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Biohaven receives agreement from FDA on initial pediatric study plan

November 28, 2017 | News

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Biohaven Pharmaceutical Holding Company Ltd. has announced that the Company has received agreement from the U.S. Food and Drug Administration (FDA) on the initial pediatric study plan (iPSP) for orally-dosed rimegepant.

Rimegepant is a second-generation, small molecule, calcitonin gene-related peptide (CGRP) receptor antagonist being developed for the acute treatment of migraine. Agreement on an iPSP is one of the regulatory requirements that must be met prior to submitting a new drug application (NDA).

Vlad Coric, M.D., Chief Executive Officer of Biohaven said, “We are pleased to have the FDA’s agreement on an iPSP, which marks another key milestone in our CGRP development program. Millions of Americans who suffer from migraine are not being helped by the current approved therapies, and we believe rimegepant has the potential to provide them with a safe and effective migraine treatment with the ease of oral dosing. We are now another step closer toward preparing our regulatory package and eagerly await topline data from our two Phase 3 trials in the first quarter of 2018.”

Biohaven recently reported completion of enrollment in the first of the Company’s two pivotal Phase 3 studies evaluating the efficacy and safety of rimegepant in the acute treatment of migraine. Patients who have participated in the Phase 3 clinical trials are eligible to participate in an ongoing long-term safety study. In addition to rimegepant, Biohaven is also pursuing the development of its third generation CGRP-receptor antagonist, BHV-3500, for acute and preventative treatment for migraine.

Marianne Frost, Head of Regulatory Affairs at Biohaven said, “Our regulatory team has been working since May of 2017 to gain alignment with the FDA on the iPSP, and we are very pleased to have now accomplished this important step toward an NDA filing. Our development program for rimegepant is designed to demonstrate comprehensive and durable treatment benefits and a favorable safety profile for migraine sufferers.”