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Apotex And Ambio Shatter Hopes Of Teriparatide Exclusivity For Teva

Another Forteo Generic Receives Approval From US FDA, With More Potentially On The Way

by David Wallace

Partners Apotex and Ambio have announced approval of a second US teriparatide generic from the FDA, adding another Forteo rival to the market and removing hopes that Teva's recently approved first generic could benefit from 180 days of market exclusivity. Further competition is also in the works with Amphastar awaiting FDA action on a further teriparatide ANDA.

A second generic rival to Eli Lilly's Forteo (teriparatide) has been given the green light by the US Food and Drug Administration, with Ambio announcing FDA approval of a version that it developed and which is set to be marketed "immediately" by partner *Apotex*.

The fresh teriparatide approval rapidly adds a second generic competitor to the market shortly after *Teva* announced its own FDA approval for the first US generic version of the osteoporosis treatment – along with its own imminent launch (*see sidebar*) – and eliminates previous hopes that Teva could benefit from a period of market exclusivity for such a key product opportunity.

Back in 2019, Teva's device partner Antares Pharma had indicated that Teva and originator Lilly had settled US Paragraph IV litigation over Forteo on "undisclosed" terms, further indicating that "based on available information, Antares believes Teva may have first-to-file status and therefore [be] entitled to 180 days of marketing exclusivity."

As recently as last year, Antares had indicated that it still expected Teva's version to benefit from six months of exclusivity on the US market once approved and launched.

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FDA records show that the Apotex/Ambio product was tentatively approved on 16 November, around the same time as Teva announced its FDA approval.

At the time, Teva did not respond to *Generics Bulletin* enquiries over any exclusivities for its teriparatide generic.

Now, however, Ambio's announcement of the second generic approval and immediate launch by Apotex – which has been under new ownership since SK Capital Partners acquired the firm earlier this year (Also see "*A New Era: Apotex Gets Fresh Leadership As SK Completes Acquisition*" - Generics Bulletin, 11 Apr, 2023.) – removes any possibility of exclusivity for Teva.

Teva Delivers First US Forteo Equivalent

By David Wallace

20 Nov 2023
Teva has celebrated a US nod for its generic version of Forteo, the first substitutable teriparatide rival to be approved by the US Food and Drug Administration.

Read the full article here

"Ambio is a world leader in developing complex peptides," declared the firm's president Simrat Singh. "Our highly skilled techniques in controlling various kinds of peptide-related synthetic impurities together with expertise in developing advanced analytical methods to thoroughly characterize the peptides sets us apart in the pharmaceutical industry. We are thrilled that the teriparatide injection developed by Ambio has received FDA approval."

Meanwhile, Ambio founder, chairman and CEO Chris Bai said the approval "further validates our expertise and technological innovation as a developer and manufacturer of complex generic drugs and supports our commitment to bring high quality and affordable therapies to patients."

"We are pleased to partner with Apotex in this effort," Bai added, "which allowed them to expeditiously secure FDA approval and immediately execute product launch."

Apotex senior vice-president of global regulatory affairs Kiran Krishnan said the launch of teriparatide "reflects Apotex's continued focus on improving access for patients to affordable complex generic drugs," underlining that "we are pleased to deliver this critical product, in partnership with Ambio, that we believe will be essential in improving the quality of life for osteoporosis patients in the US."

Amphastar Awaits ANDA Authorization

A further teriparatide generic could also be on the horizon, with *Amphastar* indicating that FDA action on a pending abbreviated new drug application for its own Forteo rival is due in the first quarter of next year.

Amphastar's ANDA was knocked back by the FDA last year in a complete response letter, albeit with analysts suggesting that the news was unsurprising and that a CRL was "the most likely outcome for first FDA review cycle." (Also see "*Amphastar's Forteo ANDA Hit With CRL As Wait Goes On*" - Generics Bulletin, 14 Jun, 2022.)

Amphastar is working on resolving its CRL and according to its latest disclosures the product has an FDA action date of Q1 2024. However, it remains to be seen whether FDA approval will follow.

Another teriparatide product already on the market is Ligand/Alvogen's Bonsity, a 505(b)(2) hybrid NDA product that was launched back in June 2020. (Also see "*Pfenex And Alvogen Launch US Teriparatide*" - Generics Bulletin, 15 Jun, 2020.) While Bonsity was approved as bioequivalent to Forteo, it does not have a determination of therapeutic equivalence based on the delivery device which would allow Bonsity to be substituted automatically for Forteo throughout the US.

Last year, Ligand management disclosed that Alvogen was "dealing with the FDA directly" on the issue, "and they continue to work with the FDA. They've recently submitted additional data that was requested by the agency." And earlier this year, Ligand suggested that a determination of therapeutic equivalence for Bonsity could arrive by the end of 2023.