



## Alkermes Announces Settlement With Teva Related to VIVITROL® Patent Litigation

August 30, 2023

—Company Grants Teva a License to Market Generic VIVITROL Beginning in January 2027 —

DUBLIN, Aug. 30, 2023 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) announced today that the company entered into a settlement agreement with Teva Pharmaceuticals USA, Inc. ("Teva") to resolve the ongoing patent litigation between the parties in the U.S. District Court for the District of New Jersey related to VIVITROL® (naltrexone for extended-release injectable suspension). Pursuant to the terms of the settlement agreement, the company has granted Teva a license under U.S. Patent No. 7,919,499 to market a generic version of VIVITROL in the United States beginning January 15, 2027, or earlier under certain customary circumstances.

Additional details regarding the settlement agreement were not disclosed. The company and Teva will submit the settlement agreement for review to the United States Federal Trade Commission and the United States Department of Justice.

This patent litigation was initiated by the company in September 2020 in response to Teva's abbreviated new drug application seeking United States Food and Drug Administration approval of a generic version of VIVITROL in the United States prior to the expiration of Alkermes' U.S. Patent No. 7,919,499, an Orange Book-listed patent for VIVITROL that expires in 2029. The parties completed a trial in March 2023. In connection with the settlement, the company and Teva will file a proposed Stipulated Consent Judgment and Injunction with the U.S. District Court for the District of New Jersey requesting that the Court dismiss the pending litigation between the parties.

### **About Alkermes plc**

Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurological disorders and cancer. Headquartered in Dublin, Ireland, Alkermes plc has a research and development center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at [www.alkermes.com](http://www.alkermes.com).

### **Note Regarding Forward-Looking Statements**

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the terms of the settlement agreement with Teva, expectations regarding the impact of the settlement agreement and submission of the settlement agreement for review to the United States Federal Trade Commission and the United States Department of Justice. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties, including the unfavorable outcome of other litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to VIVITROL, which may lead to competition from generic drug manufacturers; the outcome of any review of the settlement agreement by the United States Federal Trade Commission and United States Department of Justice; and those risks and uncertainties described under the heading "Risk Factors" in the company's most recent Annual Report on Form 10-K and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

VIVITROL® is a registered trademark of Alkermes, Inc.

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