Evaluate Vantage

January 23, 2019

Mediwound could feel the burn with Nexobrid launch

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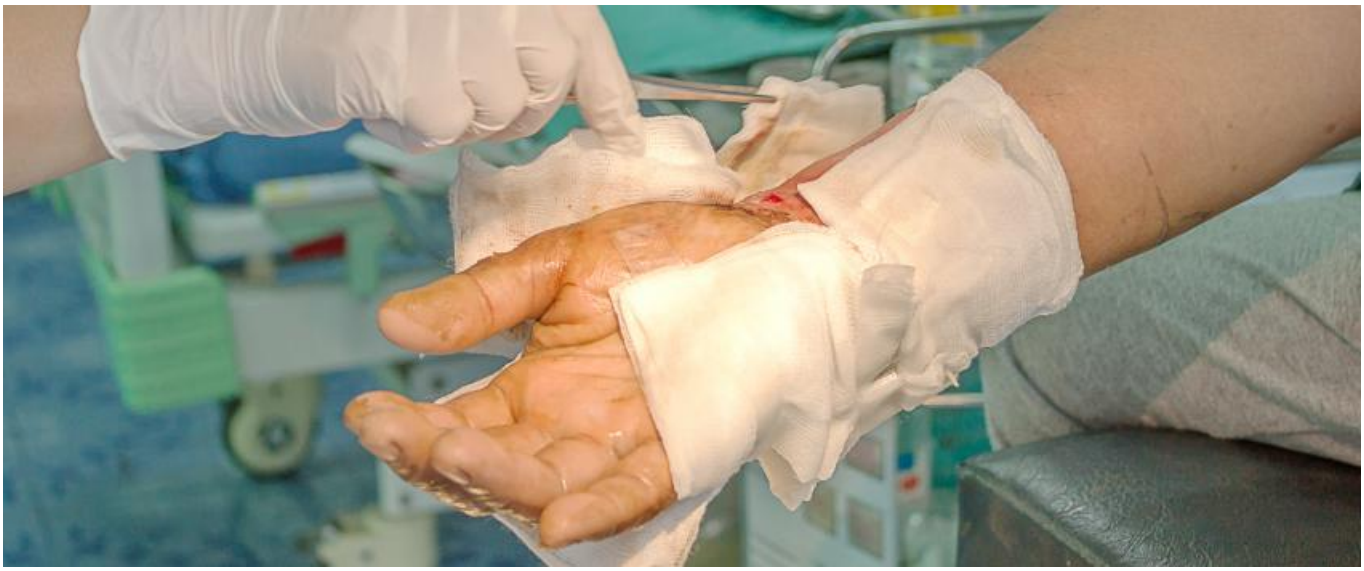

Mediwound looks set for US approval of its burn therapy Nexobrid, but driving adoption could be the real challenge.

Mediwound is taking its burn therapy Nexobrid to the FDA after posting impressive data from a phase III trial. But slow adoption in Europe, where the product has been approved since 2012, hints at a tough road ahead even if the project gets the US nod.

Harvard Medical School's Dr Jeremy Goverman, a burns specialist, was bullish about Nexobrid's chances on a conference call held by Mediwound yesterday. "It'll become standard of care," he said. "When something's so much better you do the right thing." But the stark truth is that the product sold just $2.5m in Europe in 2017.

Things seem to be picking up, slightly: in the first nine months of 2018 Mediwound reported total revenues of $2.4m, presumably all from Nexobrid, a gel formulation composed of several proteolytic enzymes that is the company's sole marketed product.

Jalopy to Ferrari

Dr Goverman was adamant that there had not been a problem with uptake in Europe. "In the past five years or so we've got up to 4,000 uses. I've never seen anything adopted that quickly."

He admitted that, in general, "surgeons as a group are pretty stubborn; it's hard for us to give up something we're used to", but added: "Here you're going from driving a jalopy to a Ferrari."

If Nexobrid gets to the US market Mediwound will be trying to shift doctors from the current standard in burn care, which at one end of the spectrum involves non-surgical approaches like topical therapies and, at the other, surgery to remove eschar, the dead tissue that surrounds burns.

The former have limited efficacy, especially for serious burns, while surgery can be traumatic and result in the removal of healthy as well as dead tissue.

Several factors might help Nexobrid compete with entrenched existing therapies, the group's chief executive, Gal Cohen, believes. For one, the US market is more focused, with around 75% of patients treated in a specialist burns centre, he estimated, versus about a third in Europe. He added that Nexobrid now had a weight of published data behind it, which was not available at the time of European launch.

Finally, he noted that surgical debridement was more expensive in the US, costing $8,000-15,000, than in Europe, a fact that should also help Nexobrid compete. Mr Cohen would not give any details about Mediwound's US pricing strategy.

The next step is FDA go-ahead, and Mediwound now has a good chance of winning this after positive data from the 175-patient Detect trial, which met all its primary and secondary endpoints.

On the way to the FDA: Nexobrid phase III data				
Endpoint	**Nexobrid**	**Gel vehicle**	**Standard of care**	**P value**
Incidence of complete debridement*	93%	4%	N/A	<0.0001
Incidence of surgical eschar removal	4%	N/A	72%	<0.0001
Time to complete eschar removal	1 day	N/A	3.8 days	<0.0001
Blood loss	14.2ml	N/A	814.5ml	<0.0001
Time to complete wound closure**	27 days	N/A	28 days	0.0003
**Primary endpoint; **non-inferiority safety endpoint. Source: company press release, conference call.*				

However, a question about the trial design was raised on the call, specifically why Mediwound had compared Nexobrid with gel vehicle, not standard of care, on the primary endpoint, incidence of complete debridement.

Mr Cohen replied that surgery was effective at removing eschar, so the comparison was not relevant – instead, Nexobrid could have an advantage over surgery by allowing earlier eschar removal, something that seems to be borne out in the secondary endpoint analysis.

Nexobrid also decreased the proportion of patients needing surgery versus standard of care.

Mediwound hopes to file Nexobrid with the FDA in the second half of this year. However, this depends on whether the agency is happy to accept the submission before 12-month safety results from the same trial are available in the first half of next year.

If the FDA agrees to this Mediwound could be looking at US approval of Nexobrid by the end of 2020. The project is forecast to bring in sales of $71m by 2024, according to *EvaluatePharma's* sellside consensus, but demand will have to pick up substantially for this number to be hit.