

Stallergenes and ALK-Abelló take a step closer to the US market



[Elizabeth Cairns](#)

Two European allergy companies hoping to make a jump across the Atlantic got a boost from an FDA panel this week. Both Stallergenes and ALK-Abelló received recommendations of approval for their rival under-the-tongue allergy immunotherapies, Oralair and Grastek. The products would represent a new option in the US.

Currently, only injections are available to Americans who suffer severe reactions to grass pollen. As such, the companies are hoping the more convenient sublingual therapies will attract patients, as well as come with fewer safety concerns, specifically severe anaphylactic reactions. However, both panels gave their backing on the condition that patients have auto-injected epinephrine available at home, suggesting safety will remain an issue for these products, as they head to the FDA and then attempt to wrestle market share from entrenched competition.

The requirement of injectable adrenaline on hand is standard practice for injected allergy immunotherapies in the US, so this ruling does not come as a huge surprise. But for those with doubts about the commercial potential of these products, the safety concerns that the panel raised will not build hopes.

Patients with asthma were also a focus, and the FDA will probably request further studies in these people. In Europe, the products are contraindicated in patients with uncontrolled asthma and this seems likely to also happen in the US. However, it cannot be ruled out that a cautious FDA takes an even more conservative approach to these patients.

The broad safety databases gathered on these products – both have been available in Europe for several years – indicates that these sublingual products are safer than the injections. No systemic anaphylactic reactions have been seen with Oralair and only one with Grazax, which has also seen epinephrine used a handful of times. But the drugs have been tested in thousands and used by hundreds of thousands. This evidence, on top of their oral administration, should allow them to attract patients.

Fighting for share

As is often the case, the commercial battle is likely to represent a bigger challenge than the regulatory path for these companies – compounding and dispensing the injectable treatments is big business for allergy doctors. But the tablets do represent a big improvement in convenience, and over time the companies hope patient preference will shift the market in their favour.

Marketing partners in the shape of big pharma player Merck & Co for ALK-Abelló and entrenched allergen supplier Greer Laboratories for Stallergenes will help.

In an interview with *EP Vantage* last week, Roberto Gradnik said they are not expecting a quick switch away from injected immunotherapies, and this cautious stance is reflected in analysts' sales forecasts. Peak sales of around \$300m are expected ([EP Vantage interview – Stallergenes poised to take first US steps, December 10, 2013](#)).

To grow the potential of these products it seems likely that efficacy needs to be shown in asthmatic patients – 80% of asthmas are allergic, dust mites being the most common trigger, and then cats. But hay fever frequently goes hand-in-hand with asthma, particularly in children. If dampening the immune response to grass pollens can be shown to have an impact on asthma symptoms, there will be a much bigger reason to use these products.

That data will take time to emerge, and in the meantime the allergy landscape is shifting ([Hay fever vaccines entering new season of innovation, March 8, 2012](#)). Both of these products require patients to take the tablets for up to six months a year, for at least three years, to produce a sustained and significant dampening of symptoms. Any product that can improve on that, without adding to safety concerns, will quickly change the game.

To contact the writer of this story email Amy Brown in London at amyb@epvantage.com or follow [@AmyEPVantage](#) on Twitter

[More from Evaluate Vantage](#)

Evaluate HQ

[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

Evaluate Americas

[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC

[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

© Copyright 2023 Evaluate Ltd.