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Upcoming events: Data from Redhill in ulcers and Ascendis in growth deficiencies

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Welcome to your weekly digest of approaching regulatory and clinical readouts. Redhill Biopharma stands to see its shares swing dramatically next week when it reports phase III data on RHB-105, its treatment for *Helicobacter pylori*-induced ulcers.

Meanwhile, Ascendis Pharma is facing a similar catalyst towards the end of July with data from a phase II paediatric trial of its growth hormone project ACP-001. Success could help validate the Danish group's Transcon technology for controlled release of therapeutic molecules.

Redhill: RHB-105

Israel-based Redhill is due next week to report results of the 118-patient Eradicate HP trial of its candidate in *H pylori* infections. As with the current standard of care, RHB-105 combines two antibiotics with a proton pump inhibitor, but does this in a single pill – in this case, amoxicillin, rifabutin and omeprazole.

Enrolees took four capsules every eight hours for two weeks. The primary endpoint was *H pylori* eradication as measured by the 13C urea breath test four to five weeks after completion of treatment.

Redhill says RHB-105 is needed because standard therapy fails in 20% of patients owing to resistance to clarithromycin and metronidazole; the latter is a component of Actavis's Helipak, a product *EvaluatePharma* forecasts will sell $24m in 2020. The FDA awarded RHB-105 Qualified Infectious Diseases Product (QIDP) status last year, giving it a fast track and five years of extra marketing exclusivity.

Medications treating *H pylori* were declared to be eligible for the QIDP programme as the organism has "potential to pose a serious threat to public health". Infections raise the risk of gastric adenocarcinoma.

RHB-105 is one of Redhill's lead candidates, joining RHB-102, a once-daily oral formulation of the chemotherapy anti-emetic ondansetron, in late-stage testing.

Ascendis: ACP-001

Ascendis's TransCon delivery technology is intended to create more effective, lower-risk therapeutics, but so far it has not worked quite like that. Sanofi walked away from the TransCon insulin formulation it had licensed before the project even reached the clinic, and a TransCon form of treprostinil for pulmonary arterial hypertension demonstrated the desired pharmacokinetic profile in phase I but had a higher than expected rate of side-effects.

The showing the TransCon form of human growth hormone makes in phase II is therefore an important indication of whether the technology is worthwhile. Data on the first 25 patients in the trial appeared in December and showed that those given ACP-001 had mean annualised increases in height of 11.9cm for the lowest of three doses and 14.5cm for the highest. The comparator, Pfizer's Genotropin, managed 11.5cm.

If ACP-001 can manage a similar showing in the second tranche of phase II patients as it did in the first – and this seems to be what analysts expect – phase III trials could start in around a year's time.

The project's safety and pharmacokinetics have been acceptable too, and this latter point is important: Genotropin is a daily subcutaneous jab, whereas '001 is injected weekly. Novo Nordisk's Norditropin SimpleXx, the bestselling growth hormone formulation, is also administered daily.

Norditropin SimpleXx could also be the biggest seller in 2020, *EvaluatePharma's* consensus forecasts show. The second biggest is set to be Versartis's VRS-317, which is in a phase III trial called Velocity with a twice-monthly dosing schedule and thus could be a significant competitor to Ascendis's formulation.

VRS-317 was placed on partial clinical hold last month as the FDA sought additional bioanalytical data. This means that the race to file is now closer, though Versartis will still win comfortably with an expected NDA filing in the second half of 2017 to Ascendis's H2 2018.

Ascendis’s phase II will be crucial for the company’s competitive position in the growth hormone market, as well as providing another chance for the TransCon technology to prove itself.

Study	Trial ID
Eradicate Hp	NCT01980095
Phase II trial of ACP-001	NCT01947907
Velocity	NCT02339090

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