Evaluate Vantage

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Upcoming events: High-risk readouts for Erytech and Heron

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Welcome to your weekly digest of approaching regulatory and clinical readouts. Pancreatic cancer and pain are two of the most difficult therapy areas in which to demonstrate a clinical benefit, but this has not stopped Erytech Pharma or Heron Therapeutics trying.

Erytech's Graspa is primarily targeting leukaemia, but a win in a phase II pancreatic cancer trial would give an added boost as the French company seeks a secondary US listing. Meanwhile, Heron's post-surgical pain candidate HTX-011 is set to report data from two phase II studies in the second half of this year; one targets bunionectomy and the other hernia surgery.

Erytech already has a small American depositary receipt programme, but in July announced plans for a full-blown secondary US offering. The company needs a licensee and is running low on cash – it had just €37m at the end of 2014 – and with positive data under its belt the attraction of the US market is easy to understand.

Graspa's pancreatic cancer trial recorded one success in July, with a third independent safety review, after enrolment of 24 patients, recommending that the study continue enrolling. The aim was to have recruited 90 patients, and the trial is to be completed this month, the data is set to be reported in early 2016.

Graspa, also known as Ery-Asp, comprises red blood cells loaded with L-asparginase; this enzyme is thought to work as an anticancer because tumours rely on circulating asparagine for cell proliferation, though in its non-encapsulated form it can be hard to tolerate.

The open-label phase II trial's primary endpoint is four-month progression-free survival, aiming to show superiority of Graspa added on top of the gemcitabine or Folfox standard of care. The setting is second line, where patients have few realistic options.

Erytech's main success has been in acute lymphoblastic leukaemia (ALL), in which a phase III win positions Graspa for an imminent EU filing. Interestingly, Edison analysts put peak pancreatic cancer sales at $336m – more than they expect from ALL – though a 20% probability of success accounts for this tumour type's extremely intractable nature.

Pain for Heron

Heron also has bigger fish to fry, with a primary focus on its chemotherapy-induced nausea project Sustol, but further down its pipeline some analysts believe that HTX-011 has promise as a best-in-class agent for post-operative pain; the two phase II trials expected to yield data shortly should help quantify this promise.

Like Sustol, HTX-011 – a long-acting injectable formulation of bupivacaine/meloxicam – uses Heron's proprietary delivery platform, potentially giving it a longer duration than current non-opioid analgesics. HTX-011 could last up to 72 hours, versus around 24 hours with long-lasting local anaesthetics like Pacira's Exparel.

HTX-011 could get the go-ahead in 2018 and bring in $700m by 2025, Leerink analysts forecast, though those at Jefferies are more conservative, expecting risk-adjusted sales of $350m that year.

However, getting the necessary data will be tough for Heron, as pain is a particularly difficult area in which to show a benefit, especially as it is complicated by the use of rescue opioids. So far the project is only backed by a phase I study in healthy volunteers, and even the bullish Leerink analysts are only giving it a 40% chance of success.

On the plus side for Heron, HTX-011 is a reformulation of drugs that have already succeeded in the market, and doctors are looking for alternatives to opioids for pain management. There is a large market to tap into – if HTX-011 can make it through clinical trials.

Project	Study	Primary completion	Trial ID
Graspa	Open-label study in 90 2nd-line pts	September 2015	NCT02195180
HTX-011	Phase II hernia trial	October 2015	NCT02504580
HTX-011	Phase II bunionectomy trial	November 2015	NCT02471898

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