# SciFluor announces positive top-line results of phase 1/2 study of SF0166 eye drops to treat wet age-related macular degeneration

# Demonstrated safety with no drug-related serious adverse events

Improvements in vision along with significant decreases in central retinal thickness and fluid levels reported

## Preparation of Phase 2 trials underway

Boston, MA, 18 December 2017 - <u>SciFluor Life Sciences, Inc</u>. (SciFluor), a subsidiary of Allied Minds, today announces positive top-line results of a Phase 1/2 trial studying the treatment of 'wet' age-related macular degeneration (AMD) patients with SF0166, the company's lead eye drop drug for back of the eye diseases. The double masked Phase 1/2 study assessed the safety, tolerability and preliminary efficacy of SF0166 in 42 evaluable subjects with neovascular (wet) AMD who were randomized 1:1 to self-administer an eye drop containing either a 2.5% or a 5% solution of SF0166 twice-a-day for 28 days.

The primary outcome measure of safety was clearly achieved with no drug-related serious adverse events observed in the study throughout the 28-day course of treatment as well as during the 28-day follow-up period. Ocular adverse events were recorded in the treated eyes of 5 patients; all events were mild or moderate in severity, with one considered possibly drug-related.

SF0166 also demonstrated clinically significant biological activity, as assessed by a panel of three leading retinal physicians, in 9 of the 42 patients who completed the study evidenced by decreases in central retinal thickness and/or subretinal fluid by spectral domain optical coherence tomography. The mean improvement in visual acuity during the treatment period among the treatment naïve group was approximately 5 letters.

"SF0166 was very well-tolerated in this phase 1/2 study, and the demonstration of biological activity seen in patients in this heterogenous population of wet-AMD patients despite the short study duration was encouraging for a topical treatment," said Jeffrey S. Heier, MD, Ophthalmic Consultants of Boston. "I look forward to the continued clinical advancement of SF0166."

"Combined with our previously reported data in diabetic macular edema patients, we now have an impressive safety profile for SF0166 in over 80 patients coupled with distinct evidence of biological activity for both indications. This implies that the drug is not only well-tolerated but that it is reaching the back of the eye and is active," said Omar Amirana, M.D., SciFluor's Chief Executive Officer and Senior Vice President at Allied Minds. "These exciting results highlight the prospect that wet-AMD and DME patients could be treated with an eye drop that penetrates to the back of the eye. If approved, an eye drop therapy could encourage earlier treatment in the course of the disease which has the potential to improve outcomes, while offering obvious patient benefits versus current injectable alternatives."

Jill Smith, Chief Executive Officer of Allied Minds, commented "These results for wet-AMD provide further validation of the preclinical work undertaken at SciFluor and there is a clear case to proceed to Phase 2 trials for both DME and wet-AMD. SF0166 is targeting a very large and growing market, with existing injectable drugs for DME and wet-AMD generating combined annual revenues exceeding \$8 billion."

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For more information contact:	
Allied Minds plc Neil Pizey, Head of Corporate Development	+44 7771 872 922
FTI Consulting Ben Atwell / Brett Pollard	+44 20 3727 1000

# About the Phase 1/2 Clinical Trial

The Phase 1/2 study assessed the safety and preliminary efficacy of SF0166 in 42 evaluable wet-AMD patients who were randomized 1:1 to either a 2.5% or a 5% solution of SF0166 self-administered as an eye drop twice-a-day for 28 days.

The patients were further assessed over an additional 28-day follow-up period off SF0166. The study was conducted at 8 sites in the US (clinicaltrials.gov ID#: <u>NCT02914639</u>) and included treatment-naïve patients as well as patients with prior anti-

### VEGF treatment.

## About SF0166

SciFluor is developing SF0166, a novel, patented, potent and selective small molecule inhibitor of integrin  $\alpha\nu\beta3$  with an optimum balance of physiochemical properties to allow it to distribute to the retina in high concentrations after topical (eye drop) administration to the eye. It has been tested in an extensive set of preclinical assays and shown to reach the back of the eye and be effective in validated in vivo models of macular disease. SF0166 has also been studied in a separate multicenter, randomized, Phase 1/2 trial has been in patients with Diabetic Macular Edema (DME) (clinicaltrials.gov ID# NCT02914613).

#### About AMD

Age-related macular degeneration (AMD) is the most common cause of severe vision loss in older Americans. It affects central vision and may interfere with daily tasks such as reading and driving. Macular degeneration affects the retina in two forms - dry and wet AMD, also called neovascular AMD. Wet-AMD is frequently accompanied by relatively sudden loss of vision. This is caused by the growth of abnormal blood vessels underneath the retina that leak fluid or blood. Recent advances in the treatment of wet-AMD can now prevent further loss of vision, or even restore vision in some cases, if treatment is sought promptly. These treatments require frequent injections of biologic drugs into the back of the eye performed in a doctor's office. Generally, the effectiveness of these treatments decreases with time, therefore improved treatments are actively being sought. A topically administered drug that is safe and effective would be a major advance in patient care.

## About SciFluor Life Sciences Inc.

SciFluor creates proprietary best-in-class drugs based on well-understood pathways in areas of significant medical need such as ophthalmology, neuroscience and fibrotic diseases. Our lead clinical drug candidate, SF0166, is an eye drop therapeutic for treating back-of-the-eye diseases. <u>www.scifluor.com</u>

#### About Allied Minds

Based in Boston, Allied Minds plc is an IP commercialisation company focused on technology and life sciences. With extensive access to U.S. federal government laboratories and universities, as well as partnerships with leading U.S. corporations, Allied Minds forms, funds, and operates a portfolio of companies with the objective of delivering successful liquidity events that will generate attractive long-term returns for its investors and stakeholders. Allied Minds supports its businesses with capital, resources, and expertise. For more information, please visit <u>www.alliedminds.com</u>

# **Allied Minds Forward-Looking Statement**

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risk and uncertainties described in the risk factors included in the company's regulatory filings. These forward-looking statements are based on assumptions regarding the present and future business strategies of the company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law, regulatory requirement, the Prospectus Rules, the Listing Rules and the Disclosure and Transparency Rules, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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