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# Arch Therapeutics Reports AC5 Topical Hemostatic Device Meets Primary and Secondary Endpoints in First Clinical Study

## Clinical Safety and Performance of AC5 Successfully Demonstrated in Dermatology Procedure Performed on 46 Skin Lesion Patients With Bleeding Wounds

FRAMINGHAM, MA -- (Marketwired) -- 08/15/16 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of devices for use in controlling bleeding and fluid loss in order to provide faster and safer surgical and interventional care, successfully met the objectives of its recently completed single-center, randomized, single-blind prospective clinical study (NCT 02704104) of the AC5 Topical Hemostatic Device in skin lesion patients with bleeding wounds. This was the first study assessing the safety and performance of AC5 in humans.

The objectives of the study were to evaluate the safety and performance of AC5 in patients scheduled to undergo excision of skin lesions on their trunk or upper limbs. The primary endpoint was safety throughout the surgical procedure and until the end of a 30-day follow-up period post procedure. Safety of the clinical investigation device was determined by monitoring for treatment related adverse events. The primary objective was met, as the safety outcomes of both the AC5 treatment group and the control group were similar. No serious adverse events were reported.

A secondary endpoint was performance as assessed by time to hemostasis. The median time to hemostasis of wounds in the AC5 treatment group was 41% faster than for those in the control group. This result was statistically significant ( $p < 0.001$ , Wilcoxon signed rank test).

An additional secondary endpoint of healing of treated wounds was assessed as measured by the ASEPSIS wound score at Days 7 and 30. There was no evidence, at either follow-up day, of an adverse effect of AC5 treatment on the wound ASEPSIS score. The ASEPSIS score did not appear to be compromised, as the majority of patients had an ASEPSIS score of 0 in both wounds at Days 7 and 30. All AC5-treated wounds healed satisfactorily as per wound healing scoring criteria.

Terrence W. Norchi, MD, President and CEO of Arch Therapeutics, said, "As we had anticipated, these top-line data support that AC5 was safe and performed as expected in

the patients enrolled in this study throughout the completion of the patient assessments post-treatment and as supported in the subsequent statistical analysis. These successful results mark a significant milestone in the development of AC5 and we are grateful to all of those involved in the process. We look forward to further advancing our self-assembling peptide technology platform for this and other applications, including through conducting additional studies."

The clinical study enrolled 46 patients, including 10 who were taking antiplatelet monotherapy. Each patient had bleeding wounds created as a result of the excision of at least two skin lesions under local anesthetic in the same setting. On a randomized basis, one lesion received AC5 and the other(s) received a control treatment consisting of standard therapy plus a sham. Each subject was followed-up for safety assessment both on Day 7 and again on Day 30, which marked the end of the subject's participation in the clinical study.

Jack Kelly, MD, Principal Investigator of the study, and a plastic, reconstructive and aesthetic surgeon and Professor of Surgery at Galway University Hospital, Galway, Ireland, said, "These study results indicate significant potential for AC5 in the treatment of bleeding skin wounds. The safety and efficacy outcomes for AC5 in this study were impressive and reassuring. While possessing a safety profile at least as good as that of the control group, AC5 was associated with a clinically significant improvement in time to hemostasis. We are encouraged by how patients responded to the unique formulation of AC5 and how easy it was for a clinician to use."

Arch's clinical advisory committee has deemed the study results to be clinically significant and have recommended submitting a manuscript to a peer-reviewed medical journal for publication. The committee said, "In completing its first human study assessing the safety and performance of AC5, Arch has obtained impressive safety and efficacy data. We are incredibly enthusiastic about AC5 and its potential scope for other applications."

The advisors include Arthur Rosenthal, PhD, Professor of Practice, Emeritus, Department of Biomedical Engineering, Boston University, and a former member of Arch's Board of Directors; Steven Schwaitzberg, MD, Professor and Chairman of the Department of Surgery at the University of Buffalo's Jacobs School of Medicine and Biomedical Sciences and past President of the Society of American Gastrointestinal Endoscopic Surgeons; Paresh Shah, MD, Vice Chair of Surgery, Director of General Surgery and Professor of Surgery at New York University Langone Medical Center, New York University Langone School of Medicine; and William Denman, MD, anesthesiologist at Massachusetts General Hospital, past Chief Medical Officer of GE Healthcare and past Chief Medical Officer of Covidien.

The Company expects to submit further study details and data, including subgroup analysis, to a peer-reviewed journal for publication. The Company also plans to include data from this trial in a CE mark application for AC5, which is currently anticipated to be filed at the earliest by the end of this year. Arch is currently planning its next clinical-regulatory steps for both the EU and the US.

The study, conducted at University College Hospital, Galway, Ireland, was carried out in collaboration with CÚRAM, Science Foundation Ireland Centre for Research in Medical

Devices and the Clinical Research Facility based at National University of Ireland in Galway.

"These results demonstrate significant improvement in efficacy without compromising patient safety. We believe that AC5 represents a unique technology that will provide both rapid and sustained hemostasis and important differentiable clinical benefits," concluded Norchi.

### ***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 the AC5 Surgical Hemostatic Device™, is being designed to achieve hemostasis in surgical procedures.

### ***About HRB Clinical Research Facility, Galway, Ireland***

The HRB Clinical Research Facility, Galway (CRFG) is a joint venture between Galway University Hospitals (GUH), Saolta, and National University of Ireland, Galway (NUIG) and has been in operation since March 2008. The HRB-CRFG provides the infrastructure, physical space, facilities, expertise and culture needed to optimally support clinical research. It focuses on studies aimed at understanding a range of diseases and speedily translating the knowledge obtained through this research work into advances in patient care.

### ***About CÚRAM***

CÚRAM is the Science Foundation Ireland Centre for Research in Medical Devices, based at NUI Galway. Supported by Science Foundation Ireland (SFI) and industry partners, CÚRAM enhances Ireland's standing as a major hub for the global medical devices industry. Its goal is to radically improve quality of life for patients with chronic illness by developing the next generation of smart, implantable medical devices. CÚRAM's innovative approach incorporates biomaterials, drug delivery, cell based technologies, glycosciences and device design to enhance, develop and validate both traditional and new combinational medical devices, from molecular design stage to implant manufacturing. CÚRAM's devices are being developed with strong clinical collaborations to enable rapid translation of research findings to clinical application. Key to the approach is the establishment of unique networks of national and international collaborations, integrating world class clinical, academic and industrial partners

### ***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](http://www.sec.gov).

On Behalf of the Board,  
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