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Quetiapine Fumarate ER gets drug registration approval by NMPA

September 9, 2019 | News

The Drug is suitable for the treatment of schizophrenia and bipolar disorder by blocking D2 and 5-HT2 receptors of the cranial nerves from binding with dopamine, a neurotransmitter, to retard the transmission among cranial nerves



Sihuan Pharmaceutical Holdings Group Ltd. on 27 August 2019, announced that the Quetiapine Fumarate ER Tablet, an antipsychotic drug jointly developed with its subsidiary PharmaDax (FoShan) Co., Ltd., has been granted drug registration approval by the National Medical Products Administration (the ‘‘NMPA’’) of China. The Drug has been approved by the Food and Drug Administration of the United States of America (‘‘US FDA’’) in 2017 and is available on the US market.

The principal composition of the Drug is quetiapine fumarate which is an atypical antipsychotic drug. The Drug is mainly suitable for the treatment of schizophrenia and bipolar disorder by blocking D2 and 5-HT2 receptors of the cranial nerves from binding with dopamine, a neurotransmitter, to retard the transmission among cranial nerves.

According to IMS Health Inc., the overall market of antipsychotic drugs in the PRC in 2018 was approximately RMB6.4 billion, of which approximately RMB780 million was attributable to quetiapine which was ranked third and commanded a market share of 12.2%. The Drug is currently available in the PRC market only in the form of originator. PharmaDax is the second pharmaceutical manufacturer in the PRC granted drug registration approval from NMPA and the first PRC enterprise granted generic drug registration approval for the Drug.

Based in FoShan of Guangdong province, PharmaDax has two US FDA-compliant production facilities with advanced drug production technology for manufacturing high quality generic drugs.

Dr. Che Fengsheng, the Chairman and Executive Director of the Group said, “The grant of Quetiapine Fumarate ER Tablet drug registration approval will further complete and enrich the Group’s product lines so as to meet market demand. Apart from meeting the patients’ medication need, it will also generate satisfactory return for the Group. Determined to overcome new challenges and capture new opportunities, Sihuan Pharmaceutical is determined to strengthen its operation fundamentals to drive its short- to mid-term growth and relocate more resources to its R&D projects, building on its

substantial experiences of close to 20 years in the pharmaceutical industry."

Some products in the Group's generic drug pipeline are expected to be the first three products of its kind to pass or to be deemed as passing quality consistency evaluation ("QCE"), being expected to pass the assessment starting from the second half of 2019. As of the end of June 2019, the Group's generic drug platform has begun QCE application procedure for 7 products, in which 3 products have already been submitted approval and 1 product has been granted approval. During the Period, 1 production approval has been acquired, 37 generic drugs projects of the Group are currently undergoing the review and approval process at NMPA and 109 projects are under research.

NMPA continues to optimize the approval process for drug registration. This not only shortens the timeframe for clinical researches of innovative drugs and generic drugs, but also contributes to more effective pharmaceutical R&D in terms of policy guidance. The Group is expected to further enrich the product portfolio by launching a number of generic drugs in the coming years, thus adding new revenue to the Group as well as meeting the market's need.