

## Event - Trius hopes tedizolid success is infectious



[Jonathan Gardner](#)

Trius Therapeutics is nearing the most important moment in its short life as a public company: readout of a second phase III trial of tedizolid in treating acute skin infections. With pivotal data already in the bag for an all-oral formulation, the chances appear good for the intravenous-to-oral treatment protocol to compare favourably to Pfizer's Zyvox, with a shorter course and better side-effect profile.

With critical US and European rights remaining unpartnered, success with the second trial could trigger significant licensing or M&A talk for the California group. Tedizolid needs to achieve a smooth launch and show significant advantages over Zyvox, which loses market exclusivity in 2015.

<b>Company</b>	Trius Therapeutics
<b>Product</b>	tedizolid (TR-701 IV)
<b>Market cap</b>	\$276m
<b>Product NPV</b>	\$381m
<b>% of market cap</b>	138%
<b>Event type</b>	Phase III results
<b>Date</b>	Q1 2013

### Watching the anti-infectives

The Establish-2 trial tests a six-day course of intravenous tedizolid (TR-701 IV) administered once daily, compared with IV Zyvox. After the second dose, patients can switch to an oral formulation. Tedizolid will need to prove to be non-inferior to Zyvox in arresting the growth of lesions, along with controlling body temperature and other infection symptoms.

The Establish-1 trial, testing an oral formulation alone, has already proved tedizolid's non-inferiority to Pfizer's incumbent; early clinical response rates were 79.5% in tedizolid patients and 79.4% with Zyvox.

That first study, largely conducted in the US, needs to be beefed up with data from patients outside the US, who in many cases respond better to systemic treatments to skin infections, according to Leerink Swann analysts. Thus, half the Establish-2 study population is from outside the US. Trius reported that the last of the 658 patients in Establish-2 enrolled in December. Analysts from Baird said the trial could read out this month.

In addition to a shorter course and less-frequent dosing, Trius is banking on fewer side effects - Establish-1 found similar adverse event rates - better resistance profile and fewer drug interactions. Key drug interactions with Zyvox are seen with selective serotonin reuptake inhibitors and monoamine oxidase inhibitors.

With 2018 sales forecast at \$163m, TR-701 IV has a net present value of \$381m - more than Trius's market capitalisation of \$276m. Thus, positive readout would likely see a share uplift based on both an improved regulatory outlook and the possibility for partnerships or acquisition.

Under legislation that took effect in October, antibiotics can qualify for priority review and fast-track approval, so speedy submission could see the agent approved as early as mid-2014 - giving it time to establish a place in the market before Zyvox goes off-patent in mid-2015.

### Strategy

A deal Trius struck with Bayer in 2011 covered Asian and Pacific countries, but valuable European and US rights remain in house. Trius management has signalled a greater willingness to license out the compound

outright in Europe, while retaining more value in the US by building its own sales force or forging a co-promotion deal.

In its short life as a public company, Trius has raised quite a lot of money - \$116m, in addition to about \$50m raised in its IPO. The Bayer deal has been a boon, netting \$25m up front and \$5m for the completion of the Establish-1 trial, out of a total of \$69m milestones.

Developing a sales force to launch alone, or even in partnership, in either of the two unpartnered territories, will entail significant cash outlays, even if a hospital-based sales force tends to be smaller than those marketing to physician practices.

At September 30, Trius had \$71m of cash, against quarterly operating expenses of about \$20m for the first three quarters of 2012; thus it has room to manoeuvre, particularly if a share uplift following positive results allows for another fundraising. However, a sales force will not come cheap, and term sheets could become increasingly attractive if they in fact materialise.

With the security of the Establish-1 data, Trius might be one of the safer bets among companies facing binary events. In the long term, it bears harder scrutiny over its strategy and indeed whether its lead product can offer any significant benefit to a well-established drug about to go generic.

<b>Trial name</b>	<b>ID</b>
Establish-1	NCT01170221
Establish-2	NCT01421511

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