

Citius Announces Results of Study that Mino-Lok Eradicates *S. aureus* Biofilm More Effectively and Expeditiously than Components

-- Mino-Lok superior to EDTA and Ethanol in eradicating most worrisome pathogen

-- Two strains of resistant *Staphylococcus aureus* tested

-- Study reinforces previous studies that all three components needed for some biofilm forming pathogens

CRANFORD, N.J., Nov. 30, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, today announced the completion of a Boston Analytical study "Silicone Disk Method for *In Vitro* Assessment of Antimicrobial Activity Against Resistant Staphylococcal Biofilms by Minocycline-EDTA-Ethanol and EDTA-Ethanol Lock Solutions." This study demonstrated that all three components of Mino-Lok (30 mg/mL EDTA, 19.5% ethanol and 1 mg/mL minocycline) were superior to EDTA/ethanol (30 mg/mL EDTA and 19.5% ethanol). There were two strains of *Staphylococcus aureus* used for the inocula and two samples of each strain were tested as four reference groups. The test solutions were examined following incubation for the following three time points: 60 minutes; 90 minutes; and 120 minutes. The Colony Forming Units (CFU)/Disk value was assessed from 10 disks at each time-point for each group. The results indicate that when the exposure time is 60 minutes, the number of CFU/Disk under the MLT group is significantly smaller than the number of CFU/Disk under the EDTA/ethanol group in one strain and very close to significance (p-value = 0.0598) in the second strain. For all exposure times, the number of CFU/Disk was always lower in the MLT treated disks compared to the EDTA/ethanol treated disks.

The researchers concluded that "... taken together, the results suggest that MLT can eradicate the biofilm quicker than EDTA/ethanol."

"*Staph aureus* is one of the most worrisome pathogens in catheter related bloodstream infections (CRBSI). This pathogen receives special consideration even in the IDSA guidelines for treating CRBSI. We are very pleased to show that Mino-Lok appears to be more effective, and work more expeditiously, than even ethanol," commented Myron Holubiak, Chief Executive Officer of Citius. "It has been demonstrated in earlier studies and reports that all three components of Mino-Lok are necessary to eradicate MRSA and *Candida parapsilosis*. More recently we showed that MLT was effective *in vitro* against 10

strains of *Candida Auris*. All of these pathogens are of great concern in cancer patients with central lines. As we approach the final stages of our pivotal trial, we are very excited to be able to report new findings about Mino-Lok. Our pivotal trial is designed to show the superiority of Mino-Lok to standard antibiotic locks in time-to-catheter-failure. If all these studies prove to be successful, we believe ready to use Mino-Lok will be superior to local pharmacy mixed antibiotic locks in both efficacy and dosing schedules."

Mino-Lok has the potential to change the standard of care, which currently calls for a procedure to remove and replace the infected catheter. Each year, up to 500,000 CVCs of the 7 million used become infected and lead to CLABSIs, increasing both patient morbidity risk and costs to the medical system. It has been shown that antibiotics alone are unable to penetrate the biofilm caused by bacteria, and there are currently no approved therapies for salvaging infected central venous catheters. According to DelveInsight, the market size of CLABSIs and closely associated catheter-related bloodstream infections (CRBSIs) in the global market is expected to reach \$1.84 billion in 2028, up from \$1.24 billion in 2017.

About Citius Pharmaceuticals, Inc.

Citius is a late-stage specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives and cancer care. For more information, please visit www.citiuspharma.com.

About Mino-Lok[®]

Mino-Lok[®] is an antibiotic lock solution being developed as an adjunctive therapy in patients with central line-associated bloodstream infections (CLABSIs) or catheter-related bloodstream infections (CRBSIs). There are currently no approved therapies for salvaging infected CVCs. Mino-Lok is used in combination with an appropriate systemic antibiotic(s) to preserve central venous access and to avoid the complications and morbidities associated with catheter removal and reinsertion. Mino-Lok is currently in a Phase 3 clinical trial.

Safe Harbor

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