IRONSHORE PHARMACEUTICALS

Dear Silver State Scripts Board Stakeholders,

My name is Dr. Justin Barnes, I am a medical science liaison for Ironshore, and I want to thank the Board for allowing me this opportunity to make a few comments regarding JORNAY PM[1].

My intention today is to articulate how JORNAY PM is fundamentally different from the other stimulant products currently on the market. Quite simply these fundamental differences are the site, rate, and extent of methylphenidate absorption[2,3]. Every other long-acting stimulant is manufactured with an immediate-release component to provide rapid onset, followed by an extended-release mechanism. JORNAY PM has a single release mechanism, with no immediate release. Every other stimulant medication is absorbed rapidly in the stomach and small intestine, however, JORNAY PM is absorbed slowly in the large intestine.

Pharmacokinetically, this means the absorption of JORNAY PM occurs gradually; achieving therapeutic levels at the time of waking, with exposure that can be individualized to continue from the late afternoon until bedtime in a dose-dependent manner, without peaks and troughs throughout the day. Clinically, this means that JORNAY PM allows physicians to tailor the duration of ADHD symptom control by simply titrating the once-daily dose so that it is working when the patient wakes up and continues working for as long as they need it[4,5]. JORNAY PM is also uniquely administered – it is taken in the evening, thought to be a less chaotic time of day, and capsules can be swallowed whole or opened and sprinkled on applesauce, giving an option for individuals who have difficulties swallowing[1,2].

Ironshore has demonstrated the PK profile of JORNAY PM in multiple studies, and its clinical profile in three randomized controlled trials. Clinical trials evaluating the effect of JORNAY PM demonstrated that most participants experienced reductions in functional impairments associated with ADHD from a level of severe impairment to a level equal to or below the 80th percentile of a representative population of youths[6,7]. Statistically significant reductions in functional impairment have been replicated in the afternoon, the evening, as well as in the morning – i.e. from the time of waking until the time the clinical trial subjects went to bed.

No other stimulant product has demonstrated the ability to control ADHD symptoms and reduce functional impairment both upon wakening in the morning and in the evening. Yes, some stimulant products work relatively quickly in the morning, and some do well in the evening, but none have been demonstrated to provide symptom control upon wakening in the morning and in the evening with a single dose.

Of course, safety is of critical importance and JORNAY PM has a clinical trial safety profile consistent with other long-acting stimulants; a finding confirmed through our first 22 months of post-marketing surveillance.

Given the need for individualized full day coverage in the treatment of ADHD, and the proven clinical attributes of JORNAY PM, Ironshore requests the Committee consider designating JORNAY PM as a preferred medication on your PDL. This addition would afford Medicaid providers and their ADHD patients with greater accessibility to a differentiated option that provides full-day coverage.

Thank you for your consideration and with that I am happy to respond to any questions you have.

Citations

[1] JORNAY PM Package Insert. Access here.

[2] Childress AC, Mehrotra S, Gobburu J, Mclean A, DeSousa NJ, and Incledon B: Single-dose Pharmacokinetics of HLD200, a Delayed-Release and Extended-Release Methylphenidate Formulation, in Healthy Adults and in Adolescents and Children with Attention-Deficit/Hyperactivity Disorder. *J Child Adolesc Psychopharmacol* 28(1): 10-18, 2018. Link here.

[3] Liu T, Gobburu J, Po MD, McLean A, DeSousa NJ, Sallee FR, and Incledon B: Pharmacokinetics of HLD200, a Delayed-Release and Extended-Release Methylphenidate: Evaluation of Dose Proportionality, Food Effect, Multiple-Dose Modeling, and Comparative Bioavailability with Immediate-Release Methylphenidate in Healthy Adults. *J Child Adolesc Psychopharmacol* 29(3): 181-191, 2019. Link here.

[4] Childress AC, Cutler AJ, Marraffino A, McDonnell MA, Turnbow JM, Brams M, DeSousa NJ, Incledon B, Sallee FR, Wigal SB: A Randomized, Double-Blind, Placebo-Controlled Study of HLD200, a Delayed-Release and Extended-Release Methylphenidate, in Children with Attention-Deficit/Hyperactivity Disorder: An Evaluation of Safety and Efficacy Throughout the Day and Across Settings. *J Child Adolesc Psychopharmacol* 30(1):2-14, 2020. Link here

[5] Pliszka SR, Wilens TE, Bostrom S, Arnold VK, Marrafino A, Cutler AJ, Lopez FA, DeSousa NJ, Sallee FR, Incledon B, Newcorn JN: Efficacy and Safety of HLD200, Delayed-Release and Extended-Release Methylphenidate, in Children with Attention-Deficit/Hyperactivity Disorder. *J Child Adolesc Psychopharmacol* 27(6):474-482, 2017. Link here.

[6] Faraone SV, DeSousa NJ, Komolova M, Sallee FR, Incledon B, and Wilens TE: Functional Impairment in Youth With ADHD: Normative data and Norm-Referenced Cutoff Points for the Before School Functioning Questionnaire and the Parent Rating of Evening and Morning Behavior Scale, Revised. *J Clin Psychiatry* 81(1): 2019. Link here.

[7] Wilens TE, Faraone SV, Hammerness PG, et al. Clinically meaningful improvements with DR/ER-MPH in at-home functional impairment during the early morning, late afternoon, and evening in children with attention-deficit/hyperactivity disorder. Poster presented at: 31stAnnual Psych Congress; October 25-28, 2018; Orlando, FL.

[8] Faraone SV, Wilens TE, Pliszka SR, et al. Improvements in at-home functional impairment with DR/ER-MPH in children with ADHD: post hoc analysis of BSFQ and PREMB-R by norm-referenced cut-offs. Poster presented at: Academy of Managed Care Pharmacy (AMCP) Annual Meeting; March 25-28, 2019; San Diego, CA.