



Praxis Precision Medicines Provides Update On PRAX-114 IND Submission For The Treatment Of Major Depressive Disorder

November 17, 2020

- Praxis expects to initiate Phase 2/3 clinical trial for PRAX-114 in MDD in 1H21 -

CAMBRIDGE, Mass., Nov. 17, 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 comments from the U.S. Food and Drug Administration (FDA) on the full clinical hold of its Investigational New Drug (IND) submission for PRAX-114 for the treatment of major depressive disorder (MDD).

The IND for PRAX-114 was placed on clinical hold by the FDA pending the resolution of certain non-clinical pharmacology and toxicology matters. In its comment letter, the FDA proposed that the Company conduct further toxicological investigation of the effect of PRAX-114 and its metabolites on fertility, reproduction, and embryofetal development to support the planned trial. The Company believes that the results of its ongoing standard fertility and reproductive studies, expected to be completed in the first quarter of 2021, together with the available toxicology package will satisfy the FDA request. The FDA also requested updates to the Investigator's Brochure and to the requirements for contraception in the protocol.

The Company now expects to initiate the randomized, placebo-controlled Phase 2/3 clinical trial for PRAX-114 in MDD in the first half of 2021. The Company is in dialogue with the FDA and intends to explore potential options to accelerate the initiation of the Phase 2/3 clinical trial.

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. Praxis is applying insights into the genetic mutations that drive excitation-inhibition imbalance in diseases to select biological targets for severe pediatric epilepsies and more broadly for prevalent psychiatric diseases and neurologic disorders. Praxis has established a broad portfolio, including five disclosed programs across multiple central nervous system disorders including, depression, epilepsy, movement disorders and pain syndromes, with three clinical-stage product candidates.

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, including resolution of the current PRAX-114 clinical hold; 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.

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