



## **Praxis Precision Medicines Provides Regulatory Update On PRAX-114 Program**

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CAMBRIDGE, Mass., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Praxis Precision Medicines, Inc. (NASDAQ: PRAX), a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system disorders characterized by neuronal imbalance, today announced that it has received a response from the U.S. Food and Drug Administration (FDA) on the Investigational New Drug (IND) submission for PRAX-114 for the treatment of major depressive disorder (MDD).

In October 2020, Praxis submitted the IND for PRAX-114 in connection with the initiation of its randomized, placebo-controlled Phase 2/3 clinical trial for PRAX-114 in MDD, as previously discussed with the FDA at a pre-IND meeting earlier this year. At the end of the 30-day IND review period, the FDA notified the Company that the IND has been placed on full clinical hold. The FDA has not provided any reason for the clinical hold. The Company has subsequently been in communication with the FDA, which advised that comments have not been finalized. The Company expects to receive final comments from the FDA within 30 days and intends to work closely with the agency to understand and resolve key issues.

### **About Praxis**

Praxis Precision Medicines is a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system disorders characterized by neuronal imbalance.

### **Cautionary Statement Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the Company's expectations regarding the timing in which it will receive additional communications regarding the clinical hold on its IND submission for PRAX-114 from the FDA. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: ; the timing and outcome of the Company's planned interactions with regulatory authorities; the timing and anticipated results of our current preclinical studies and future clinical trials, strategy and future operations; the impact of COVID-19 on countries or regions in which we have operations or do business; the delay of any current preclinical studies or future clinical trials or the development of Praxis' drug candidates; the risk that the results of current preclinical studies may not be predictive of future results in connection with future clinical trials; Praxis' ability to successfully demonstrate the safety and efficacy of its drug candidates; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Praxis' final prospectus related to its initial public offering, dated October 20, 2020, as well as discussions of potential risks, uncertainties, and other important factors in Praxis' subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Praxis' views only as of today and should not be relied upon as representing its views as of any subsequent date. Praxis explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

### **Investor Contact:**

Alex Kane [investors@praxismedicines.com](mailto:investors@praxismedicines.com)  
617-300-8481



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