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Arch Therapeutics Receives Clearance to Initiate Clinical Trial in Europe

Achieves Milestone in CE Mark Evaluation Process for the AC5 Surgical Hemostatic Device(TM)

FRAMINGHAM, MA -- (Marketwired) -- 12/16/15 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), a life sciences company and developer of the AC5 Surgical Hemostatic Device™ ("AC5™"), a novel product aimed at controlling bleeding and fluid loss in order to provide faster and safer surgical and interventional care, has received clearance to initiate a human clinical trial from a regulatory authority in Western Europe.

The randomized controlled single-blind investigation is designed to assess safety and performance of AC5™ in bleeding wounds created during the course of a dermatological procedure in fewer than 50 patients. The endpoints include product related adverse effects, with a planned patient follow-up assessment 30 days following the procedure, and time to hemostasis. A portion of the patients will be taking a therapeutics dose of an antithrombotic medication (commonly referred to as a "blood thinner") during the study period.

Dr. Terence Norchi, President and CEO of Arch, said, "This is an important milestone for the Company as we continue to bring AC5 and our technology platform another step closer to market. We expect to apply for a CE Mark if the data from our study is supportive. We remain committed to completing subsequent clinical trials and expanding the indications for product use."

Arch assembled a comprehensive preclinical package for submission with the application to a European regulatory authority to commence the first clinical trial of AC5 that assesses safety and efficacy. The clearance is a requirement for trial commencement. Administrative obligations, including product shipment and site initiation, are currently being fulfilled and are expected to last through the impending holiday period. The Company expects the initial patient to be treated early in the first quarter 2016. Data are projected to be available within two quarters of the start of the trial.

"We were very encouraged by the preclinical data observed to date, and we believe that AC5 will have similar results in humans," added Dr. Norchi.

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 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 obtain required regulatory approvals, 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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