

Schrödinger Announces FDA Clearance of Investigational New Drug Application for SGR-1505, a MALT1 Inhibitor

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Phase 1 Clinical Trial in Patients with Advanced B-Cell Malignancies Expected to Begin in the Second Half of 2022

NEW YORK--(BUSINESS WIRE)--Jun. 28, 2022-- **Schrödinger, Inc.** (Nasdaq: SDGR), whose physics-based software platform is transforming the way therapeutics and materials are discovered, today announced that the U.S. Food and Drug Administration (FDA) cleared its investigational new drug (IND) application for its MALT1 inhibitor, SGR-1505. Schrödinger expects to initiate a Phase 1 clinical trial of SGR-1505 in patients with relapsed or refractory B-cell lymphoma in the second half of 2022.

“Based on the preclinical data for SGR-1505, we believe we have an opportunity to advance a potential best-in-class MALT1 inhibitor into the clinic,” stated Karen Akinsanya, Ph.D., president of R&D, therapeutics at Schrödinger. “There is a significant medical need for patients with relapsed or refractory B-cell lymphoma who have exhausted currently approved treatment options, and we look forward to initiating our Phase 1 clinical study of SGR-1505 later this year.”

The planned multi-center, dose-escalation study will be conducted in patients with relapsed or refractory B-cell malignancies to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary signals of therapeutic activity of SGR-1505 as a monotherapy. Once the recommended dose is determined, an expansion cohort is planned to evaluate SGR-1505 in combination with other anti-cancer agents, such as BTK and BCL-2 inhibitors, in patients with specific B-cell malignancies.

“Our platform, which combines physics and machine learning, enabled us to accurately assess 8.2 billion

compounds computationally and to synthesize only 78 molecules over a 10-month period of iterative “design, make, test” optimization cycles, ultimately selecting SGR-1505 as our development candidate,” said Robert Abel, Ph.D., chief computational scientist at Schrödinger. “FDA clearance of the IND for SGR-1505 marks an important milestone for our MALT1 program and underscores the impact of incorporating a digital chemistry strategy into research programs.”

About SGR-1505

SGR-1505 is a mucosa-associated lymphoid tissue lymphoma translocation protein 1 (MALT1) inhibitor that was discovered using Schrödinger’s proprietary physics-based computational platform. MALT1 is a protease that is downstream of Bruton’s tyrosine kinase (BTK), in the NF-κB signaling pathway. Constant activation of NF-κB is a hallmark of several subtypes of lymphoma. MALT1 is considered a potential therapeutic target for several non-Hodgkin’s B-cell lymphomas. Data presented at the American Society of Hematology 2021 Annual Meeting showed that inhibiting MALT1 may provide additional therapeutic options for patients with certain subtypes of non-Hodgkin’s B-cell lymphomas such as ABC-DLBCL, with the possibility of expanding into other B-cell lymphomas such as mantle cell lymphoma. Furthermore, the data showed that Schrödinger’s MALT1 inhibitors demonstrated strong anti-tumor activity alone and in combination with BTK inhibitors and overcame drug-induced resistance in samples derived from patients with relapsed and resistant B-cell lymphomas. SGR-1505 is initially being developed for the treatment of non-Hodgkin’s B-cell lymphomas.

About Schrödinger

Schrödinger is transforming the way therapeutics and materials are discovered. Schrödinger has pioneered a physics-based software platform that enables discovery of high-quality, novel molecules for drug development and materials applications more rapidly and at lower cost compared to traditional methods. The software platform is used by biopharmaceutical and industrial companies, academic institutions, and government laboratories around the world. Schrödinger’s multidisciplinary drug discovery team also leverages the software platform to advance collaborative programs and its own pipeline of novel therapeutics to address unmet medical needs, including eight compounds currently in clinical development.

Founded in 1990, Schrödinger has over 700 employees and is engaged with customers and collaborators in more than 70 countries. To learn more, visit www.schrodinger.com follow us on [LinkedIn](#) and [Twitter](#), 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 regarding the expected timing of the initiation of a Phase 1 clinical trial of SGR-1505, the therapeutic potential of SGR-1505, the potential of MALT1 inhibitors, including SGR-



1505, to be used for the treatment of certain subtypes of non-Hodgkin's B-cell lymphomas and for other B-cell lymphomas such as mantle cell lymphoma, and the potential for SGR-1505 to be used in combination with other anti-cancer agents. Statements including words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "look forward," "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 factors that are beyond Schrödinger's control, including the uncertainties inherent in early stage drug development, including the conduct of research activities, the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies; the company's ability to enroll patients in its planned clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials, as well as the other risks and uncertainties identified under the caption "Risk Factors" and elsewhere in the company's Securities and Exchange Commission filings and reports, including the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 4, 2022, 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, the company 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.

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