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Arch Therapeutics Reports Favorable Results in Repeat Dose Testing of AC5™ for Subchronic Systemic Toxicity

AC5 was comparable to control when dosed 16 times over two months

FRAMINGHAM, Mass., Sept. 12, 2017 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB:ARTH) ("Arch" or the "Company"), developer of novel liquid, gel and solid hemostatic and wound care devices reported that AC5™ Topical Gel (AC5™) was found to be biocompatible in testing designed to investigate subchronic systemic toxicity. The subchronic systemic testing, which involved repeat, frequent dosing over 8 weeks, is one of a panel of biocompatibility evaluation endpoints recommended by US FDA regulatory guidelines for devices such as AC5 to allow use in humans.

This study was designed to provide information on the health hazards that might arise from repeated exposure to AC5. A total of 80 animals (40 male and 40 female) were assigned to either a group dosed with one of three dose levels of AC5 or control. Accordingly, AC5 solutions and control were administered two times per week by intraperitoneal administration for eight weeks (16 doses). Animals were observed for signs of toxicity before and immediately post administration and daily throughout study duration of 90±2 days. At the end of the survival period, standard blood tests, macroscopic exams and target tissue histopathologic evaluations were conducted.

All animals appeared normal over the course of the study and survived to the scheduled end of the study. Clinical observations throughout the study, including weight, food consumption, blood tests, and other observations were comparable among animals receiving AC5 or control. Gross pathology and histopathology differences for AC5 were minimal and not clinically significant.

This test was conducted in compliance with the International Organization for Standardization (ISO) and in full accordance with the Food and Drug Administration's Good Laboratory Practice (GLP) regulations (21 CFR Part 58).

Arch Therapeutics President and CEO Terrence Norchi, MD, stated, "This is an important study in the battery of biocompatibility tests in animals needed to demonstrate the safety of AC5, because it supports that even with repeat dosing over two months, AC5 was well tolerated and not associated with clinical toxicity. The favorable results demonstrated in this study are consistent with the other safety studies conducted to date, and provide important new safety information pertaining to repeat, long-term exposure to AC5. We continue to be pleased with the data generated."

In July, Arch submitted a 510(k) to the U.S. FDA for AC5 Topical Gel, which is under active

review.

About Arch Therapeutics, Inc.

Arch Therapeutics, Inc. is a biotechnology company developing a novel approach to stop bleeding (hemostasis), control leaking (sealant) and manage wounds during surgery, trauma and interventional care. Arch is developing products based on an innovative self-assembling barrier technology platform with the goal of making care faster and safer for patients. Arch's development stage product candidates include the AC5™ Topical Gel and the AC5™ Surgical Hemostatic Device.

Notice Regarding Forward-Looking Statements

This news release contains "forward-looking statements" as that term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E 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 produce commercial quantities of our products within projected timeframes, 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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