Scholar Rock to Present Clinical and Biomarker Data from the Phase 1 DRAGON Trial at the SITC 38th Annual Meeting

October 19, 2023

- Poster presentations to include safety, efficacy, and biomarker data from Part A and B of the DRAGON trial in patients with advanced solid tumors treated with SRK-181

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 19, 2023-- 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, announced today that it will present data from DRAGON, a Phase 1 study of SRK-181 in patients with advanced solid tumors at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting in San Diego on November 1-5. In one poster presentation, Scholar Rock will share preliminary biomarker data from Part B of the trial, and in a second poster presentation, provide safety, efficacy, and biomarker results of SRK-181 in anti-PD-1 resistant metastatic clear cell renal cell carcinoma (ccRCC) patients from both Parts A and B.

“We are excited to present clinical and biomarker updates on the DRAGON study, which build upon the safety and efficacy data to date in the ccRCC cohort of the trial and support our goal of establishing the proof of mechanism of SRK-181,” said Jay Backstrom, M.D., MPH, President and Chief Executive Officer of Scholar Rock. “As a selective latent TGFβ1 inhibitor, SRK-181 has the potential to transform cancer immunotherapy by helping to overcome resistance to checkpoint inhibitor therapy. This investigational medicine demonstrates the promise of Scholar Rock’s unique discovery platform.”

Details of the presentations are as follows:

Title: Establishing Proof of Mechanism in Patients: Preliminary Biomarker Data of SRK-181 (a latent TGFβ1 inhibitor) from DRAGON Study
Presentation Type: Poster 726
Presenter: Susan Henry, PhD, Senior Director, Translational Sciences, Scholar Rock, Inc.
Location: Exhibit Halls A and B1, San Diego Convention Center
Date/Time: November 4, 11:55 AM – 1:25 PM PDT and 7 – 8:30 PM PDT

Title: Safety, efficacy, and biomarker results of SRK-181, a latent TGFβ1 inhibitor, in anti-PD-1 resistant metastatic ccRCC patients
Presentation Type: Poster 666
Presenter: Timothy Yap, MBBS, PhD, FRCP, Medical Oncologist and Physician-Scientist; and Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas MD Anderson Cancer Center
Location: Exhibit Halls A and B1, San Diego Convention Center
Date/Time: November 4, 11:55 AM – 1:25 PM PDT and 7 – 8:30 PM PDT

The abstracts for these presentations will be available on SITC’s website on Oct 31, 2023: https://www.sitcancer.org/2023/abstracts/abstract-titles-publications

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

For conference information, visit https://www.sitcancer.org/2023/home

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, in advanced cancer. 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 that 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)] SRK-181 specifically targets the latent TGFβ1 isoform in a context-independent manner, designed to enable complete inhibition of TGFβ1 in all compartments within the tumor microenvironment. Scholar Rock believes that SRK-181 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 trial is currently enrolling and dosing patients in multiple proof of concept cohorts conducted in parallel, including urothelial carcinoma (UC), cutaneous melanoma (MEL), non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and clear cell renal cell carcinoma (ccRCC). 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 or 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/).

Availability of Other Information About 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.

Scholar Rock® is a registered trademark of Scholar Rock, Inc.

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, that clinical data, including the results from the Phase 2 clinical trial of apitegromab, or Part B of the Phase 1 clinical trial of SRK-181, and are not predictive of, may be inconsistent with, or more favorable than, data generated from future clinical trials of the same product candidates, 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 June 30, 2023, 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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