Scholar Rock to Present at Upcoming ACCP Annual Meeting and World CB & CDx Summit

September 16, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 16, 2022-- Scholar Rock (NASDAQ: SRRK), a Phase 3, clinical-stage biopharmaceutical company focused on the treatment of serious diseases in which protein growth factors play a fundamental role, today announced two upcoming presentations, – one at the American College of Clinical Pharmacology Annual Meeting being held September 25-27 in Bethesda, Maryland, and another at the 12th Annual World Clinical Biomarkers & CDx Summit being held September 26-29 in Boston, Massachusetts.

The presentations will provide insight into SRK-181, a selective inhibitor of latent TGFβ1 activation being developed with the aim of overcoming primary resistance to checkpoint therapy in advanced cancer patients. Combination therapy with selective TGFβ1 blockade may modulate the tumor microenvironment, allowing for immune cell infiltration and potential improvements in the response rate and survival time of cancer patients.

Specifically, the ACCP presentation will include new pharmacokinetic data from the Phase 1 dose escalation study (DRAGON Part A). The presentation at the World Clinical Biomarkers & CDx Summit includes a discussion of pre-clinical validation studies to assess biomarker utility, overcoming challenges and hurdles that create barriers to assay translatability to the clinic, and early clinical biomarker data including image-based analysis.

Details of the presentations are as follows:

ACCP Annual Meeting:

Title: Preliminary Population Pharmacokinetic Modeling of SRK-181 from Phase 1 Dose Escalation Study
Presentation Type: Poster 015
Presenter: Amanda Hoerres, PharmD, independent consultant for Scholar Rock and Senior Scientist II, Clinical Pharmacologist, Vanadro Consulting
Date/Time: September 25, 5-7 p.m. ET

12th Annual World Clinical Biomarkers & CDx Summit:

Title: Development of a Comprehensive Biomarker Strategy for the Latent TGFβ1 Inhibitor SRK-181 Phase 1 Clinical Trial, DRAGON
Presentation Type: Oral
Presenter: Si Tuen Lee-Hoeflich, Senior Director, Translational Sciences at Scholar Rock
Date/Time: September 28, 3:25 p.m. ET

The presentations will be made available in the Publications & Posters section of Scholar Rock's website following the conferences.

For conference information, visit https://accp1.org/ and https://world-cdx.com/

About SRK-181

SRK-181 is a selective inhibitor of TGFβ1 activation 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. SRK-181 is an investigational product candidate and its efficacy and safety 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/). Investors and others should note that we communicate with our investors and the public using our company website www.scholarrock.com, including, but not limited to, company disclosures, investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference call transcripts, and webcast transcripts, as well as on Twitter and LinkedIn. The information that we post on our website or on Twitter or LinkedIn could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website or social media shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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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, and progress and indication selection and development timing, 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," "could," "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, without limitation, 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, and Scholar Rock's ability to manage expenses and to obtain additional funding when needed to support its business activities, 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 March 31, 2022, 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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