



## **SciFluor Announces Positive Results of Phase 1/2 Study of SF0166 Topical Ophthalmic Solution in Diabetic Macular Edema Patients**

*-- Demonstrated safety with no drug-related serious adverse events --*

*-- Greater than 50% of treated patients experienced a decrease in retinal thickness--*

**Cambridge, Mass. (September 28, 2017)** – [SciFluor Life Sciences, Inc.](#) today announced positive top-line results of a Phase 1/2 study of SF0166, the company's lead drug in development for the topical treatment of patients with diabetic macular edema (DME). The Phase 1/2 study assessed the safety and preliminary efficacy of SF0166 in 40 evaluable patients with DME who were randomized to one of two dose strengths (2.5% and 5.0% solutions) self-administered by patients as an eye drop twice-a-day for 28 days.

The primary outcome measure of safety was 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 6 patients; all events were mild in severity, with one considered possibly drug-related.

SF0166 demonstrated biological activity in both (2.5% and 5.0%) patient groups with 53% of the evaluable patients demonstrating a reduction in retinal thickness (RT) and improvements in visual acuity were also reported. Durability of RT response to the 28 day course of therapy was observed during the month after discontinuing treatment.

There were no significant decreases in visual acuity in study eyes during treatment or follow-up and no patient required rescue treatment with an anti-VEGF injection during the treatment phase.

"The safety and biological activity, clearly demonstrated in this first-in-patient study, supports continued clinical development of SF0166," said David Boyer, MD, Retina-Vitreous Associates Medical Group of Los Angeles. "DME is a devastating condition that often results in vision loss. A safe and effective eye drop treatment for patients living with DME would be a major advance in the fight against this debilitating disease. A potential eye-drop treatment for DME may not only increase compliance, but also allow the opportunity to prevent vision loss by treating earlier in the disease pathway."

"We believe SF0166 represents an important breakthrough in the treatment of retinal disease given its unique mode of action and its administration as an eye drop," said Omar Amirana, MD, SciFluor's Chief Executive Officer and Senior Vice President at Allied Minds. "We look forward to further advancing SF0166. We would like to thank the patients who participated in this study

and the investigators and study staff who share our commitment to advancing the treatment of DME.”

#### **About the Phase 1/2 Clinical Trial**

The Phase 1/2 study assessed the safety and preliminary efficacy of SF0166 in 40 evaluable patients with DME who were randomized to one of two dose strengths (2.5% and 5.0% solutions) self-administered by patients 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 6 sites in the US (clinicaltrials.gov ID#[NCT02914613](#)) 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  $\alpha\beta3$  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 pre-clinical assays and shown to reach the back of the eye and be effective in validated in vivo models of macular disease. SF0166 is also being studied in a separate multi-center, randomized, Phase 1/2 trial has been in patients with neovascular (wet) age-related macular degeneration (AMD) (clinicaltrials.gov ID#[NCT02914639](#)).

#### **About DME**

Diabetic Macular Edema (DME) is the swelling of the retina in diabetic patients due to the leakage of fluid from blood vessels within the macula. The macula is important for the sharp, straight-ahead vision. As macular edema develops, blurring occurs in the middle or just to the side of the central visual field. Visual loss from DME can progress over a period of months and make it impossible to focus clearly. Treatment options for patients with DME traditionally include anti-VEGF drugs, corticosteroid drugs, and laser surgery. The anti-VEGF drugs are administered by frequent intravitreal injections into the back of the eye. While the biology and pathology of DME have been generally understood, safe and effective topical therapy in the form of an eye drop has remained elusive. According to the U.S. Centers for Disease Control, approximately 30 million Americans are living with diabetes and approximately 4% of patients living with diabetes, or over 1 million diabetic patients, experience DME<sup>1</sup>.

#### **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. [www.scifluor.com](http://www.scifluor.com)

<sup>1</sup>Varma, R., Bressler, N. M., Doan, Q. V., Gleeson, M., Danese, M., Bower, J. K., ... Turpcu, A. (2014). Prevalence of and risk factors for diabetic macular edema in the United States. *JAMA Ophthalmology*, 132(11), 1334-1340. DOI: [10.1001/jamaophthalmol.2014.2854](https://doi.org/10.1001/jamaophthalmol.2014.2854)

**About Allied Minds**

Allied Minds (LSE: ALM) is a diversified holding company focused on venture creation within the life science and technology sectors. With unparalleled access to hundreds of university and federal labs across the U.S., Allied Minds forms, funds, and operates a portfolio of companies to generate long-term value for its investors and stakeholders. Based in Boston, with nationwide presence in Los Angeles and New York, Allied Minds supports its businesses with capital, central management, and shared services. For more information, please visit [www.alliedminds.com](http://www.alliedminds.com).

**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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