Pardes Biosciences Announces Commencement of Phase 2 Trial Evaluating PBI-0451 for the Treatment of SARS-CoV-2 Infections

September 13, 2022

Phase 2 trial expected to enroll 210 patients at approximately 75 sites to evaluate antiviral activity, safety, and efficacy of PBI-0451 versus placebo

Interim data from Phase 2 anticipated in Q1 2023

CARLSBAD, Calif., Sept. 13, 2022 (GLOBE NEWSWIRE) -- Pardes Biosciences, Inc. (Nasdaq: PRDS), a clinical-stage biopharmaceutical company developing PBI-0451 as a potential stand-alone, 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 reported commencement of a Phase 2 double-blind, randomized study to evaluate the antiviral activity, safety, and efficacy of orally administered PBI-0451 compared with placebo in non-hospitalized symptomatic adults with COVID-19 who are not at increased risk of progressing to severe illness.

Pardes Biosciences expects to enroll 210 patients in the Phase 2 clinical trial at approximately 75 sites within the United States. Study eligibility will include symptoms of COVID-19 for 5 or less days and a positive test for SARS-CoV-2 infection. Use of concomitant medications for underlying health conditions will not be restricted in the clinical trial. Participants will be administered PBI-0451 orally with food, twice daily, at a 700 mg (2x 350 mg tablets) dose or placebo over five days. The primary objective will be to determine the proportion of patients below the limit of detection in nasal swab samples for infectious SARS-CoV-2 on day three. Secondary objectives will include assessments of safety and tolerability, time to sustained clinical recovery through day 28 defined as key COVID-19 symptoms, and hospitalizations and deaths.

“Initiation of our PBI-0451 Phase 2 study marks a significant step towards our goal of bringing a self-administered, oral, well-tolerated and easy-to-use COVID-19 treatment option to a broad patient population due to a unique, favorable drug-drug interaction profile,” said Tom Wiggans, Chief Executive Officer and Chair of Pardes Biosciences. “PBI-0451 has the potential to be a stand-alone SARS-CoV-2 protease inhibitor that can be easily prescribed and administered to alleviate the burden of COVID-19 to patients and healthcare systems. We look forward to evaluating PBI-0451 in this broad patient population and sharing preliminary results in the first quarter of 2023.”

In a Phase 1 clinical trial, PBI-0451 at single and multiple doses demonstrated favorable tolerability without any study drug discontinuations and there were no treatment emergent drug-related adverse events assessed as greater than mild in severity. Additionally, no direct drug-related adverse findings were observed in 14-day or 28-day toxicology studies conducted across multiple preclinical species. PBI-0451 does not require ritonavir boosting and has the potential to be used broadly due to a favorable drug-drug interaction profile.

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 dedicated to discovering and developing potent and easy-to-prescribe oral antiviral drug candidates so that patients everywhere can get well sooner. For more information, please visit www.pardesbio.com.

About PBI-0451
PBI-0451 is a potential stand-alone, novel, direct-acting oral antiviral drug candidate for the treatment and prevention of SARS-CoV-2 infections in Phase 2 clinical development. PBI-0451 was developed to inhibit the main cysteine protease (Mpro) of all known coronaviruses, including SARS-CoV-2. Inhibiting Mpro prevents the liberation and assembly of the viral replication complex, blocking replication before it begins. The potent antiviral activity observed across SARS-CoV-2 variants in preclinical in vitro studies as well as the favorable safety and tolerability data from Pardes Biosciences’ first-in-human Phase 1 clinical trial (Study PBI-0451-0001, NCT 05011812) support continued clinical development of PBI-0451, which it believes has the potential to be a safe, effective and easy-to-prescribe oral antiviral for preventing and treating SARS-CoV-2 infections, including patients unable or unwilling to take currently authorized or approved therapies.

Availability of Other Information about Pardes Biosciences
Pardes Biosciences 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. Accordingly, investors should monitor Pardes Biosciences’ Investors website, in addition to following Pardes Biosciences’ press releases, Securities and Exchange Commission (SEC) filings, public conference calls, presentations and webcasts.

Forward Looking Statement
This press release contains statements that relate to future events and expectations and, as such, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When or if used in this press release, the words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “outlook,” “plan,” “possible,” “predict,” “should,” “will,” and similar expressions and their variants, as they relate to Pardes Biosciences (Pardes), may identify forward-looking statements. All statements that reflect Pardes’ expectations, assumptions or projections about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, statements regarding Pardes’ future financial or business performance, conditions, plans, prospects, trends or strategies and other financial and business matters, including statements regarding PBI-0451’s potential as a safe, well-tolerated, easy to use and easy to prescribe SARs-CoV-2 oral antiviral treatment for all patients; the planned conduct of the Phase 2 clinical trial for PBI-0451; and the expected timing of reporting preliminary data from the Phase 2 clinical trial for PBI-0451. Forward-looking statements reflect Pardes’ current beliefs, expectations, and assumptions regarding the future of its business, its future plans and strategies, its development plans, its preclinical and clinical results, future conditions and other factors Pardes believes are appropriate in the circumstances. Although Pardes believes the expectations and assumptions reflected in such forward-looking statements are reasonable, Pardes can give no assurance that they will prove to be correct. Forward-looking statements are not guarantees of future performance

and are subject to risks, uncertainties and changes in circumstances that are difficult to predict, which could cause Pardes' actual activities and results to differ materially from those expressed in any forward-looking statement. Such risks and uncertainties include, but are not limited to: (i) risks and uncertainties related to Pardes' ability to advance, obtain regulatory approval of and ultimately commercialize its product candidates; (ii) the timing and results of clinical trials; (iii) Pardes' ability to maintain financial resources necessary to continue its clinical trials, fund development goals and fund business operations; (iv) the impact of the COVID-19 pandemic on Pardes' business, clinical trials, financial condition, liquidity and results of operations; (v) Pardes' ability to protect its intellectual property; and (vi) other risks and uncertainties described under the heading "Risk Factors" in Pardes' Annual Report on Form 10-K for the year ended December 31, 2021, Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, and other SEC filings. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. The statements in this press release speak only as of the date of this press release, even if subsequently made available by Pardes on its website or otherwise. Pardes disclaims any intention or obligation to update publicly any forward-looking statements, whether in response to new information, future events, or otherwise, except as required by applicable law.

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