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July 17, 2015

To the media

POLA Pharma Inc.

## **Launch of Duac<sup>®</sup> Gel, a combination drug for the treatment of acne vulgaris, and a sales alliance between GSK and POLA Pharma**

GlaxoSmithKline K.K. (President: Philippe Fauchet; head office: Shibuya-ku, Tokyo; hereinafter "GSK") and POLA Pharma Inc. (President: Yasunori Inaoka; head office: Shinagawa-ku, Tokyo; hereinafter "POLA Pharma") today announced the launch of Duac<sup>®</sup> Gel, and their collaboration in conducting its sales promotion and distribution activities.

Commenting on the launch and sales alliance of Duac<sup>®</sup>, GSK President Philippe Fauchet said, "I am delighted that we are finally able to deliver Duac<sup>®</sup> Gel, which has been widely used globally as a combination drug for the treatment of acne vulgaris, to patients in Japan. POLA Pharma, our partner in the sales collaboration of Duac<sup>®</sup> has long specialized in the dermatology sector, and has extensive experience in dealing with skin diseases. I am confident, therefore, that this arrangement will enable us to offer appropriate information, and deliver Duac<sup>®</sup> to patients in need of this drug."

POLA Pharma President Yasunori Inaoka commented on the launch and sales alliance of Duac<sup>®</sup> as follows:

"We intend to carry out business activities specializing in the dermatology sector by gathering an extensive line-up of products, from prescription drugs to dermocosmetics, and meet the broad range of patients' needs and requests, from treatment to care. Leveraging this opportunity to provide information on Duac<sup>®</sup> Gel on this occasion, we hope to do our best to deliver new treatment options to patients who suffer from acne vulgaris, thereby further contributing to these patients".

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## About acne vulgaris

Acne vulgaris, generally known as "pimples," is a disease in which a variety of eruptions develop after adolescence, mostly on the face, chest and the back. In Japan, over 90% of the people are estimated to be affected by acne vulgaris<sup>1</sup> at some time in their lives. Acne vulgaris develops in parts of the body that become most noticeable, such as the face, and is a disease that raises concerns about a decline in the patient's quality of life (QOL) since it has an adverse impact on his or her emotions and feelings. Despite this, the notion that it is a skin disease that must be aggressively treated has not spread among the general public. Therefore, the rate of patients visiting medical institutions to undergo treatment is low<sup>1</sup>, and it is believed that there are many patients who are not receiving treatment.

## About Duac<sup>®</sup> Gel

Duac<sup>®</sup> Gel is a combination agent containing clindamycin (hereinafter "CLDM"), a lincomycin antibacterial drug that can be expected to demonstrate actions to suppress the growth of *Propionibacterium acnes* in the skin and the hair follicle infundibulum, and benzoyl peroxide (hereinafter "BPO"), an oxidant possessing disinfectant and keratin peeling actions which has been used overseas for more than 50 years as a standard treatment drug for acne vulgaris. Duac<sup>®</sup> Gel obtained its approval on March 26 2015.

Duac<sup>®</sup> is currently approved and available in more than 80 countries around the world including US, Europe, Asia, Australia, Latin America and Canada, and also introduced as the first-line treatment for Mild-to-moderate papulopustular acne in European Evidence-based (S3) Guidelines for the treatment of acne<sup>2</sup>.

Duac<sup>®</sup> Gel will be Japan's first combination drug for use in the treatment of acne vulgaris.

## **Product overview of Duac<sup>®</sup> Gel**

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<sup>1</sup> Nobukazu Hayashi, Hirohiko Akamatsu, Keiji Iwatsuki et al. Guidelines for the Treatment of Acne Vulgaris. The Japanese. Journal of dermatology 118: 1893-923, 2008.

<sup>2</sup> Nast A., Dreno B., Bettoli V., Degitz K. et al. European evidence-based (S3) guidelines for the treatment of acne. JEADV 2012; 26(suppl. 1): 1-29

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Product name	Duac® Gel
Generic name	1% Clindamycin -3% benzoyl peroxide gel
Date of approval	March 26, 2015
Date of Launch	July 17, 2015
Price	¥ 157.40 / 1g
Indications	Bacterial strains: <i>Staphylococcus</i> and <i>Propionibacterium acnes</i> that have sensitivity to the drug Indication: Acne vulgaris
Dosage and administration	Apply adequate amounts to the affected area once a day after facial washing.