

## pSivida new trial to treat AMD (age related macular degeneration)

Boston, MA. and Perth, Australia – pSivida Limited (ASX: PSD, NASDAQ: PSDV, FSE: PSI) announced today that enrolment has begun for a clinical trial to assess the safety and efficacy of Medidur™ FA in conjunction with Lucen® (ranibizumab injection, Genentech) in patients with exudative age-related macular degeneration (wet AMD). The study is designed to provide preliminary information on the potential of Medidur FA to maintain the efficacy established with Lucentis while reducing the overall number of Lucentis treatments.

Performed under an investigator sponsored IND, the study will compare two doses of Medidur FA (0.2 and 0.5 ug/day) in patients that have been treated with Lucentis for at least six months. The change from baseline in parameters such as visual acuity and retinal thickness will be assessed, and the number of Lucentis injections required pre and post-treatment will be compared.

- "The approval of Medidur to treat Wet AMD could dramatically increase the market potential for Medidur FA. Under our revised agreement with Alimera Sciences, Alimera is responsible for funding all Medidur FA development costs," said Dr. Paul Ashton, Managing Director of pSivida.
- Medidur FA is a tiny injectable intravitreal device designed to release fluocinolone acetonide to the retina for up to three years. It is presently in a fully enrolled Phase III clinical trial for the treatment of Diabetic Macular Edema (DME).
- Wet AMD is the leading cause of vision loss in people over 65 in the developed world and is characterized by the formation of leaky new blood vessels originating in the choroid which may haemorrhage and cause accumulation of sub- and intraretinal fluid.
- Lucentis is approved for the treatment of wet AMD and requires repeated injections directly into the eye to maintain efficacy.

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About pSivida Limited

pSivida is a global drug delivery company committed to the biomedical sector and the development of drug delivery products.

Retisert® is FDA approved for the treatment of uveitis. Vitrasert® is FDA approved for the treatment of AIDS-related CMV Retinitis. Bausch & Lomb owns the trademarks Vitrasert® and Retisert®. pSivida has licensed the technologies underlying both

of these products to Bausch & Lomb. The technology underlying Medidur<sup>™</sup> for diabetic macular edema is licensed to Alimera Sciences and is in Phase III clinical trials. pSivida has a worldwide collaborative research and license agreement with Pfizer Inc. for other ophthalmic applications of the Medidur<sup>™</sup> technology (excluding FA).

pSivida owns the rights to develop and commercialize a modified form of silicon (porosified or nano-structured silicon) known as BioSilicon™, which has applications in drug delivery, wound healing, orthopedics, and tissue engineering. The most advanced BioSilicon™ product, BrachySil™, delivers a therapeutic, P32 directly to solid tumors and is presently in Phase II clinical tria for the treatment of pancreatic cancer.

pSivida's intellectual property portfolio consists of 64 patent families, 113 granted patents, including patents accepted for issuance, and over 280 patent applications. pSivida conducts its operations from Boston in the United States, Malvern in the United Kingdom and Perth in Australia.

pSivida is listed on NASDAQ (PSDV), the Australian Stock Exchange (PSD) and on the Frankfurt Stock Exchange (PSI). pSivida is a founding member of the NASDAQ Health Care Index and the Merrill Lynch Nanotechnology Index.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking and involve a number of risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. The following are some of the factors that could cause actual results to differ materially from the forward-looking statements: the scheme of arrangement for reincorporation of the company, including whether or not it is implemented; the achievement of milestones and other contingent contractual payment events; failure to prove efficacy for BrachySil; inability to raise capital; continued losses and lack of profitability; inability to develop or obtain regulatory approval for new products; inability to protect intellectual property or infringement of others' intellectual property; inability to obtain partners to develop and market products; termination of license agreements; competition; inability to pay any registration penalties; costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; inability to manage change; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; amortization or impairment of intangibles; issues relating to Australian incorporation; potential inability to retain the independent auditor; potential delisting from ASX or NASDAQ; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; potential restrictions from capital raises; possible influence by Pfizer; and other factors that may be described in our filings with the Securities and Exchange Commission. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. We do not undertake to publicly update or revise our forwardlooking statements even if experience or future changes make it clear that any projected results expressed or implied in such statements will not be realized.