



# Silence Therapeutics and Mallinckrodt Announce Submission of Clinical Trial Application for SLN501

3/23/2022

Silence to receive \$3 million research milestone payment from Mallinckrodt

Phase 1 study expected to begin in the first half of 2022

LONDON & DUBLIN--(BUSINESS WIRE)-- Silence Therapeutics plc (Nasdaq: SLN), a leader in the discovery, development and delivery of novel short interfering ribonucleic acid (siRNA) therapeutics for the treatment of diseases with significant unmet medical need, and Mallinckrodt plc (OTCMKTS:MNKKQ), a global biopharmaceutical company, today announced filing of a clinical trial application (CTA) for SLN501, an siRNA targeting the complement C3 protein, triggering a \$3 million milestone payment to Silence.

This press release features multimedia. View the full release here:  
<https://www.businesswire.com/news/home/20220323005220/en/>

Craig Tooman, President and Chief Executive Officer at Silence, commented: “ The CTA submission for SLN501 represents another key milestone in our Mallinckrodt collaboration leveraging our proprietary mRNAi GOLD™ platform for complement-mediated diseases. This highlights the importance of partnerships to expand our pipeline opportunities while also providing non-dilutive financing to support our development activities.”

Mark Trudeau, President and Chief Executive Officer of Mallinckrodt, said: “We remain excited about the potential of Silence’s mRNAi GOLD™ platform to address the unmet needs of patients suffering from a range of complement-mediated diseases. We look forward to entering into the clinic with our first product candidate, SLN501, in the first half of this year as well as progressing work on two other complement targets.”

Under the collaboration, Silence is responsible for executing the development program for SLN501 until the end of

phase I, after which Mallinckrodt will assume responsibility for clinical development and global commercialization. The phase I study is expected to start in the first half of 2022.

In July 2019, Silence and Mallinckrodt initiated a collaboration focused on leveraging Silence's proprietary mRNAi GOLD™ platform to develop siRNAs for complement-mediated diseases. Under the agreement, Silence received an upfront payment of \$20 million from Mallinckrodt for an exclusive worldwide license to siRNAs developed against one complement target, C3, and options to license siRNAs against up to two additional complement targets, each of which Mallinckrodt exercised in 2021 at \$2 million per target. Silence is responsible for preclinical activities and for executing development of each target through phase 1, after which Mallinckrodt will assume responsibility for clinical development and global commercialization. Silence is also eligible to receive tiered double-digit royalties on net sales for each product candidate and up to \$2 billion in total milestone payments across all three targets.

### About Silence Therapeutics

Silence Therapeutics is developing a new generation of medicines by harnessing the body's natural mechanism of RNA interference, or RNAi, to inhibit the expression of specific target genes thought to play a role in the pathology of diseases with significant unmet need. Silence's proprietary mRNAi GOLD™ platform can be used to create siRNAs (short interfering RNAs) that precisely target and silence disease-associated genes in the liver, which represents a substantial opportunity. Silence's wholly owned product candidates include SLN360 designed to address the high and prevalent unmet medical need in reducing cardiovascular risk in people born with high levels of lipoprotein(a) and SLN124 designed to address rare hematological diseases. Silence also maintains ongoing research and development collaborations with AstraZeneca, Mallinckrodt Pharmaceuticals, and Hansoh Pharma, among others. For more information, please visit <https://www.silence-therapeutics.com/>.

### About Mallinckrodt

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology, ophthalmology, and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit [www.mallinckrodt.com](http://www.mallinckrodt.com).

### Forward-Looking Statements

Certain statements made in this announcement are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and other securities laws, including with respect to clinical and commercial prospects and the anticipated timing of data reports from the clinical trials. These forward-looking

statements are not historical facts but rather are based on current expectations, estimates, and projections about the industry; beliefs; and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the companies' control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements, including those risks identified from time to time in filings the Company and/or Mallinckrodt make with the U.S. Securities and Exchange Commission ("SEC"), including in the Company's most recent Admission Document and its Annual Report on Form 20-F filed with the SEC on March 17, 2022 and/or Mallinckrodt's most recent Annual Report on Form 10-K and other filings with the SEC. Each company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of each company only as of the date of this announcement. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The companies will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20220323005220/en/>

#### Silence Therapeutics plc

Gem Hopkins, Head of IR and Corporate Communications

**[ir@silence-therapeutics.com](mailto:ir@silence-therapeutics.com)**

Tel: +1 (646) 637-3208

#### US Media Relations

MKC STRATEGIES, LLC

Mary Conway

**[MConway@MKCStrategies.com](mailto:MConway@MKCStrategies.com)**

Tel: +1 (516) 606-6545

#### Mallinckrodt Investor Relations

Daniel J. Speciale

Global Corporate Controller & Chief Investor Relations Officers

**[Daniel.speciale@mnk.com](mailto:Daniel.speciale@mnk.com)**

#### Jamie Tinsley

H+K Strategies

**jamie.tinsley@hkstrategies.com**

M: +1 713 301 4874

Ron Bartlett

H+K Strategies

**ron.bartlett@hkstrategies.com**

M: +1 813 545 2399

Source: Silence Therapeutics plc