

PRESS RELEASE



February 1 2016

POLA Pharma Inc.

Execution of Licence Agreement in Japan for “Duac[®] Gel”, a combination drug for the treatment of acne vulgaris

It is announced today that Stiefel Laboratories (Ireland) Limited, a group company of GlaxoSmithKline, plc. and POLA Pharma Inc. (President: Yasunori Inaoka; head office: Shinagawa-ku, Tokyo; hereinafter “POLA Pharma”) executed the Licence Agreement (hereinafter “this Agreement”) for “Duac[®] Gel”, the treatment of acne vulgaris, of which approval in Japan was obtained by GlaxoSmithKline K.K. As announced on July 17th POLA Pharma has started promotion activities of “Duac[®] Gel” in accordance with a sales alliance between both companies.

Under the terms of this Agreement, Marketing Authorization of “Duac[®] Gel” in Japan will be transferred to POLA Pharma in due course.

1. Object of this Agreement

- POLA Pharma carries out prescription drug business activities specializing in the dermatology sector. In addition to providing brand drugs, the company's aim is to dedicate to the treatment of patients who suffer from dermatology ailment by proposing the solution to the skin troubles associated with dermatology diseases. Leveraging this opportunity to add “Duac[®] Gel” to its product line, POLA Pharma hopes to strengthen its contribution to dermatology field.
- POLA-ORBIS Group performs research and development activities of acne care in cosmetics sector. The group expects synergy effect in acne field by this Agreement.

2. Execution Date of this Agreement:

29 January, 2016

3. Future Prospects

In accordance with this Agreement, GlaxoSmithKline group will be in charge of manufacture of “Duac[®] Gel” and POLA Pharma will carry out the exclusive business activities of “Duac[®] Gel” in Japan on a long term basis.

About “Duac[®] Gel”

Acne vulgaris, generally known as "pimples," is a disease caused by “abnormal lipid metabolism (endocrine factors)”, “keratosis(hyper keratosis)”, and “growth of bacteria” 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 vulgaris¹. 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 low¹, and it is believed that there are many patients who are not receiving treatment.

“Duac[®] Gel” is a combination agent containing clindamycin, 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, 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[®] Gel obtained its approval on March 26th 2015.

Duac[®] is currently approved and available in more than 80 countries around the world including US, Europe, Asia, Australia, and also introduced as the first-line treatment for Mild-to-moderate papulopustular acne in European Evidence-based (S3) Guidelines for the treatment of acne².

“Duac[®] Gel” is Japan’s first combination drug for use in the treatment of acne vulgaris. Available dosage of “Duac[®] Gel” in Japan is combination of 1% clindamycin and 3% benzoyl peroxide.

For further information of “Duac[®] Gel,” please visit

<http://www.pola-pharma.co.jp/medicalmedicines/duac/medical/index.html>

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

² 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

About GlaxoSmithKline plc

Company name	GlaxoSmithKline plc
Headquarters	United Kingdom
CEO	Andrew Witty
Business description	Research & development and sales & marketing of prescription drug, Vaccines, OTC drug and consumer goods

About GlaxoSmithKline K.K.

Company name	GlaxoSmithKline K.K.
Headquarters	4-6-15 Sendagaya, Shibuya-ku, Tokyo, Japan
President	Philippe Fauchet
Business description	Research & development, import and sales & marketing of prescription drugs, OTC drugs and consumer goods
Capital	JPY2,067,410,000
Establishment	August 18, 1953

About POLA Pharma

Company name	POLA Pharma Inc.
Headquarters	8-9-5 Nishigotanda, Shinagawa-ku, Tokyo, Japan
Representative	Yasunori Inaoka, Representative Director and President
Business description	Research & development, import and sales & marketing of prescription drugs and dermocosmetics
Capital	JPY100,000,000
Establishment	January 5, 2007

About GSK

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GSK – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

About POLA Pharma

POLA Pharma, one of the group companies of POLA ORBIS Group that holds up group policy “Inspire all people and touch their hearts”, started operation in 2007 as the dermatology specialty pharma. With our wish that people around the world will live healthy and beautifully, we will devote our total efforts towards fully understanding the problems and needs of our patients, investigating to find the true cause of dermatologic diseases and offer effective solutions.

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<http://www.pola-pharma.co.jp>