

**Rapid relief of pain in oral mucositis, New episil® oral liquid approved in China**

Tokyo, Japan, February 21, 2019—Solasia Pharma K.K. (TOKYO:4597, Headquarters:Tokyo, Japan, President & CEO:Yoshihiro Arai, hereinafter “Solasia”), a specialty pharmaceutical company based in Asia, today officially announced that episil® oral liquid (SP-03, hereinafter “episil®”) has been approved by the National Medical Products Administration (NMPA, formerly CFDA) in China to relieve pain in the oral cavity, soothing lesions caused by chemotherapy and/or radiotherapy. As the only ready-to-use, pocket-sized medical device for managing and relieving oral mucositis, episil® will provide a new treatment option for patients with oral mucositis in China. Especially for cancer patients undergoing radiotherapy and/or chemotherapy, episil® can effectively reduce the severity of oral mucosal inflammation and significantly improve compliance and convenience of cancer patients during the entire chemo/radiotherapy.

Oral mucositis (OM) is a common side effect, which occurs in 20%-40% of chemotherapy, approximately 80% of high-dose chemotherapy (such as hematopoietic stem cell transplantation pretreatment) and most of head and neck cancer patients receiving radiotherapy.<sup>1,2</sup> OM usually manifests as redness, erosion, ulcers and pain, affecting swallowing and eating and often leads to decreased dose, interruption or delay of radiotherapy, and even hospitalization. OM seriously affects patients' quality of life, treatment progress and efficacy. At present, there is a lack of fast, effective, safe and comfortable product for OM caused by cancer radiotherapy and chemotherapy, so the unmet needs are urgent and huge. Currently, there is no standard treatment with clear effect in China. Mouth care guidance and support by UK Oral Mucositis in Cancer Group (UKOMiC)<sup>3</sup> and European Oral Care in Cancer Group (EOCC) oral care guidance and support<sup>4</sup> recommend the use of episil® to prevent the occurrence of oral mucositis and relieve pain.

episil® uses the patented FluidCrystal® technology from Camurus AB, Sweden. It is a lipid-based, preservative-free fluid that adhere to the oral mucosa, and form a layer of protective membrane within 5 minutes after contacting with the oral mucosa.<sup>5</sup> It provides physical protection to the oral sensitive and ulcerated epithelium and relieves pain for up to 8 hours.<sup>5,6</sup>

China registry trial<sup>7</sup> compared episil® with commercially available oral rinse in cancer patients with OM caused by chemotherapy and/or radiotherapy and evaluated the efficacy, safety and mucoadhesiveness of episil®. The results showed that single use of episil® significantly decreased the oral mucosal pain score within 6 hours, and the local analgesic effect and duration effect were superior to control group; in addition, episil® was easy to adhere to the mucosa and the film formation time was fast (within 5 minutes). Patients reported the taste as pleasant, comfortable, without irritation and they were willing to accept its treatment. This trial has confirmed the efficacy and safety of episil® in OM treatment.

Yoshihiro Arai, President and Chief Executive Officer, Solasia, said: “Solasia company mission is [Better Medicine for a Brighter Tomorrow]. We have always focused on the patients, and striven to develop innovative products to treat cancer and support cancer treatment. We continue to bring ‘quality medicines’ to the market, to benefit more patients in China, Japan and other Asian countries. The approval of episil® will help Solasia to deliver its unwavering commitment to Chinese patients. All of team members will continue to work hard to meet the needs of patients and healthcare professionals and embrace new challenges going forward.”

**About episil®**

episil® uses the patented FluidCrystal® technology from Camurus AB (STO:CAMX), Sweden. It is a lipid-based liquid, preservative-free liquid that adhere to the oral mucosa, and form a protective film within 5 minutes after contacting with the oral mucosa. It provides physical protection to the oral sensitive and ulcerated epithelium. episil® is the only ready-to-use, pocket-sized medical device that manages and relieves oral mucositis, helping patients improve the quality of their daily lives during cancer treatment. episil® was first registered in Europe in 2009 and is now launched in the United States, Europe, Japan and other countries. episil® oral liquid is registered as Class I medical device in Europe, 510(k) medical device in the United States, and approved as Class II medical device in China and Japan.

For more information about episil®, please access Camurus AB, episil® website:

<https://www.episil.net/>

## About Solasia

Solasia is an Asia-based pharmaceutical company dedicated to developing and selling innovative cancer treatment supportive drugs for local markets. As to benefit patients in China, the company is focused on creating a cancer treatment system in Asia, by developing innovative cancer drugs, introducing and getting commercial development licenses for great products from leading pharmaceutical and biotech companies in Japan, Europe and U.S.A, and other Asian countries. Solasia actively responds to the needs of patients and healthcare professionals and works hard to improve patient's life and meet the key unmet needs in oncology. For more information about the company, please visit [www.solasia.co.jp/en/](http://www.solasia.co.jp/en/)

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- <sup>3</sup> UKOMiC OM Guidelines. Mouth care guidance and support in cancer and palliative care, June 2015  
[http://www.ukomic.co.uk/pdf/UK\\_OM\\_Guidelines.pdf](http://www.ukomic.co.uk/pdf/UK_OM_Guidelines.pdf)
- <sup>4</sup> EOCC Guidelines. <http://www.cancernurse.eu/documents/EOCCGuidelinesv7.pdf>
- <sup>5</sup> Camurus. episil® package insert. May 2017.
- <sup>6</sup> Hadjieva, T et al. Treatment of oral mucositis pain following radiation therapy for head-and-neck cancer using a bioadhesive barrier-forming lipid solution. Support Care Cancer 2014, 22:1557–1562
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