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Alvotech Marks Denosumab Milestone

AVT03 Proposed Biosimilar To Prolia/Xgeva Passes PK Study; Further Trials Ongoing

by David Wallace

Alvotech has reported the latest clinical trial results for its AVT03 proposed denosumab biosimilar rival to Prolia and Xgeva.

Alvotech's AVT03 proposed denosumab biosimilar to Prolia and Xgeva has passed a pharmacokinetics, safety, and tolerability study compared to Prolia and is advancing into further trials, the company has reported.

The positive news for denosumab comes shortly after Alvotech had revealed that it expects to soon obtain long-awaited US Food and Drug Administration approvals for its AVT02 adalimumab and AVT04 ustekinumab candidates, after an FDA reinspection of a key manufacturing facility returned just one "readily addressable" observation. (Also see "*Alvotech Lines Up US Biosimilar Approvals After FDA Inspection*" - Generics Bulletin, 22 Jan, 2024.)

While the company had provided a slew of updates on various pipeline assets late last year, denosumab was not among them (*see sidebar*), after the firm had announced the start of trials in mid-2022. (Also see "*Alvotech Makes It Four With Denosumab Trial*" - Generics Bulletin, 22 Jul, 2022.)

The company had dropped AVT03 from a biosimilars partnership with Stada midway through last year. (Also see "*Alvotech Makes Multiple Moves As It Allies*

Golimumab Results Lead Off A Raft Of Updates For Alvotech

By David Wallace

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Alvotech has provided a slew of updates on its biosimilars business, including clinical trial results for its Simponi rival as well as the latest on a key US FDA inspection of its

With Advanz For Five European Biosimilars" - Generics Bulletin, 24 May, 2023.)

Now, however, Alvotech has revealed that "the PK study (AVT03-GL-P01), which assessed the pharmacokinetics, safety, and tolerability of AVT03 compared to Prolia in healthy adult subjects, met its primary endpoints."

manufacturing facility and fresh details around its launches of Humira and Stelara rivals in the US and around the world.

Read the full article here

"A confirmatory efficacy study for AVT03 in patients is currently underway," Alvotech indicated, "as well as a PK study comparing AVT03 to Xgeva in healthy adult subjects."

Joseph McClellan, Alvotech's chief scientific officer, said the firm was "very pleased with the progress in our AVT03 program," adding that "this milestone, and recent positive top-line results from other clinical studies, clearly demonstrate our capabilities and the excellence of [our] biosimilars development platform."

A $6bn Opportunity With Many Rivals In The Works

Underlining the size of the potential market opportunity, Alvotech noted that the Prolia osteoporosis brand and Xgeva treatment for prevention of skeletal-related events and giant cell tumor together accounted for more than $6bn in annual sales, according to Amgen data for the year to 30 September 2023.

However, other developers are also chasing Prolia and Xgeva, with Sandoz having previously declared itself the frontrunner. The company has filed its GP2411 version in both Europe and the US. (Also see "*Sandoz Follows US Denosumab Filing With European Acceptance*" - Generics Bulletin, 25 May, 2023.)

Meanwhile, other firms in the race include Teva with an in-house candidate; Shanghai Henlius Biotech with its HLX14 version that entered Phase III trials in 2022 – with Organon picking up rights outside China (Also see "*Henlius Denosumab Biosimilar Trial Enters Phase III*" - Generics Bulletin, 29 Jun, 2022.) – and Luye Pharma's Boan Biotech, which recently reported that it was kicking off a Phase III trial. (Also see "*Boan Biotech Nears Denosumab Registration After Phase III Enrollment Completion*" - Generics Bulletin, 26 Jan, 2024.)

Biocon and Celltrion have also publicly disclosed denosumab development programs. (Also see "*Biocon Joins Fray For Denosumab, Ustekinumab Biosimilars*" - Generics Bulletin, 6 May, 2022.) (Also see "*Celltrion Gets Ready For Denosumab Phase III*" - Generics Bulletin, 14 Jan, 2021.)

Lupin and Mabwell also have partnerships in place for their candidates. (Also see "*Lupin*

Liquidating Japan JV With Yoshindo, Partners With I'Rom For Denosumab Biosimilar" - Generics Bulletin, 30 Aug, 2022.) (Also see "*Russia's Binnopharm Brings In Mabwell's Adalimumab, Denosumab Biosimilars*" - Generics Bulletin, 21 Dec, 2022.)

And for mAbxience – which is majority owned by Fresenius Kabi – denosumab featured heavily late last year, with the Spanish developer striking deals with Amneal for the US market and with MS Pharma in the Middle East and Africa region. (Also see "*Amneal And mAbxience Ally On Denosumab In US*" - Generics Bulletin, 13 Oct, 2023.) (Also see "*Another Denosumab Deal For mAbxience In MEA*" - Generics Bulletin, 15 Nov, 2023.)

Earlier in 2023, the firm had out-licensed denosumab marketing rights in Korea to local player HK inno.N. (Also see "*HK inno.N Eyes 2025 Korea Opportunity With mAbxience Denosumab Deal*" - Generics Bulletin, 31 Jan, 2023.)