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Sandoz Feels It Has The Ingredients To Make A Splash In ADCs

No Chance Of Launch Until Next Decade; LOE Opportunity Upwards Of $30bn

by Dean Rudge

Sandoz's Strategic Review 2024 event gave the firm the chance to speak at length about its aspirations in the development of highly complex antibody-drug-conjugates, as well as the opportunity to build on its strong analytical characterization and regulatory experience in biosimilars and peptide development to offer oligonucleotides.

Sandoz is "particularly excited" about the antibody-drug-conjugate (ADC) space, buoyed by its belief that the firm's "excellence" in small molecule and biosimilar development will converge and "set a great platform for us to succeed."

Speaking during the firm's Sandoz Strategic Review 2024 event in Zurich, Switzerland, Sandoz's chief science officer Claire D'Abreu-Hayling noted, "as we look at 2029 and beyond, where we are actually selecting products now that we will be developing and filing in the future, we see an increasing wave of products in the ADC space."

Citing Evaluate data, Sandoz pointed to the value of ADC loss of exclusivities mushrooming from $4bn until 2028, to $32bn between 2029 and 2034. It is a "rapidly growing, commercially attractive opportunity," the firm underlined.

Pressed further on these opportunities and the potential roadblocks for development during the event's Q&A session, D'Abreu-Hayling conceded there were very real manufacturing challenges "that are quite significant, and there are some toxicity considerations that need to be taken into account."

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From a timing standpoint, “it would take six years to eight years typically to develop a biosimilar. So, even if we were to start tomorrow, we would not to be able to launch in 2029,” D’Abreu-Hayling observed.

“So, I think you’re looking at 2030 and beyond in terms of coming to market with one of the ADCs. And I think our approach is very rigorous and disciplined, selecting the portfolio to define which particular assets we will go after.”

D’Abreu-Hayling reiterated Sandoz’s acumen in both small molecule and monoclonal antibody development. “This is a good example where those two things actually create a beneficial synergy between those two things,” she noted.

Meanwhile, Sandoz’s chief science officer pointed to the potential boost provided by the firm’s partnership with Evotec, which she said, “allows us potentially a development and manufacturing platform as well.”

Struck last year, the multi-year arrangement covers the development and manufacturing of multiple biosimilars, making use of a Evotec’s proprietary AI-driven technology platform that delivers fully integrated drug substance development and continuous manufacturing. (Also see "*Sandoz Makes Major Moves To Bolster Biosimilars Ahead Of Spinoff*" - Generics Bulletin, 10 May, 2023.)

Described as a gamechanger by Sandoz, the deal was expanded earlier this year to potentially add further biosimilars to the joint development pipeline and offer further guarantees for Sandoz’s long-term commercial supply security. (Also see "*Sandoz And Just-Evotec Expand Biosimilars Collaboration*" - Generics Bulletin, 8 Jul, 2024.)

Meanwhile, D’Abreu-Hayling also pointed to opportunities for Sandoz in oligonucleotides to treat genetic and rare diseases: “again, a complex API in a solution in a vial or a device. We have demonstrated the capability to develop and manufacture those products successfully.”

Sandoz would be able, she predicted, to “tap into what we already know, as a platform and as a foundation, to secure the future.”

“There’s little point launching products in very, very tiny indications unless we think by bringing it we can bring the price points down and expand the market. I would apply the same logic to things like

cell and gene – no technical reason why we couldn't potentially invest and do that. But even if we could bring cell and gene at $100,000 a patient, I don't think they have enough addressable market to recover the investment."

"So, I'm very confident that as the commercial opportunities for these technologies increase and we work on selecting the right products, we have what's required to bring them successfully to market."

While Sandoz was interested in getting ahead in oligonucleotides, the firm distanced itself from any chance of developing vaccines in the space ("We're not a vaccines company," underlined Sandoz's CEO Richard Saynor); while distancing itself for now from even more complex therapeutics, such as antisense oligonucleotides or small interfering ribonucleic acid (siRNA).

Oligonucleotides are strands of DNA or RNA molecules that contain a small number of nucleotides, while oligonucleotide therapeutics are chemically synthesized products for treating disease.

On the back of the first FDA-approved oligonucleotide, Isis Pharmaceuticals' Vitravene (fomivirsen) for CMV retinitis, developers have advanced to ligand-modified siRNA conjugates and aptamers, as well as gene editing.

"I think we would need to evaluate," Saynor said. "I mean, a lot of these are orphan drugs, very niche. So, it's really where we see the potential that we could massively expand the market."

"There's little point," he continued, "launching products in very, very tiny indications unless we think by bringing it we can bring the price points down and expand the market. I would apply the same logic to things like cell and gene – no technical reason why we couldn't potentially invest and do that. But even if we could bring cell and gene at $100,000 a patient, I don't think they have enough addressable market to recover the investment."

Chipped in Sandoz's newly appointed chief commercial officer, Rebecca Guntern, "of course we're going to explore oligonucleotides, but we first need to understand how the market is going to evolve and then maybe also look for partnerships."

"We've said we're always going to look to how we leverage internal capabilities and then how we explore partnerships. And I could imagine that oligonucleotide could be one area where we want

to go for partnerships."

Nevertheless, Saynor stressed that there remained for Sandoz "a significant amount of portfolio. There's something like 45 biologics with no biosimilar development pathway that we see. So, there is a very broad opportunity in terms of both basic monoclonals, ADCs, and then also potentially targeted oligonucleotides."

"At the end of the day I want to be clear about what we *don't* do as much as what we *do* do," Saynor stated. "Clearly, we're already a strong leader in biosimilars, in monoclonals. That's a space with significant opportunity to expand and grow. So ultimately, I want to own a lot of that space, bring as much portfolio [as possible], and then there are these other products on the periphery."