrogenic, which is a desirable characteristic.

In the sensitization test, a product is assessed for sensitization or allergenic potential over more than two weeks in an *in vivo* model using guinea pigs. AC5 was deemed a "non-sensitizer" with no evidence of causing delayed contact sensitization.

In the systemic toxicity test, the acute systemic toxicity potential of a product is assessed in an *in vivo* rodent model designed to provide general information on the health hazards likely to arise from acute exposure. AC5 was classified as "not toxic."

Dr. Norchi stated further, "We have seen consistently favorable safety outcomes in our preclinical program to date. Strong safety data are critical to a product's potential for use in humans. Next, we look forward to assessing both safety and efficacy in humans."

About Arch Therapeutics, Inc.

Arch Therapeutics, Inc. is a biotechnology 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 during surgical procedures.

Find out more at 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.

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