# CHARLOTTE'S WEB

PRESS RELEASE

# Charlotte's Web Announces DeFloria to enter Phase 2 FDA Clinical Trial for Autism Spectrum Disorder Treatment

**LOUISVILLE, Colo. – Feb 24, 2025** - (TSX: CWEB) (OTCQX: CWBHF) Charlotte's Web Holdings, Inc. ("**Charlotte's Web**" or the "**Company**"), a market leader in hemp extract wellness products, is pleased to announce that the U.S. Food and Drug Administration (FDA) has completed its review of Phase 1 data and Investigational New Drug (IND) application submitted by DeFloria, Inc. ("DeFloria"). The FDA has concluded that DeFloria may now proceed with its planned FDA Phase 2 clinical trial for its botanical pharmaceutical candidate, AJA001 Oral Solution, a treatment for symptoms of autism spectrum disorder (ASD).

"Progressing to Phase 2 of an IND study with the FDA marks an important milestone in the development of our proprietary hemp genetics as regulated medicine," said **Bill Morachnick, Chief Executive Officer of Charlotte's Web.** "By leveraging our deep expertise in hemp cultivation and proprietary formulations, we are reinforcing and extending our leadership in hemp wellness from the consumer sector into the regulated medical sector. A safe and effective botanical treatment for autism spectrum disorder would be a medical asset that could provide immense value to millions of families and Charlotte's Web."

DeFloria is a collaboration including Charlotte's Web and Ajna BioSciences PBC, a botanical drug development company, to develop AJA001 as a treatment for irritability associated with autism spectrum disorder. AJA001 employs Charlotte's Web proprietary full-spectrum cannabidiol (CBD) hemp extract derived from one of its patented cultivars. Drawing on a decade of research, innovation, and rigorous cultivation methods from Charlotte's Web, DeFloria is developing AJA001 with the Company's proprietary hemp genetics as the foundation of the botanical drug.

"Advancing AJA001 to Phase 2 is a landmark moment for botanical drug development," stated **Dr. Marcel Bonn-Miller, Chief Scientific Officer at Charlotte's Web and DeFloria Board Member.** "Charlotte's Web has aimed to meet the needs of those underserved by current therapies for the past decade. AJA001's journey through the FDA's botanical drug pathway showcases the wide therapeutical potential of hemp. We feel this research strongly supports cannabinoids as a viable therapy for irritability associated with autism spectrum disorder, which currently lacks adequate treatment options. DeFloria is at the cutting edge with AJA001, and we are eager for DeFloria to begin Phase 2 of development."

DeFloria's planned Phase 2 clinical trial will evaluate the safety, tolerability, and effectiveness of AJA001 among adolescents and adults with ASD, building on the promising results from Phase 1. Data from Phase 2 studies will be used to inform the design of larger Phase 3 clinical trials, the results from which will be submitted to FDA for drug approval.

For more information see today's announcement from DeFloria: <a href="https://www.prnewswire.com/news-releases/defloria-receives-investigational-new-drug-application-clearance-from-fda-for-phase-2-clinical-trial-of-aja001-an-oral-cannabinoid-drug-being-developed-for-the-treatment-of-autism-spectrum-disorder-asd-302382573.html">https://www.prnewswire.com/news-releases/defloria-receives-investigational-new-drug-application-clearance-from-fda-for-phase-2-clinical-trial-of-aja001-an-oral-cannabinoid-drug-being-developed-for-the-treatment-of-autism-spectrum-disorder-asd-302382573.html</a>

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# About Charlotte's Web Holdings, Inc.

Charlotte's Web Holdings, Inc., a Certified B Corporation headquartered in Louisville, Colorado, is the market leader in innovative hemp extract wellness products that include Charlotte's Web whole-plant full-spectrum CBD extracts as well as broad-spectrum CBD certified NSF for Sport®. Charlotte's Web branded premium quality products start with proprietary hemp genetics that are North American farm-grown using organic and regenerative cultivation practices. The Company's hemp extracts have naturally occurring botanical compounds including cannabidiol ("CBD"), CBN, CBC, CBG, terpenes, flavonoids, and other beneficial compounds. Charlotte's Web product categories include CBD oil tinctures (liquid products), CBD gummies (sleep, calming, exercise recovery, immunity), CBN gummies, functional mushroom gummies, CBD capsules, CBD topical creams, and lotions, as well as CBD pet products for dogs. Through its substantially vertically integrated business model, Charlotte's Web maintains stringent control over product quality and consistency with analytic testing from soil to shelf for quality assurance. Charlotte's Web products are distributed to retailers and healthcare practitioners throughout the U.S.A. and online through the Company's website at <a href="http://www.charlottesweb.com">http://www.charlottesweb.com</a>.

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#### **Forward-Looking Information**

Certain information provided herein constitutes forward-looking statements or information (collectively, "forward-looking statements") within the meaning of applicable securities laws. Forward-looking statements are typically identified by words such as "may", "will", "should", "could", "anticipate", "expect", "project", "estimate", "forecast", "plan", "intend", "target", "believe" and similar words suggesting future outcomes or statements regarding an outlook. Forward-looking statements are not guarantees of future performance and readers are cautioned against placing undue reliance on forward-looking statements. This press release includes forward-looking statements including: the future performance or achievements of DeFloria, Inc., future dose trial results, therapeutic efficacy, or approvals of AJA001 Oral Solution the results of which may be materially different from those expressed or implied by the forward-looking statements contained in this press release.

By their nature, these statements involve a variety of assumptions, known and unknown risks and uncertainties, and other factors which may cause actual results, levels of activity, and achievements to differ materially from those expressed or implied by such statements. The forward-looking statements contained in this press release are based on certain assumptions and analysis by management of the Company in light of its experience and perception of historical trends, current conditions and expected future development and other factors that it believes are appropriate and reasonable.

The material factors and assumptions used to develop other forward-looking information herein include factors discussed throughout the "Risk Factors" section of the Company's most recently filed annual information form available on www.SEDARplus.ca and in the Company's most recently filed Annual Report on Form 10-K and quarterly report on Form 10-Q as amended, and other filings with the Securities and Exchange Commission available on www.SEC.gov. Except as required by applicable securities laws, the Company undertakes no obligation to publicly update any forward-looking information, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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