

Heron wades into crowded pain-relief waters



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Heron Therapeutics looks like it has threaded the needle of developing a post-surgical treatment that provides superior pain relief to generic anaesthetics and keeps patients from turning to opioids.

Its approach with HTX-011 is to add Cox2 inhibition to the old standby bupivacaine, which ought at least to stimulate others to look into trying this strategy. Nevertheless, Heron has established a lead here, and its most immediate concern beyond approval is how to set a price that recognises the added value without turning off hospital formulary committees.

Investors were encouraged by the findings, sending shares up 29% in early trading today. Heron's good news was taken as bad news for Pacira Pharmaceuticals, the maker of a liposomal form of bupivacaine called Exparel, whose shares sank 6%.

Anaesthetic plus

HTX-011, a combination of bupivacaine and the active ingredient from Boehringer Ingelheim's Mobic, provided significantly better pain relief and opioid sparing than placebo or a bupivacaine solution when locally administered at the surgical site of bunionectomies or hernia repairs.

On bunionectomies, the pain intensity for subjects on HTX-011 was 27% lower than placebo and 18% lower than bupivacaine; on hernia repair, the respective figures were 23% and 21%.

The results in two separate phase III trials in 412 and 418 patients respectively set Heron up for US FDA submission later this year. HTX-011 has already received fast-track designation, so if approved on an expected timeline it could be launched in the middle of 2019.

EvaluatePharma's consensus of sellside forecasts puts sales of HTX-011 at \$238m in 2022, which would add substantially to Heron's revenues. Along with the marketed anti-emetics Sustol and Cinvati the group's total sales are expected to reach \$599m in 2022.

Two phase II studies of HTX-011 are expected to read out later this year, and should help reveal the project's full potential - one in breast augmentation, where it will be used as a nerve block, and one in total knee arthroplasty. Leerink analyst Ami Fadia gives the breast trial a 50% chance of success and the knee study less than that, citing the complexity of the procedure and the level of associated pain.

Save us money

Clinical trials aside, what Heron might need to focus on next is showing HTX-011's larger value to the health system. If the company wants to price its product at a premium to generic bupivacaine or Exparel, demonstrating that it can save hospitals and other health providers money downstream will be a must.

Obviously the opioid-sparing data - bunionectomy patients taking HTX-011 consumed 37% less opioids than patients on bupivacaine, and in hernia repair the number was 25% - will be eagerly received, not just because opioid pain relievers have a cost but also because of the risk of addiction. Policymakers will certainly be interested in this aspect of Heron's drug.

Hospitals and payers, however, will want to see data showing that HTX-011 can reduce the lengths of inpatient stays, which can be one of the costlier items in any surgical procedure. The pain relief data are a start, but Heron will have more work to do if HTX-011 is to be a commercial success.

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