

Synthetic Antibacterial Agent, Baktar[®]
Approval for Additional Indication of Prophylaxis and Treatment for
Pneumocystis Pneumonia

Osaka, Japan, August 10, 2012 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced it has received an approval for an additional indication of prophylaxis and treatment for Pneumocystis pneumonia of “Baktar[®] combination tablet” and “Baktar[®] combination granule” (generic name: sulfamethoxazole/trimethoprim combination).

The Second Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, held on February 1, 2012, was evaluated preliminary and allowed to submit an additional indication of Baktar[®]. Shionogi submitted an additional indication of prophylaxis and treatment for Pneumocystis pneumonia on February 13, 2012. Regarding this additional indication of Baktar[®], the Investigational Committee for the Unapproved Drugs and Off-label Drug Use with High Medical Needs, established by the Ministry of Health, Labour and Welfare (hereafter “MHLW”), agreed with the medical necessity and MHLW requested its development to Shionogi.

Shionogi anticipates Baktar[®] will bring a new treatment option to patients and medical experts by the approval and is striving to make contributions to the resolution of the Unapproved Drugs and Off-label Drug Use.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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