

Citius Pharmaceuticals Presents Data on Mino-Lok® Showing 98% Clinical Efficacy

The Data Provides Proof of Salvaging Central Venous Catheters Colonized with Highly Virulent Pathogens in Patients with CLABSI/CRBSI

CRANFORD, N.J., April 30, 2019 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius") (Nasdaq: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, provided a report today on the clinical efficacy of Mino-Lok against various pathogens that are encountered in colonized catheters that cause bacteremia, either central line associated bloodstream infection ("CLABSI") or catheter related bloodstream infection ("CRBSI"). In a meta-analysis of two separate studies conducted in four institutions in four different countries (see table), it was shown that Mino-Lok was 98% effective (49/50) in salvaging catheters that caused bacteremia. These data included *Staph. aureus*, and a number of gram negative, highly virulent pathogens.

Mino-Lok Therapy (MLT): Analysis of CVC Salvage by Pathogen
(meta-analysis of four centers*)

Bacteria causing bacteremia	MDA MLT Treated ¹ (n)	Ex-U.S. MLT Treated ² (n)	All MLT Treated (n)	Catheters Salvaged (n/N) (%)
<i>Gram +</i>	16	10	26	26/26 (100%)
Coagulase negative staphylococci (CNS)	5	7	12	12
Streptococcus	5	1	6	6
Staphylococcus aureus ³	4	1	5	5
Enterococcus ⁴	2	1	3	3
<i>Gram -</i>	14	10	24	23/24 (96%)
<i>E. coli</i> ⁵	7	2	9	9
Pseudomonas	3	1	4	4
Klebsiella	1	4	5	5
Enterobacter	3	1	4	4
Burkholderia cepacia	0	1	1	0
Rhizobium radiobacter	0	1	1	1
Total subjects treated	30	20	50	49/50 (98%)

*30 patients treated at MD Anderson Cancer Center in U.S.; nine patients treated at American University of Beirut Medical Center in Beirut, Lebanon; nine patients treated at Hospital Israelita Albert Einstein in Sao Paulo, Brazil; and two patients treated at St. Luke's International Hospital in Tokyo, Japan.

1. Raad I, et al. Antimicrob Agents Chemother. 2016; 60(6): 3426-3432.
2. Hachem R, et al. Expert Rev Med Devices. 2018; 15(6):461-466.
3. One subject in the MDA study was also positive for *Corynebacterium*.
4. One subject in the MDA study was also positive for *Corynebacterium*.
5. One subject in the Ex-US study was also positive for *Streptococcus*.

Mr. Myron Holubiak, CEO of Citius, said, "The changing microbiology of catheter associated bacteremia in cancer patients is a very important development. Gram negative organisms and fungi such as *Candida* have increased substantially since the 1990s and present difficult treatment challenges. Furthermore, the low salvage rates with antibiotic locks for CLABSI/CRBSI caused by *S. aureus* are also a significant concern. The current evidence for antibiotic locks is mainly based on treatment for coagulase-negative staphylococci. IDSA guidelines do not support antibiotic locks for CLABSI/CRBSI with *S. aureus* or yeast, or resistant gram-negative pathogens. We have now demonstrated that Mino-Lok may be very effective clinically in salvaging catheters that have been colonized with a wide range of pathogens including the most virulent. While the clinical data for Mino-Lok are highly encouraging as they relate to these highly virulent pathogens, we recognize more work needs to be done. The company is currently studying Mino-Lok in a phase 3 trial in participating institutions, all located in the U.S."

Mino-Lok®

Mino-Lok is an antibiotic lock solution used to treat patients with CLABSIs/CRBSIs. CLABSIs/CRBSIs are very serious, especially in cancer patients receiving therapy through central venous catheters (CVCs), and in hemodialysis patients for whom venous access presents a challenge. There are currently no approved therapies to salvage infected central venous catheters (CVCs).

About Citius Pharmaceuticals, Inc.

Citius is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives, cancer care and unique prescription products that use innovative, patented or proprietary formulations of previously approved active pharmaceutical ingredients. We seek to achieve leading market positions by providing therapeutic products that address unmet medical needs. By using previously approved drugs with substantial safety and efficacy data, we seek to reduce the risks associated with pharmaceutical product development and regulatory requirements. Citius develops products that have intellectual property protection and competitive advantages to existing therapeutic approaches. For more information, please visit www.citiuspharma.com.

Safe Harbor

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements are made based on our expectations and beliefs concerning future events impacting Citius. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "expect," "should," and "may" and other words and terms of similar meaning or use of future dates. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price.

Factors that could cause actual results to differ materially from those currently anticipated are risks relating to the results of research and development activities, including that preclinical results may not be replicated in clinical trials; uncertainties relating to preclinical and clinical testing; patent and intellectual property matters; risks associated with conducting our phase 3 trial for Mino-Lok, including completing patient enrollment and opening study sites; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our growth strategy; the early stage of products under development; our ability to obtain, perform under, and maintain financing and strategic agreements and relationships; our ability to identify, acquire, close, and integrate product candidates and companies successfully and on a timely basis; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; our need for substantial additional funds; government regulation; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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