

Translation

Synthetic Antibacterial Agent, Bactramin[®] Filed for Additional Indication By “Application Based on Evidence in the Public Domain”

February 13, 2012-Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, “Chugai”)] announced today that on February 13, it filed an “application based on evidence in the public domain” to the Japanese Ministry of Health, Labour and Welfare seeking approval for the indication “*Pneumocystis pneumonia* and prevention of its development^{*1}” for Bactramin[®]. Bactramin[®] is a synthetic antibacterial trimethoprim - sulfamethoxazole (TMP-SMX) combination with brand names: “Bactramin[®] Combination Tablet” and “Bactramin[®] Combination Granule.” In Japan, Bactramin[®] is currently approved for the indications of “pneumonia, secondary infection caused by chronic respiratory lesion, complicated cystitis, pyelonephritis, infectious enteritis, typhoid, or paratyphoid^{*2}.”

As a result of the evaluation by the “Review Committee on Unapproved Drugs and Indications with High Medical Needs^{*3}” held on December 22, 2011, an application based on evidence in the public domain is applicable when filing for this indication. The filing was made based on the decision at the meeting of the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on February 1, 2012, which confirmed that filing through the “application based on evidence in the public domain” was reasonable for this additional indication.

Pneumocystis pneumonia (PCP) is a so-called opportunistic infection occurring in immunocompromised patients due to HIV infection or the use of immunosuppressants. It is a serious disease with a mortality of almost 100% if left untreated. In patients with HIV infection, the incidence of PCP is highest (approximately 40%) among AIDS indicator diseases, and the mortality (per month) of PCP is estimated to be 15 to 20%. In non-HIV infected patients who are on immunosuppressants, symptoms often rapidly deteriorate, and the mortality (per month) is assumed to be approximately 40% for non-HIV infected patients, and as high as approximately 60% for patients requiring artificial respiratory management. Furthermore, the prognosis is often poor in patients with underlying lung disease, and PCP may progress to pulmonary impairment even after recovering.

Chugai will make efforts toward an early approval so that Bactramin[®] can be provided to patients as a treatment for “*Pneumocystis pneumonia* and prevention of its development.”

- *1 Applicable strains are sulfamethoxazole/trimethoprim-sensitive *Enterococcus*, *Escherichia coli*, *dysentery bacillus*, *typhoid bacillus*, *paratyphoid bacillus*, *Citrobacter*, *Klebsiella*, *Enterobacter*, *Proteus*, *Morganella morganii*, *Providencia rettgeri* and *Haemophilus influenza*.
- *2 An applicable strain is *Pneumocystis jiroveci*.
- *3 The “Review Committee on Unapproved Drugs and Indications with High Medical Needs” was established for the purpose of “enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of “application based on evidence in the public domain” and investigating the need for studies that should be additionally conducted.”