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Arch Therapeutics Receives Marketing Clearance from the US FDA Related to the AC5® Topical Gel Supply Chain

FRAMINGHAM, Mass., March 23, 2020 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of novel liquid, gel and solid hemostatic and wound care devices, today announced that the U.S. Food and Drug Administration (FDA) provided clearance to market AC5® Topical Gel that is manufactured using an additional supplier and additional manufacturing processes. AC5 Topical Gel is to be used in the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

To better harmonize US and European supply chains, Arch sought this marketing clearance from the FDA to use an additional supplier and manufacturing processes in the production of AC5® Topical Gel. Marketing clearances, such as this, require the provision of necessary documentation and data to the FDA, and they are essential milestones to the path to commercialization.

Chief Executive Officer, Terrence W. Norchi, MD, said, "This is an important step. While the review process took significantly longer than anticipated, we are pleased with the achievement, and we are awaiting comparable news from the Notified Body regarding a CE Mark."

As previously indicated, the Company was recently notified that the Notified Body review team has completed its review of Arch's technical documentation, provided the Company a draft of the CE certificate to review, and has recommended to its decision-making panel that CE Marking be granted.

Norchi added, "Despite the current pandemic that challenges us all, our staff has been enabled to work remotely, we are working with our supply chain to manage inventory, and we are assessing our roll-out strategy to consider the evolving needs of our key clinicians."

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 AC5® Topical Gel, AC5® Topical Hemostat¹ and AC5® Surgical Hemostat.¹

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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1. AC5[®] Topical Hemostat and AC5[®] Surgical Hemostat are currently investigational devices limited by law to investigational use.



Source: Arch Therapeutics, Inc.