Scholar Rock Provides Update on Timing of Committee for Medicinal Products for Human Use (CHMP) Opinion for Apitegromab Marketing Authorisation Application (MAA) for Spinal Muscular Atrophy (SMA)

July 20, 2026

- *July 2026 CHMP meeting commences today, prior to FDA inspection classification for Catalent Indiana LLC (part of Novo Nordisk) fill-finish facility*
- *Apitegromab CHMP Opinion expected following resolution of Catalent Indiana classification status or inclusion of second fill-finish facility in MAA*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 20, 2026-- Scholar Rock (NASDAQ: SRRK), a global biopharmaceutical company dedicated to improving the lives of patients with rare, severe, and debilitating neuromuscular diseases by applying its world-leading platform in myostatin biology, today provided an update on the anticipated timing of a Committee for Medicinal Products for Human Use (CHMP) opinion for the apitegromab marketing authorisation application (MAA) for children and adults with spinal muscular atrophy (SMA). The European Medicines Agency (EMA) is reviewing the apitegromab MAA, which includes the Catalent Indiana LLC (part of Novo Nordisk) fill-finish facility, and is awaiting an update on the inspection classification of Catalent Indiana from the FDA following an April 2026 general site inspection.

Should the FDA reclassify Catalent Indiana, a CHMP opinion would be expected later in 2026. In the event that Catalent Indiana is not reclassified, Scholar Rock will work with the EMA to advance the apitegromab MAA with the Company's second fill-finish facility, which is included in the apitegromab Biologics License Application (BLA) under FDA review in the U.S. with a September 30, 2026 Prescription Drug User Fee Act (PDUFA) action date. The Company will provide an update during its second quarter earnings call on Thursday, August 6, 2026.

"We are very pleased with the EMA's review of the apitegromab MAA and with the level of engagement we have from the Agency," said David L. Hallal, Board Chair and Chief Executive Officer of Scholar Rock. "We expect clarity from the FDA on the inspection classification of Catalent Indiana in the near term, and we remain confident in our ability to advance our MAA through the EMA review process either with Catalent Indiana or by taking the necessary steps to include our second fill-finish facility."

Scholar Rock's second fill-finish facility for apitegromab is a U.S.-based facility producing numerous commercial products and is in good standing with both the FDA and EMA.

About Scholar Rock

Scholar Rock is a late-stage biopharmaceutical company focused on developing and commercializing apitegromab for children and adults with spinal muscular atrophy (SMA) and other rare, severe and debilitating neuromuscular diseases. As a global leader in myostatin biology, a field focused on proteins that regulate muscle mass, the biopharmaceutical company is named for the visual resemblance of a scholar rock to protein structures. Our commitment to unlock fundamentally different treatment approaches is powered by broad application of a proprietary platform, which has developed novel monoclonal antibodies to modulate protein growth factors with extraordinary selectivity. Scholar Rock works every day to create new possibilities for patients through its highly innovative anti-myostatin program, including opportunities in additional rare neuromuscular diseases. Learn more at **ScholarRock.com** and follow @ScholarRock on X and on LinkedIn.

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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 X (formerly known as Twitter) and LinkedIn. The information that we post on our website, X 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.

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, statements regarding the anticipated timing and outcome of the EMA's review of the MAA for apitegromab; the expected timing of a CHMP opinion; the anticipated timing and outcome of any action by the FDA relating to the Catalent Indiana fill-finish

facility; the EMA's reliance on any decision by the FDA with respect to Catalent Indiana; its expectation and plans to work with the EMA to advance the MAA using an additional fill-finish facility, if necessary; the expected review of its additional fill finish facility; expectations regarding actions by the FDA after its reinspection of the Catalent Indiana facility; the expected timing and outcome of FDA review of the accepted BLA for apitegromab, including the September 30, 2026 PDUFA action date and its expectations regarding regulatory interactions, manufacturing readiness and potential commercialization of apitegromab. 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, risks related to the timing and outcome of the EMA's review of the MAA, including the EMA's evaluation of manufacturing facilities; whether the FDA will accept the remediations to the Catalent Indiana fill finish facility in response to the FDA observations; whether the updated BLA will be sufficient to support regulatory approval; Scholar Rock’s ability to manage expenses or provide the financial support, resources and expertise necessary to identify and develop product candidates on the expected timeline; information provided to or decisions made by regulatory authorities; Scholar Rock’s ability to obtain, maintain and protect its intellectual property; and Scholar Rock’s dependence on third parties for development and manufacture of product candidates including, without limitation, to supply any clinical trials 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, 2026, 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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