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Synthon Pharmaceuticals Receives FDA Final Approval for Paroxetine Mesylate

CHAPEL HILL, N.C. -- Synthon Pharmaceuticals, Ltd. today announced that the U. S. Food and Drug Administration granted final approval to its Paroxetine Mesylate 10 mg, 20 mg, 30 mg, and 40 mg tablets for the treatment of depression, obsessive/compulsive disorder and/or panic disorder. Synthon's Paroxetine is an alternative for patients in need of, or currently undergoing, selective serotonin reuptake inhibitor (SSRI) therapy and will be an alternative for physicians prescribing paroxetine therapy.

"This is great news for those currently undergoing paroxetine therapy to treat their depression, panic disorder or obsessive/compulsive disorder. Synthon's new product will provide patients, taxpayers, insurers and other third-party payers with a safe, effective, more affordable alternative for patients on paroxetine or other branded SSRI therapies. Synthon's Paroxetine offers an opportunity for those who pay for paroxetine or other SSRI therapy to find real value in their healthcare expenditures while ensuring safe, effective treatment," said Dr. William J. Taylor, President of Synthon Pharmaceuticals, Ltd.

Synthon's Paroxetine will be a brand product composed of paroxetine mesylate. Paxil? is composed of paroxetine hydrochloride. The chemical difference between the two products is that the inactive part of the salt (mesylate or hydrochloride) is separated from the active paroxetine molecule in the gastrointestinal tract, leaving only the active paroxetine molecule to be absorbed into the bloodstream and provide the intended therapeutic effect.

"Doctors will be able to prescribe Synthon's Paroxetine with confidence, knowing they are providing their patients with a safe and effective treatment at a price that is more affordable. Last year, U.S. patients, employers and insurers spent over $2 billion in the paroxetine therapy market. Synthon's new product will provide consumers, insurers and other third-party payers with a chance to vote with their pocketbooks: they will be able obtain savings in this important and growing market by using Synthon's Paroxetine. The market tells us that the medical community and third-party payers want a reasonably priced SSRI product, and that's what Synthon will deliver," Dr. Taylor continued.

European clinicians have used Synthon's Paroxetine with confidence for over two years, resulting in considerable savings for European consumers. Synthon will be bringing those savings to U.S. consumers.

"Competition and choice bring savings, and those savings will allow patients, payers and governments to stretch limited healthcare resources as far as possible. Synthon's Paroxetine brings real competition and benefit to the American SSRI and paroxetine therapy market and the ultimate winners will be patients and payers," Dr. Taylor concluded.

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