Scholar Rock Appoints Heather Faulds as Vice President of Regulatory Affairs

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Regulatory expert brings SMA expertise to clinical advancement of SRK-015

CAMBRIDGE, Mass., September 14, 2017 – Scholar Rock, a biotechnology company focused on discovering and developing drugs that selectively modulate growth factor activation in the disease microenvironment, today announced the appointment of Heather Faulds as Vice President of Regulatory Affairs. Ms. Faulds has over 15 years of regulatory experience at innovative biotechnology companies, including her most recent role in Regulatory Affairs at Biogen where she led the regulatory and cross-functional team that attained the expedited FDA approval of Spinraza® (nusinersen) for Spinal Muscular Atrophy (SMA). Ms. Faulds will be responsible for managing the regulatory strategy for Scholar Rock's pipeline of drug candidates, including SRK-015, which is in development as a treatment to improve muscle strength and motor function in patients with SMA.

"I am delighted to welcome Heather to our team at this pivotal moment for Scholar Rock, as we plan and implement our regulatory strategy to advance SRK-015 into the clinic to address unmet needs for SMA patients," said Nagesh Mahanthappa, PhD, President and Chief Executive Officer of Scholar Rock. "She brings key expertise, with a wide range of experience in regulatory affairs across all stages of development, from first-in-human studies to product approvals and product label expansions."

"I am excited about Scholar Rock's passionate team and inspiring vision for developing innovative medicines in areas of high unmet medical need," said Ms. Faulds. "It was a privilege for me to contribute to the approval of the first drug product that has made such a meaningful difference in the lives of patients with SMA, and I look forward to building on that experience with the team at Scholar Rock to continue to bring SMA patients new therapeutic options."

In Ms. Faulds' most recent role as Senior Director of Regulatory Affairs at Biogen, she designed and implemented innovative regulatory strategies that expedited the development path and approval for multiple products, including Spinraza, an orphan product for the treatment of SMA, which was approved by FDA in an unprecedented 90 days and received an FDA Priority Review Voucher. Ms. Faulds also led regulatory activities for programs in Alzheimer's Disease and Multiple Sclerosis. Prior to working at Biogen, Ms. Faulds was Manager, Regulatory Affairs and CMC Operations at Oxigene, Inc. Ms. Faulds earned her Masters in Drug Regulatory Affairs and Health Policy at the Massachusetts College of Pharmacy. She also holds a Bachelor of Science in Biology from the University at Albany.

About SRK-015

SRK-015 is a selective and local inhibitor of the activation of latent myostatin. Myostatin, a member of the TGFβ superfamily of growth factors that is expressed primarily in skeletal muscle cells, is a genetically validated target that regulates muscle mass. Scholar Rock is actively working to advance SRK-015 into clinical trials to improve muscle strength and motor function in patients with Spinal Muscular Atrophy (SMA). Scholar Rock plans to develop SRK-015 both in combination with therapies aimed at correcting the underlying genetic defect and as monotherapy in certain subpopulations of SMA patients. SRK-015 is an investigational drug candidate. The effectiveness and safety of SRK-015 have not been established and SRK-015 has not been approved by the FDA or any other regulatory agency.

About Scholar Rock

Scholar Rock is discovering and developing a pipeline of innovative new medicines to treat a range of serious diseases in which growth factors play a fundamental role, including neuromuscular diseases, cancer and fibrosis. By focusing on newly elucidated biology of growth factor activation, Scholar Rock has developed insights which allow us to selectively target growth factors in the disease microenvironment – through the mechanism of supracellular activation. With our proprietary technology, we are developing novel medicines aimed at achieving therapeutic effects specifically at the source of disease to deliver new solutions for patients. Scholar Rock is led by a highly-experienced management team of leaders who have built successful biotechnology companies, and is backed by leading investors.

Spinraza® is a registered trademark of Biogen.

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