

July 16, 2008
Asubio Pharma Co., Ltd.
DAIICHI SANKYO COMPANY, LIMITED

Asubio Pharma's Inherited Metabolic Disease Agent Biopten® Receives Approval for Additional Indication

Asubio Pharma Co., Ltd. (Asubio Pharma; Head Office: Minato-ku, Tokyo; President & CEO: Seiichi Yokoyama), one of the group companies of DAIICHI SANKYO COMPANY, LIMITED, announced an additional indication for the inherited metabolic disease agent **Biopten®** (generic name: sapropterin hydrochloride) for the treatment of “tetrahydrobiopterin (BH4) responsive hyperphenylalaninemia (HPA).”

The pharmaceutical **Biopten®** is a highly pure chemically synthesized form of the BH4 that occurs naturally in the human body. It treats HPA patients by ameliorating the serum phenylalanine level as summarized below.

	Existing Indication	Additional Indication
Indication	Atypical HPA ¹	BH4 responsive HPA ²
Cause of Disease	Inherited genetic abnormality affecting the enzymes that biosynthesize BH4	Inherited genetic abnormality affecting phenylalanine hydroxylase
Action	Treats hyperphenylalaninemia (HPA) by ameliorating the serum phenylalanine level	
Approval	March 1992	July 2008

¹ Lowers serum phenylalanine levels associated with atypical HPA based on deficiency of dihydrobiopterin synthase and/or dihydrobiopterin reductase.

² Lowers serum phenylalanine levels associated with BH4 responsive HPA based on deficiency of phenylalanine hydroxylase.

Maruho Co., Ltd. marketed **Biopten®** under a contract that expired at the end of June, 2008. From July 1, DAIICHI SANKYO COMPANY, LIMITED began marketing **Biopten®** under a contract.

For inquiries:

Asubio Pharma Co., Ltd., Management Planning Department, Tel: +81-3-3588-9600
DAIICHI SANKYO COMPANY, LIMITED, Corporate Communication Department,
Tel:+81-3-6225-1126

Reference:

About Biopten®

Biopten®, an inherited metabolic disease agent, was developed by the Pharmaceuticals Division of Suntory Limited (now Asubio Pharma Co., Ltd.) for the treatment of atypical HPA and launched in 1992 in Japan. The recently approved additional indication is an authorized orphan drug for treating rare diseases. In the year ended March 2008, sales of **Biopten®** in Japan on a National Health Insurance price basis were approximately ¥1 billion.

About BH4 Responsive HPA

HPA results because of an inability to metabolize the essential amino acid phenylalanine due to a genetic disorder in phenylalanine hydroxylase. This metabolic abnormality is expressed as an inability to maintain blood phenylalanine levels within the normal range. If treatment does not begin soon after birth, the accumulation of phenylalanine causes mental retardation and other irreversible damage to the central nervous system. Treatment was not previously available in Japan, except for a restricted phenylalanine diet. However, strict, long-term control of protein intake through dietary management was difficult.

Research of this treatment in Japan in 1999 was the first in the world to confirm subtypes in which treatment with **Biopten®** normalized blood phenylalanine levels. Subsequent clinical research confirmed long-term efficacy in maintaining blood phenylalanine levels within a normal range. Continued use of **Biopten®** promotes normal development while notably improving treatment compliance, and we expect **Biopten®** to improve the quality of life of infants diagnosed with the condition as well as their parents.

Corporate Profile

Asubio Pharma Co., Ltd.

Head Office:	Minato-ku, Tokyo, Japan
President & CEO:	Seiichi Yokoyama
Date of Inauguration:	December, 2002
Capital:	¥11.0 billion
Stockholder:	DAIICHI SANKYO COMPANY, LIMITED, 100%
Employees:	317 (including group companies; as of March 31, 2008)
Primary Business:	Research and development, manufacturing and sale of pharmaceuticals

DAIICHI SANKYO COMPANY, LIMITED

Head Office:	Chuo-ku, Tokyo, Japan
President & CEO:	Takashi Shoda
Date of Inauguration:	September, 2005
Capital:	¥50.0 billion
Employees:	15,349 (consolidated; as of March 31, 2008)
Primary Business:	Research & development, manufacturing and sales & marketing of pharmaceutical products