

Arch Therapeutics Receives ISO 13485 Certification for AC5

Company Completes a Critical Step in Its Progress Toward Commercialization of AC5

FRAMINGHAM, MA -- (Marketwired) -- 03/09/16 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of the AC5 Surgical Hemostatic Device™ ("AC5™"), today announces that it has received an internationally recognized ISO quality certification, marking completion of a critical step for Arch in its plans to commercialize AC5.

The certification, which was awarded by British Standards Institution Group America, Inc., attests that the Company's quality management system complies with the requirements of ISO 13485:2003 for the design and manufacture of AC5 for hemostasis. ISO 13485 is a quality management system standard accepted as the basis for CE marking medical devices under European Directives.

ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. Receipt of the certification is a regulatory requirement that needs to be fulfilled before a medical device may be commercialized in the EU.

Dr. Terrence Norchi, President and CEO of Arch, stated, "Obtaining this certification is an important milestone and an essential component of Arch's strategy to obtain CE marking for our first product and patented technology. It is the culmination of a tremendous effort aimed at fulfilling consumer requirements, and resulting from the implementation and execution of improvements to our quality management systems. As previously disclosed, we have started to prepare a dossier of information for our CE marking application, which we intend to file this summer."

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 in minimally invasive and open surgical procedures and is intended to be regulated as a medical device.

Find out more at <u>www.archtherapeutics.com</u>.

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.

On Behalf of the Board, Terrence W. Norchi, MD Arch Therapeutics, Inc.

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