

## **NICE recommends the use of IKERVIS<sup>®</sup> in England for the treatment of severe keratitis in adult patients with dry eye disease**

November 4, 2015, Osaka, Japan – Santen Pharmaceutical Co., Ltd. (hereinafter, Santen) announced today that the National Institute for Health and Care Excellence (NICE) has issued positive Final Appraisal Determination (FAD) recommending the use of Santen's IKERVIS<sup>®</sup> (ciclosporin 1 mg/mL eye drops emulsion in single-dose containers) in England for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes.<sup>1</sup>

IKERVIS<sup>®</sup> is the first and only topical preparation licensed for the treatment of severe keratitis in patients with dry eye disease in the UK.<sup>2</sup> Approximately 700,000 adults in Europe suffer from the severe form of dry eye disease.<sup>3</sup> Symptoms of dry eye disease include burning, itching and dryness, gritty sensation and photophobia.<sup>4,5</sup> Severe keratitis is an inflammation of the cornea, which can result from dry eye disease.

It is a distressing condition for patients and has a very significant impact on their well-being and quality of life. Severe keratitis in patients with dry eye disease presents another major challenge: patients may present with signs of serious ocular surface damage but their symptoms may not correlate to the clinical signs, making diagnosis difficult<sup>6</sup>. However, inflammation if left untreated can lead to further complications, permanent corneal damage and even loss of sight.<sup>6</sup>

Ciclosporin works by reducing inflammation in dry eye disease.<sup>2</sup> However, until the launch of IKERVIS<sup>®</sup>, there has been no topical preparation of ciclosporin licensed in the UK.<sup>2</sup> IKERVIS<sup>®</sup> has a novel cationic nano-emulsion formulation to effectively deliver the anti-inflammatory potential of ciclosporin.<sup>7,8</sup> With this recommendation from NICE, IKERVIS<sup>®</sup> provides an important new option for the treatment of patients in England who have not responded to tear substitutes. In October of this year the Scottish Medicines Consortium (SMC) determined that IKERVIS<sup>®</sup> should be made available to patients in Scotland.<sup>9</sup>

The NICE decision was based on data from the SANSIKA trial. This was a double-masked multicentre, randomised, vehicle-controlled six month pivotal phase III trial with a six month open label treatment safety follow up period, which evaluated the efficacy and safety of IKERVIS<sup>®</sup>, administered once daily in adult patients with severe dry eye disease. Key evidence from SANSIKA showed that IKERVIS<sup>®</sup> with once-daily dosing, reduces ocular surface inflammation and reduces corneal damage, and is consistent with an improvement in patients' disease severity.<sup>10</sup>

## **About Santen**

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, sales, and marketing of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in over 50 countries. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more details, please see Santen's website ([www.santen.com](http://www.santen.com)).

## **Santen Forward-looking Statements**

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial conditions are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

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<sup>1</sup> NICE advice, published at:

<http://www.nice.org.uk/guidance/GID-TAG466/documents/final-appraisal-determination-document>

<sup>2</sup> Ikervis SmPC June 2015, available at <https://www.medicines.org.uk/emc/medicine/30584>

<sup>3</sup> Data on file, Santen

<sup>4</sup> Lemp MA. Am J Ophthalmol. 2008;146(3):350-6.

<sup>5</sup> Report of the international dry eye workshop (DEWS). Ocul Surf. 2007;5(2):65-204.)

<sup>6</sup> Baudouin C, et al. Br J Ophthalmol 2014;98:1168–1176

<sup>7</sup> Lalleman F et al. J Drug Deliv 2012: 604204

<sup>8</sup> Daull P, et al. 2013 Mar; 32 (3): 345-54

<sup>9</sup> SMC advice, published at

[https://www.scottishmedicines.org.uk/SMC\\_Advice/Advice\\_Directory/SMC\\_Advice\\_Directory](https://www.scottishmedicines.org.uk/SMC_Advice/Advice_Directory/SMC_Advice_Directory)

<sup>10</sup> SANSIKA study. Data on file. Santen UK Limited