

## NEWS RELEASE

# Schrödinger Receives Fast Track Designation for SGR-1505 for the Treatment of Relapsed/Refractory Waldenström Macroglobulinemia

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Demonstrates the potential of SGR-1505 as a novel approach for diseases with high unmet medical need

NEW YORK--(BUSINESS WIRE)-- **Schrödinger**, Inc. (Nasdaq: SDGR) today announced that SGR-1505, its clinical stage MALT1 inhibitor, was designated as a Fast Track product by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with Waldenström macroglobulinemia that have failed at least two lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

"We are excited to receive Fast Track designation for SGR-1505, which underscores the significant need in patients with Waldenström macroglobulinemia," said Karen Akinsanya, Ph.D., president, head of therapeutics R&D and chief strategy officer, partnerships at Schrödinger. "Despite the continued therapeutic advances in the treatment of hematologic malignancies, treatment failure and disease progression due to BTK resistance remains a challenge for a growing number of patients. This unmet need represents an opportunity for novel mechanisms such as MALT1 as monotherapy and as part of new combination regimens."

"We believe this Fast Track designation in Waldenström macroglobulinemia, combined with our encouraging Phase 1 data across a broad range of relapsed/refractory B-cell malignancies such as chronic lymphocytic leukemia, diffuse large B-cell lymphoma, and marginal zone lymphoma, reinforce the potential of SGR-1505 as a future therapeutic option for patients," said Margaret Dugan, chief medical officer at Schrödinger. "We look forward to discussing our Phase 1 study results and recommended Phase 2 dose with the FDA later this year."

The FDA Fast Track program is designed to facilitate the development and expedite the review of drug candidates

to treat serious conditions and fill an unmet medical need. A drug granted Fast Track designation is eligible for multiple benefits, including more frequent meetings and written communications with the FDA, as well as eligibility for Accelerated Approval, Priority Review or Rolling Review, if relevant criteria are met.

SGR-1505 is currently being evaluated in a Phase 1 clinical study as a treatment for patients with relapsed/refractory B-cell malignancies. Initial data were recently **presented** at the European Hematology Association Annual Congress and International Conference on Malignant Lymphoma where SGR-1505 was observed to have a favorable safety profile and was well tolerated. Encouraging signs of preliminary efficacy were observed in multiple B-cell malignancy subtypes, including Waldenström macroglobulinemia patients, previously treated with a BTK inhibitor prior to starting SGR-1505.

On August 11, 2023, the FDA granted orphan drug designation to SGR-1505 for Mantle Cell Lymphoma (MCL) based on preclinical data.

## About SGR-1505

SGR-1505 is an oral investigational MALT1 inhibitor being evaluated for the treatment of relapsed/refractory B-cell malignancies. MALT1 plays a central role in key signaling pathways that drive cancer cell survival and proliferation, making its location downstream of BTK in the NF- $\kappa$ B signaling pathway an attractive target for the development of novel therapeutics for a potentially broad range of B-cell malignancies. In preclinical studies, SGR-1505 was observed to be highly potent and selective, and has demonstrated anti-tumor activity in preclinical models both as a monotherapy and in combination with BTK and BCL-2 inhibitors. There is also emerging therapeutic rationale supporting MALT1 inhibition as a potential treatment for inflammatory and autoimmune disorders.

SGR-1505 was designed using Schrödinger's computational platform at scale and was discovered approximately 10 months after the company started its MALT1 program. A Phase 1 study in patients with relapsed/refractory B-cell malignancies is ongoing (NCT05544019).

## About Schrödinger

Schrödinger is transforming molecular discovery with its computational platform, which enables the discovery of novel, highly optimized molecules for drug development and materials design. Schrödinger's software platform is built on more than 30 years of R&D investment and is licensed by biotechnology, pharmaceutical and industrial companies, and academic institutions around the world. Schrödinger also leverages the platform to advance a portfolio of collaborative and proprietary programs and is advancing three clinical-stage oncology programs. Founded in 1990, Schrödinger has approximately 800 employees operating from 15 locations globally. To learn more, visit [www.schrodinger.com](http://www.schrodinger.com), follow us on **LinkedIn** and **Instagram**, or visit our blog, **Extrapolations.com**.

## Cautionary Note Regarding 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 those statements regarding the potential advantages of Schrödinger's computational platform, the clinical potential and favorable properties of SGR-1505, its MALT1 inhibitor, the potential for SGR-1505 to be used for the treatment of relapsed/refractory B-cell malignancies, including Waldenström macroglobulinemia, chronic lymphocytic leukemia, diffuse large B-cell lymphoma, and marginal zone lymphoma, the potential benefits of Fast Track designation, including frequency of interactions with the FDA during clinical development and potentially accelerated approval and/or priority review, and Schrödinger's plans to engage with regulators. Statements including words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would" and statements in the future tense are forward-looking statements. These forward-looking statements reflect Schrödinger's current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to the company and on assumptions the company has made. Actual results may differ materially from those described in these forward-looking statements and are subject to a variety of assumptions, uncertainties, risks and important factors that are beyond Schrödinger's control, including the uncertainties inherent in drug development and commercialization, such as the conduct of research activities and the timing of and its ability to initiate and complete preclinical studies and clinical trials, whether results from preclinical and early clinical studies will be predictive of the results of later preclinical studies and clinical trials, whether initial data from clinical results will be predictive of the final results of the clinical trials, uncertainties associated with the regulatory review of clinical trials and applications for marketing approvals and the ability to retain and hire key personnel on its business and other risks detailed under the caption "Risk Factors" and elsewhere in the company's Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the Securities and Exchange Commission on May 7, 2025, as well as future filings and reports by the company. Any forward-looking statements contained in this press release speak only as of the date hereof. Except as required by law, Schrödinger undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events, changes in expectations or otherwise.

Matthew Luchini (Investors)

**[matthew.luchini@schrodinger.com](mailto:matthew.luchini@schrodinger.com)**

917-719-0636

Allie Nicodemo (Media)

**[allie.nicodemo@schrodinger.com](mailto:allie.nicodemo@schrodinger.com)**

617-356-2325

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