

Alkermes Announces Settlement With Amneal Over VIVITROL® Patent Dispute

July 29, 2019

-- Patent Trial and Appeal Board Oral Hearing Cancelled --

DUBLIN, July 29, 2019 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) announced today that it has entered into a settlement and license agreement (the agreement) with Amneal Pharmaceuticals LLC (Amneal) to resolve Amneal's inter partes review (IPR) petition challenging U.S. Patent Number 7,919,499 ('499 Patent), an Orange Book-listed patent for VIVITROL® (naltrexone for extended-release injectable suspension) that expires in 2029.

Under the agreement, the parties agreed to request termination of the IPR and Alkermes granted Amneal the non-exclusive right to market a generic formulation of VIVITROL in the U.S. beginning sometime in 2028 or earlier under certain circumstances. Additional terms of the agreement are confidential.

"We believe this settlement recognizes the strength of the VIVITROL intellectual property. We are pleased to come to this resolution which provides more clarity regarding the outlook for VIVITROL," said Richard Pops, Chief Executive Officer of Alkermes. "VIVITROL is a complex medicine that requires sophisticated manufacturing expertise and capabilities, along with nuanced commercial capabilities to successfully navigate a fragmented treatment system."

An oral hearing with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office, that was scheduled to take place on July 29, 2019, was cancelled by the PTAB in light of this settlement.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction, multiple sclerosis and cancer. Headquartered in Dublin, Ireland, Alkermes plc has an R&D 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.

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 company's future performance, business plans or prospects, and expected growth; the strength of the intellectual property, including the '499 Patent, covering VIVITROL; the clarity in the outlook for VIVITROL provided by the settlement with Amneal; and the potential therapeutic and commercial value of VIVITROL. 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 litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to VIVITROL, which may lead to competition from generic drug manufacturers; 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. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. The information contained in this press release is provided by the company as of the date hereof, and, 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.

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