



Scholar Rock to Present New Clinical and Biomarker Data from the Phase 1 DRAGON Trial at the SITC 39th Annual Meeting

October 31, 2024

- Poster presentation to include new safety, efficacy, and biomarker data from the long-term expansion phase of the DRAGON trial in patients with advanced solid tumors treated with SRK-181

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 31, 2024-- Scholar Rock (NASDAQ: SRRK), a late-stage biopharmaceutical company focused on advancing innovative treatments for spinal muscular atrophy (SMA), cardiometabolic disorders, and other serious diseases where protein growth factors play a fundamental role, announced today that it will present data from the Phase 1 DRAGON trial of SRK-181, an investigational selective inhibitor of latent TGFβ1 activation, in patients with advanced solid tumors at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting in Houston on November 6–10. In a poster presentation, Scholar Rock will share updated safety, efficacy, and biomarker results for SRK-181 in anti-PD-1 resistant patients with advanced solid tumors from the expansion phase (Part B) of the DRAGON trial.

“These promising new clinical and biomarker data from the DRAGON trial build upon our robust safety and efficacy data on SRK-181 in multiple solid tumor types,” said Jay Backstrom, M.D., MPH, President and Chief Executive Officer of Scholar Rock. “We are excited to share these updates, which support the potential of our highly selective approach to inhibiting TGFβ1 with durable responses observed in heavily pretreated patients. While DRAGON completed enrollment last year, patients have remained on therapy, and we look forward to providing additional updates.”

Details of the presentations are as follows:

Title: DRAGON Trial: Durable remission rate with the latent TGFβ1 inhibitor linavonkibart (SRK-181) and pembrolizumab in patients with immune checkpoint inhibitor resistant advanced cancers

Presentation Type: Poster 812

Presenter: Timothy A. Yap, M.D., The University of Texas MD Anderson Cancer Center

Location: Level 1, Exhibit Halls AB, George R. Brown Convention Center, Houston, TX

Date/Time: November 9, 2024, 7:10-8:30 p.m. CST

The abstracts for these presentations are available on SITC’s website on November 5, 2024: <https://www.sitcancer.org/2024/abstracts/titles-and-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/2024/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, as well as suppressing T cell activity, thereby inhibiting anti-tumor immunity.

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 immunosuppressive tumor microenvironment and induce tumor regression when administered in combination with anti-PD-(L)1 therapy while potentially avoiding toxicities associated with non-selective TGFβ inhibition. Enrollment of the DRAGON Phase 1 proof-of-concept clinical trial (NCT04291079) was completed in December 2023, and patients who remain on the study continue to be treated. The trial enrolled 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.

About Scholar Rock

Scholar Rock is a biopharmaceutical company that discovers, develops, and delivers life-changing therapies for people with serious diseases that have high unmet need. As a global leader in the biology of the transforming growth factor beta (TGFβ) superfamily of cell proteins and named for the visual resemblance of a scholar rock to protein structures, the clinical-stage company is focused on advancing innovative treatments where protein growth factors are fundamental. Over the past decade, Scholar Rock has created a pipeline with the potential to advance the standard of care for neuromuscular disease, cardiometabolic disorders, cancer, and other conditions where growth factor-targeted drugs can play a transformational role.

This commitment to unlocking fundamentally different therapeutic approaches is powered by broad application of a proprietary platform, which has developed novel monoclonal antibodies to modulate protein growth factors with extraordinary selectivity. By harnessing cutting-edge science in disease spaces that are historically under-addressed through traditional therapies, Scholar Rock works every day to create new possibilities for patients. Learn more about our approach at [ScholarRock.com](https://www.ScholarRock.com) and follow @ScholarRock and on LinkedIn.

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, progress and timing of its clinical trials for SRK-181, and indication selection and development timing, including the therapeutic potential, clinical benefits and safety thereof, expectations regarding timing, success and data announcements of current ongoing clinical trials, 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 preclinical and clinical data, including the results from the Phase 1 clinical trial of SRK-181, are not predictive of, may be inconsistent with, or more favorable than, data generated from future or ongoing 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; 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; and 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; 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, 2024, 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20241031472436/en/): <https://www.businesswire.com/news/home/20241031472436/en/>

Scholar Rock:

Investors

Rushmie Nofsinger
Scholar Rock
rnofsinger@scholarrock.com
ir@scholarrock.com
857-259-5573

Media

Molly MacLeod
Scholar Rock
mmacleod@scholarrock.com
media@scholarrock.com
802-579-5995

Source: Scholar Rock