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# Investors Spooked By High Prices For Advanced Therapies

*PCSK9 Inhibitor Pricing Issues Sounded The Alarm*

by Francesca Bruce

To keep investors happy, companies will have to start showing that their high-priced advanced therapies offset costs elsewhere in the health care system.

Hefty prices mean and resulting market access restrictions will make investors increasingly reluctant to invest in companies developing advanced therapies, and companies will need to show that their products offset costs elsewhere in the health care system to win broad recommendations, says Michael Schröter, a founding partner at Swiss-based asset management firm Viopas.

Speaking at the virtual World Pharma Pricing Market Access and Evidence Congress in September, Schröter pointed out that the handful of very costly advanced therapies currently on the market were "only the tip of the iceberg" for payers.

Nearly 400 cell and gene therapies are in development, he said. While around one third of these are targeted at rare diseases, the rest are being developed for conditions with large patient populations, such as Alzheimer's disease, diabetes and cardiovascular disease.

Though advanced therapies represent a step change in treatment, the prices they command can reach millions of dollars, raising questions over how long payers will continue to accept them. To manage the costs, payers are applying increasingly strict restrictions on market access recommendations for expensive products. "Great but unaffordable drugs only help a few patients, and drugs that remain on the shelf do not help companies' bottom line either," said Schröter.

According to Schröter, investors are slowly starting to catch on that market access restrictions do impact companies' profitability. The wakeup call came when *Sanofi* and *Amgen, Inc.*, manufacturers of PCSK9 inhibitors for migraine, had to drop their prices by up to 60% to generate uptake, he told *Scrip*.

"Why would you invest in a company that has a high likelihood of incurring access restrictions and the financial consequences that will have?" he asked. Amgen and Sanofi were able to weather the storm and absorb the price drops across their portfolios. Nevertheless, they did suffer a blow, one which would have been devastating for a small biotech with just one product, he said.

## New Paradigm

New ways of meeting shareholder needs are therefore required, he said. One promising option is to design products to reduce overall healthcare spending. "If the healthcare industry wants to survive the coming tsunami of advanced therapies then this is the trend to join," he advised.

Medicines represent a small part of healthcare costs, most of which are associated with hospitalization and administration. New therapies that can reduce overall spending are those that can replace treatments, reduce hospitalization or prevent disease in the first place, he said. Such drugs can and should be priced high as long as they reduce the overall spend, he added.

Schröter pointed to *Roche Holding AG*'s hemophilia A treatment Hemlibra (emicizumab), which costs almost $500,000 per patient per year, as an example of how this model can work.

Treating hemophilia A in the US can cost up to $2.5m per patient per year. However, Hemlibra, which reduces bleeds by 98%, cuts overall healthcare costs by 50%, despite its high price. This is because it replaces expensive but less effective treatments and also removes the need for costly follow ups, said Schröter.

The savings mean that Hemlibra faces no or minimal access restrictions and is therefore achieving or exceeding sales forecasts, he said. The drug is forecast to generate $3.9bn by 2024.

"In the end patients receive a better drug that prevents many more bleeds than current standard of care, payers are embracing it since it helps them save money and the company is rewarded with solid sales due to no access restrictions," said Schröter.

He advised companies to formally build cost-offsets into their drug development processes "from the get-go" by including them in target product profiles. These profiles traditionally set out a drug's targets in terms of safety, efficacy and price.

The medtech industry has already embraced this model, said Schröter. This is largely because the

incremental nature of innovation in the sector means companies have to work harder to differentiate themselves. Schröter added that some small to medium sized pharma and biotech companies were beginning to express an interest in the model.