Scholar Rock to Present Biomarker Strategy for SRK-181 at the TGFβ for Immuno-Oncology Drug Development Summit

January 25, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 25, 2022-- Scholar Rock (NASDAQ: SRRK), a clinical-stage biopharmaceutical company focused on the treatment of serious diseases in which protein growth factors play a fundamental role, today announced a presentation at the 2nd Annual TGFβ for Immuno-Oncology Drug Development Summit (January 25-27, 2022).

"Development of a Comprehensive Biomarker Strategy to Support DRAGON, a Phase 1 Clinical Trial of SRK-181, the latent TGFβ1 Inhibitor" will be presented on January 27th, 2022, at 11:00 AM EST. The presentation, led by Si Tuen Lee-Hoeflich, Director, Translational Sciences at Scholar Rock, will discuss the SRK-181 biomarker strategy in relation to the DRAGON Phase 1 proof-of-concept trial (NCT04291079). The goal of the trial is to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and efficacy of SRK-181 administered alone and in combination with an anti-PD-(L)-1 in adult patients with locally advanced or metastatic solid tumors. The biomarker strategy will focus on the evaluation of biomarkers relevant to the mechanism of action of SRK-181 to facilitate the clinical development of Scholar Rock's immuno-oncology (IO) program and to identify the next wave of IO biomarkers that correlate with anti-tumor response.

"We are excited to be presenting at the TGFβ for Immuno-Oncology Drug Development Summit on our biomarker strategy for SRK-181 in support of DRAGON," said Gregory Carven, Ph.D., Chief Scientific Officer. "Our biomarker efforts play an important role in advancing our understanding of the mechanisms of action of selective inhibition of TGFβ1 and for facilitating the development of SRK-181, which we hope will positively impact the lives of those affected by cancers that are resistant to checkpoint blockade."

Initial Part A data from the ongoing DRAGON trial in patients with locally advanced or metastatic solid tumors were presented by Scholar Rock at the 36th Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2021, supporting dose selection and advancement into Part B. Part B will assess SRK-181 in combination with an approved anti-PD-(L)1 therapy across multiple solid tumor cohorts to test proof of concept. To learn more about DRAGON, visit clinicaltrials.gov.

For Summit information, visit: www.tgf-beta-summit.com

About SRK-181

SRK-181 is a selective inhibitor of TGFβ1 activation and is an investigational product candidate being developed to overcome primary resistance to checkpoint inhibitor therapy, such as anti-PD-(L)1 antibodies. TGFβ1 is the predominant TGFβ isoform expressed in many human tumor types. Based on analyses of various human tumors that are resistant to anti-PD-(L)1 therapy, data suggest TGFβ1 is a key contributor to the immunosuppressive tumor microenvironment, excluding and preventing entry of cytotoxic T cells into the tumor, thereby inhibiting anti-tumor immunity (1). Scholar Rock believes SRK-181, which specifically targets the latent TGFβ1 isoform, has the potential to overcome this immune cell exclusion and induce tumor regression when administered in combination with anti-PD-(L)1 therapy while potentially avoiding toxicities associated with non-selective TGFβ inhibition. The DRAGON Phase 1 proof-of-concept clinical trial (NCT04291079) in patients with locally advanced or metastatic solid tumors is ongoing. The efficacy and safety of SRK-181 have not been established. SRK-181 has not been approved for any use by the FDA nor any other regulatory agency.

(1) Martin et al., Sci. Transl. Med. 12: 25 March 2020

About Scholar Rock

Scholar Rock is a clinical-stage biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. Scholar Rock is creating a pipeline of novel product candidates with the potential to transform the lives of patients suffering from a wide range of serious diseases, including neuromuscular disorders, cancer, and fibrosis. Scholar Rock's approach to targeting the molecular mechanisms of growth factor activation enabled it to develop a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target these signaling proteins at the cellular level. By developing product candidates that act in the disease microenvironment, the Company intends to avoid the historical challenges associated with inhibiting growth factors for therapeutic effect. Scholar Rock believes its focus on biologically validated growth factors may facilitate a more efficient development path. For more information, please visit www.ScholarRock.com or follow Scholar Rock on Twitter (@ScholarRock) and LinkedIn (https://www.linkedin.com/company/scholar-rock/).

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Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Scholar Rock's future expectations, plans and prospects, including without limitation, Scholar Rock's expectations regarding its growth, strategy, progress and timing of its clinical trials for SRK-181, and other product candidates and indication selection and development timing, the ability of our biomarker approaches to identify disease or anti-tumor response, the ability of any product candidate to perform in humans in a manner consistent with earlier nonclinical, preclinical or clinical trial data, and the potential of its product candidates and proprietary platform. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify such forward-looking statements. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include preclinical and clinical data, including the results from Part A of the Phase 1 trial of SRK-181, are not predictive of, may be inconsistent with, or more favorable than, data generated from future clinical trials of the same product candidate, including, without limitation, Part B of the Phase 1 trial of SRK-181, Scholar Rock's ability to provide the financial support, resources and expertise necessary to identify and develop product candidates on the expected timeline, the data generated from Scholar Rock's nonclinical and preclinical studies and clinical trials, information provided or decisions made by regulatory authorities, competition from third parties that are developing products for similar uses, Scholar Rock's ability to obtain, maintain and protect its intellectual property, Scholar Rock's dependence on third parties for development and manufacture of product candidates including, without limitation, to supply any clinical trials, Scholar Rock's ability to manage expenses and to obtain additional funding when needed to support its business activities and establish and maintain strategic business alliances and new business initiatives, and the impacts of public health pandemics such as COVID-19 on business operations and expectations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Scholar Rock's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, as well as discussions of potential risks, uncertainties, and other important factors in Scholar Rock's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements represent Scholar Rock's views only as of today and should not be relied upon as representing its views as of any subsequent date. All information in this press release is as of the date of the release, and Scholar Rock undertakes no duty to update this information unless required by law.

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