

# Arch Therapeutics Selects BSI as Its European Union Notified Body

# Critical Step on Path to Commercialization of AC5 Surgical Hemostatic Device(TM) in Europe

WELLESLEY, MA -- (Marketwired) -- 07/15/14 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), a life sciences company and developer of the AC5 Surgical Hemostatic Device™, a novel product aimed at controlling bleeding and fluid loss in order to provide faster and safer surgical and interventional care, has selected the British Standards Institution ("BSI") as its Notified Body. A Notified Body is an organization that has been accredited by a member state of the European Union to assess whether a product meets certain preordained standards to receive a CE Mark designation.

Arch intends to enter the hemostasis and sealant market in Europe. According to a 2012 report produced by MedMarket Diligence, LLC, the European market for hemostatic agents and sealants, including fibrin sealants, is increasing and is expected to surpass \$1.7 billion in revenues in 2017.

Arch has contracted with BSI for the certification of its Quality Management System to ISO 13485:2003 standards and for CE approval of its flagship product AC5™. Widely known and broadly accredited, BSI has demonstrated one of the most extensive testing and certification capabilities in the world.

Terrence W. Norchi, MD, President and CEO of Arch Therapeutics, said, "The medical device industry is an extensively regulated sector in which product criteria and quality systems are held to high standards. It was essential that we select a Notified Body with significant breadth and experience to confirm that the systems and procedures we put in place will yield products that meet these standards. BSI's commitment to excellence, as supported by their track record, fulfills a critical criterion that Arch seeks in the groups with which we work. Achieving ISO certification with BSI reaffirms our commitment to the high standards and best practices of our products."

## **About BSI Group**

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Famed for its marks of excellence including the instantly recognizable Kitemark®, BSI's influence spans multiple

sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 64,000 clients in 147 countries, BSI is an organization whose standards inspire excellence across the globe.

## 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 AC5 Surgical Hemostatic Device ™, is being designed to achieve hemostasis in minimally invasive and open surgical procedures.

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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