

# **Arch Therapeutics Provides Skin Sensitization Study Status Update**

## Approximately two-thirds of applications in the repeat dosing induction phase are completed; Study remains on track

FRAMINGHAM, Mass., June 26, 2018 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of liquid, gel and solid hemostatic and wound care devices, provided an update today in which it announced that in the recently initiated skin sensitization study of AC5<sup>TM</sup> Topical Gel (AC5), two-thirds of the applications of AC5 in the repeat dosing induction phase have occurred and the study remains on schedule.

The sensitization study protocol was designed by Arch and its subject matter experts, and it incorporates recommendations provided by the Food and Drug Administration (FDA or "the Agency"). The study, designed as a single-center, prospective, clinical investigation, in approximately 50 healthy subjects, comprises an induction phase separated from a challenge phase by a rest period.

During the induction phase, AC5 on a patch is applied to each subject's back three times weekly over 21 days for a total of 9 applications. With each re-application, the skin beneath the patch is evaluated, and any findings are scored per protocol. After a 14-day rest period, subjects enter the challenge phase, receive one additional application of AC5, and after a two-day rest period, are evaluated over 48 hours. If significant positive reactions occur subjects may be re-challenged in order to provide further information.

The Company is pleased to report that two-thirds of the induction phase applications have been completed and the study remains on schedule to conclude in the third calendar quarter of 2018.

Terrence W. Norchi, MD, President and CEO of Arch, said, "While the study and report must be completed before we can draw conclusion, we remain optimistic about the outcome based on the results of the prior study for sensitization that was performed in animals. We are also pleased that the study remains on budget, and we now anticipate that our corporate cash runway has extended into the fourth calendar quarter of 2018."

The study is intended to support the Company's 510(k) notification for its AC5 Topical Gel, which is expected to be filed by the end of the third quarter of calendar 2018.

### **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.

Source: Arch Therapeutics, Inc.

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