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# Arch Therapeutics Reports AC5 Topical Hemostatic Device Successfully Stopped Bleeding in Patients on Antiplatelet Therapy in Recently Completed Clinical Study

## Treatment Effect of AC5-Significantly Shortening of Time To Hemostasis vs Control- Was Consistent Whether Patients Were Taking Antiplatelet Therapy or Not

FRAMINGHAM, MA -- (Marketwired) -- 10/31/16 -- 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, reports additional positive data in its recently completed single-center, randomized, single-blind prospective clinical study (NCT 02704104) of the AC5 Topical Hemostatic Device™ ("AC5™") in skin lesion patients with bleeding wounds. On August 15, 2016, the Company reported top-line data from the clinical study that indicated that AC5 was safe and that it reduced time to hemostasis in wounds versus controls. Today, the Company released the results of additional analysis of the subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, which indicated that AC5 had similar effects for the subgroup of patients taking an antiplatelet agent.

In particular, in this newly reported analysis of the primary and secondary outcomes for wounds among patients treated with an antiplatelet agent, the primary objective of safety throughout the surgical procedure and until the end of a 30-day follow-up period post procedure was met and AC5 was well tolerated. Moreover, AC5 shortened time to hemostasis ("TTH") versus a control whether or not patients were taking antiplatelet therapy, suggesting that AC5 performance is not affected by antiplatelet therapy. The reduced median TTH of the AC5 treated wounds versus the control wounds was statistically significant for both the overall group of 46 patients ( $p < 0.001$ ) and for the subgroup of 10 patients on antiplatelet therapy ( $p = 0.005$ ). Further, the median TTH for wounds treated with AC5 was less than 30 seconds for both the overall study group and for the subset of patients taking antiplatelet therapy.

Terrence W. Norchi, MD, President and CEO of Arch Therapeutics, said, "We have eagerly awaited initial data to support the hypothesis that the mechanism of action of AC5 is independent of a patient's underlying bleeding or coagulation status. These results are an important first step in highlighting an important differentiating feature of AC5 and our self-assembling peptide technology platform."

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, "We have been impressed with how patients in this study responded to treatment and how easy AC5 was to use. The favorable safety and efficacy profile of AC5 in the overall study was supported when looking at the subset of patients taking antiplatelet therapy, which is particularly noteworthy. Many patients have perturbed hemostasis pathways, whether from natural disease or the use of prescribed or over the counter blood thinners, therefore we always have a concern about more bleeding in these patients. AC5 may provide their care providers a valuable tool to address those challenges."

As previously reported, this first study assessing the safety and performance of AC5 in humans served to evaluate the safety and performance of AC5 in patients scheduled to undergo excision of skin lesions on their trunk or upper limbs. Of the 46 patients enrolled in the human study, 10 patients were taking an antiplatelet agent and 36 were not. Each patient had two wounds, of which one was treated with AC5 and the other received standard care plus a sham treatment according to a randomization process. Consequently, each patient served as her/his own control.

The study's overall primary objective of safety throughout the surgical procedure and until the end of a 30-day follow-up period post procedure was met and AC5 was well tolerated. 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. The majority of patients had an ASEPSIS score of 0 in both wounds on both days, and all AC5-treated wounds healed satisfactorily as per wound healing scoring criteria.

Previously, Arch's clinical advisory committee deemed the study results to be clinically significant and have recommended submitting a manuscript to a peer-reviewed medical journal for publication. In light of this new data, the committee added, "This first human study assessing the safety and performance of AC5 has revealed an impressive and statistically significant result in patients on an antiplatelet agent, indicating that it may have broad potential scope in different 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 Schwaartzberg, 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 to a peer-reviewed journal for publication. The Company also plans to include data from this trial in its regulatory filings, including 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 HRB Clinical Research Facility based at National University of Ireland Galway.

### ***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,  
Terrence W. Norchi, MD  
Arch Therapeutics, Inc.

Source: Arch Therapeutics, Inc.