Pardes Biosciences Announces FDA Clearance of IND Application for PBI-0451, an Oral Antiviral Drug Candidate for the Treatment and Prevention of SARS-CoV-2 Infections

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CARLSBAD, Calif., Feb. 03, 2022 (GLOBE NEWSWIRE) -- Pardes Biosciences, Inc. (NASDAQ: PRDS), a clinical-stage biopharmaceutical company developing PBI-0451 as a potential novel direct-acting, oral antiviral drug candidate for the treatment and prevention of SARS-CoV-2 infections and associated diseases (i.e., COVID-19), today announced that its Investigational New Drug (IND) application for PBI-0451 has been cleared by the United States Food and Drug Administration (FDA).

“As we enter our third year of a global pandemic, we believe the value of oral direct-acting antivirals for SARS-CoV-2 has become increasingly clear, especially if they can be given as standalone therapies,” said Uri A. Lopatin, M.D., Chief Executive Officer. “The clearance of our IND for PBI-0451 enables us to proceed with the initiation of additional Phase 1 clinical trials for PBI-0451 in the U.S. Pending additional engagement with FDA and other regulators, we anticipate initiating our global Phase 2/3 studies of PBI-0451 in SARS-CoV-2 infected patients in mid-2022.”

PB-0451 is currently under evaluation in a Phase 1 placebo-controlled, blinded, randomized, dose escalation study in healthy volunteers in New Zealand evaluating the safety, tolerability, and pharmacokinetics of PBI-0451 after single and multiple ascending doses. Pardes anticipates reporting data from this ongoing study at a scientific conference later this quarter.

About Pardes Biosciences, Inc.

Pardes Biosciences is a clinical-stage biopharmaceutical company created to help solve pandemic-sized problems, starting with COVID-19. We are applying modern reversible-covalent chemistry as a starting point to discover and develop novel oral drug candidates, including our lead product candidate PBI-0451, while reimagining the patient journey to access these medicines. For more information, please visit www.pardesbio.com.

About PBI-0451
PBI-0451 is an investigational orally bioavailable direct-acting antiviral (DAA) inhibitor of the main protease (Mpro), an essential protein required for the replication of coronaviruses, including the novel SARS-CoV-2 that causes COVID-19. This protease is highly similar across all coronaviruses, including known and emerging coronavirus variants. PBI-0451 is being developed for the treatment and prevention of SARS-CoV-2 infection and associated diseases. PBI-0451 is currently in a Phase 1 placebo-controlled, blinded, randomized, dose escalation study in healthy volunteers in New Zealand evaluating the safety, tolerability, and pharmacokinetics of PBI-0451 after single and multiple ascending doses. For more information, please visit www.pardesbio.com.

Availability of Other Information about Pardes Biosciences

Pardes intends to use the Investors page of its website (https://ir.pardesbio.com) as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD (Fair Disclosure). Accordingly, investors should monitor Pardes’ Investors website, in addition to following Pardes’ press releases, Securities and Exchange Commission filings, public conference calls, presentations and webcasts.

Forward-Looking Statements

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results or events to materially differ. In some cases, you can identify forward-looking statements by the use of words, such as “anticipates,” “potential” or “will” or the negative of these terms or other comparable terminology. Forward-looking statements in this press release include, but are not limited to, statements regarding the advancement of our product candidate, PBI-0451, the timing of reporting clinical data, and statements about the potential attributes and benefits of Pardes’ product candidate and the role of oral antivirals in addressing the pandemic and future pandemics. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, development of competing therapeutic treatments for COVID-19 on Pardes’ business, results of nonclinical and early clinical studies may not be representative or predictive of the outcomes of on-going or future clinical studies and/or other risks and uncertainties, including those included under the header “Risk Factors” in the final registration statement/prospectus filed with the SEC for our recently completed business combination and any subsequent filings with the SEC. Most of these factors are outside of Pardes’ control and are difficult to predict. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. The forward-looking statements in this press release represent our views as of the date of this press release. Except as required by law, Pardes assumes no obligation to update publicly any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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