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Celltrion Takes Aim At US Infliximab Market With Subcutaneous Launch

Korean Firm's Zymfentra Is First And Only SC Version Of Infliximab Approved By The FDA

by David Wallace

Celltrion has delivered on its long-awaited US launch of its Zymfentra subcutaneous formulation of infliximab, sold in other territories as Remsima SC.

Celltrion is hoping to make waves in the US infliximab market after launching its flagship Zymfentra (infliximab-dyyb) product, billed as "the first US Food and Drug Administration-approved subcutaneous infliximab."

Zymfentra is approved for maintenance therapy in adults with moderately to severely active ulcerative colitis or moderately to severely active Crohn's disease following an induction treatment regimen with an infliximab product administered intravenously, with a recommended dose of 120mg every two weeks.

The product – which was approved by the FDA in October last year (*see sidebar*) – "will be under patent protection through 2037 for its dosage form and route of administration by 2040," Celltrion underlined.

In Europe – where the product is sold as Remsima SC and began capturing market share soon after launch (Also see "*Celltrion's Remsima SC Biosimilar Starts Strong In EU5 Countries*" - Generics Bulletin, 20 Jan, 2021.) – approval came as an extension to the marketing

Celltrion Gets FDA Nod For Subcutaneous Infliximab

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authorization for the Remsima biosimilar to reference brand Remicade.

This process was followed because there was no existing subcutaneous infliximab brand to use as a basis for extrapolation of indications, meaning that the firm had to submit studies to support each indication for the subcutaneous version.

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Celltrion has received FDA approval for Zymfentra, its subcutaneous formulation of infliximab that is marketed in other global territories as Remsima SC.

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However, in the US the product was approved as a biologics license application under the 351(a) novel pathway, meaning it is considered a new biologic. The approval was based on phase III pivotal data that demonstrated Zymfentra's superiority in clinical remission and endoscopic response compared to placebo for maintenance treatment after induction therapy with the intravenous formulation of infliximab in patients with UC and CD over a 54-week study period.

"The overall safety profile of Zymfentra was similar to that of placebo during maintenance period in both studies, with no new safety signals seen," Celltrion detailed.

"Infliximab is a well-established treatment for people living with ulcerative colitis or Crohn's disease," commented Thomas Nusbickel, chief commercial officer at Celltrion USA. "The novel subcutaneous administration represents an important advancement in patient care that can offer a convenient treatment option, allowing patients in the US to have greater flexibility in managing their disease."

Adding Value Through Innovation

Last year, Nusbickel highlighted Zymfentra as one of the key upcoming product opportunities for the company as Celltrion built out its US front-end business (*see sidebar*).

In particular, he emphasized the opportunity to "add additional value" thanks to the product's innovative subcutaneous formulation.

"Celltrion filed for the approval through the normal [BLA] pathway," he noted. "That's what the FDA was looking for." The result was "a unique product with differentiation," he summarized.

"You know, here's a product where

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By David Wallace

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With Celltrion transitioning to a direct sales model in the US after previously partnering with other firms to market its biosimilars, the

previously a patient and a health care provider would provide an infusion, up to two hours. You can think about how convenient this would be for the patient and the health care providers, the insurers also will be looking at this, and seeing that this could potentially have additional value for them to be able to manage these patients at home. So I think it's really an exciting development."

company's new US chief commercial officer, Tom Nusbickel, talks to *Generics Bulletin* about how the firm is gearing up to launch three key products.

Read the full article here

The US introduction of Zymfentra ultimately came a couple of weeks later than expected, with Celltrion having previously trailed a launch by the end of February. (Also see "*What's Next? Five Things To Look Out For In February*" - Generics Bulletin, 1 Feb, 2024.)