

CHMP issues positive opinion on Mylan/Biocon's Semglee (biosimilar insulin glargine); EMA decision expected April 2018 - January 30, 2018

Mylan [announced](#) yesterday that its Biocon-partnered biosimilar insulin glargine has been recommended by CHMP (Committee for Medicinal Products for Human Use) for EMA approval. The hopeful EU brand name for the product is Semglee, and a final EMA decision is expected in April.

Semglee now stands to become the second-to-market biosimilar basal insulin in Europe, after Lilly/BI's Abasaglar, also a biosimilar formulation of glargine (Sanofi's Lantus). Per management's [remarks at JPM](#), Mylan is very committed to this product and to launching in both the EU and US.

The company filed an NDA for biosimilar insulin glargine in [September 2017](#), meaning an FDA decision is expected between July-September 2018. That said, Mylan is now facing a [patent infringement lawsuit](#) from Sanofi in the US, which could push back full FDA approval and launch until mid-2020. If this follows the story of Sanofi's lawsuits past, Mylan/Biocon's biosimilar glargine will eventually make it to market, despite the delay. Sanofi also alleged Lilly/BI's Basaglar of patent infringement, but the companies [reached an agreement](#) before trial (Basaglar's US launch was delayed, and Sanofi received undisclosed royalty payments). Merck's biosimilar insulin glargine (brand name Lusduna Nexvue) has been [tentatively FDA-approved](#), pending resolution of a separate patent lawsuit from Sanofi.

In our view, [biosimilar insulins are inevitable](#) market entries at this point. Basaglar has been an impressive commercial success, and is paving the way for the second and third biosimilar basals as HCPs become more familiar and comfortable with equivalent safety/efficacy. We do anticipate that Mylan/Biocon may face greater challenges on this front, because neither company has as much experience in insulin manufacturing, which may raise concerns about quality control.

-- by Payal Marathe and Kelly Close