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Amneal Targets Migraine With 505(b)(2) Filing

Pursues Headache Market In US With Dihydroergotamine Autoinjector

by David Wallace

Amneal is setting its sights on the migraine and cluster headache market in the US with a new hybrid 505(b)(2) filing for a dihydroergotamine autoinjector.

Amneal says it will leverage its commercial infrastructure and experience in the neurology space to capitalize on its latest product opportunity, a hybrid 505(b)(2) filing for a dihydroergotamine pre-filled syringe autoinjector aimed at the migraine and cluster headache market in the US.

Announcing the US Food and Drug Administration's acceptance of its 505(b)(2) new drug application, Amneal said it "anticipates a decision by the middle of 2022."

"If approved, Amneal anticipates a commercial launch in the second half of 2022," the firm said, confirming that it "plans to commercialize the product solely in the US market."

Noting that dihydroergotamine is commonly administered in emergency rooms, urgent care facilities and headache clinics intravenously, Amneal pointed out that the product was currently available as ampules for injection or as a nasal spray formulation for at-home use. But the firm's autoinjector version "would allow patients to self-administer dihydroergotamine via a single-dose, ready-to-use autoinjector pen without the need for assembly."

The proposed indication for the product is acute migraine with and without aura and cluster headache in adults.

Explaining how the product fits with Amneal's overall strategy, Joseph Todisco – chief

commercial officer for Amneal Specialty – said “the addition of the dihydroergotamine autoinjector reflects our commitment to expand our Specialty portfolio by bringing impactful therapies that deliver differentiated value for patients in need.” He added, “we plan to leverage our existing commercial infrastructure in neurology and experience in the migraine and headache space to bring this product to market.”

Citing IQVIA data, Amneal said US sales of all forms of dihydroergotamine for the year ended March 2021 were around \$70m.

“Over 39 million Americans are living with migraine, and up to one million with cluster headache,” the firm noted. “Headache is the fourth most common reason for emergency department visits, and accounts for 3% of all emergency room visits in the US.”

Amneal recently set out its goal of launching six to seven “high-value” products annually, with a goal of driving up profitability as it transitions to more “complex dosage forms, drug-device combinations and other high-value programs.” (Also see "[Amneal Aims To Bolster Generics Margins](#)" - Generics Bulletin, 13 May, 2021.)

The company’s recent acquisition of Kashiv Specialty Pharmaceuticals (*see sidebar*) gave the firm a pipeline of “valuable 505(b)(2) branded products primarily in neurology and endocrinology, where we have a well-established commercial infrastructure, as well as a valuable pipeline of complex generics.”

Amneal’s specialty segment, that centers around neurology and endocrinology, saw a 9% jump in revenues to \$96m in the first quarter of 2021, while the generics side of the business saw an 11% slide in its net revenue to \$313m.

Amneal Takes Control Of Kashiv Specialty In \$100m+ Deal

By **David Wallace**

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Amneal will take a majority stake in Kashiv Specialty Pharmaceuticals after striking a deal worth potentially more than \$100m for a 98% stake in the hybrid 505(b)(2) and complex generics specialist.

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