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Singapore's MerLion eyes partner for Phase III of Finafloxacin urinary infection trials

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SINGAPORE--MerLion Pharmaceuticals said it is in sustained talks with potential investors to take its successful Phase II trials of a urinary tract infection application for its Finafloxacin antibiotic into Phase III as it moves into a competitive landscape for the fluoroquinolone class of antibiotics with approval for an ear infection treatment by the U.S. FDA.


MerLion CEO David Dally

CEO David Dally told *FierceBiotech* that the company came away from meetings at the annual JP Morgan Healthcare Conference upbeat on prospects to get an estimated $40 million to $60 million for Phase III development of Finafloxacin for the treatment of serious infections, including those caused by a number of resistant Gram-negative pathogens, after holding talks with regulators in the U.S. and Europe to determine the scale of any trial.

"We had solid data to bring to people we've been talking to for some time," Dally said in a phone interview, adding that even though firms like Forest and AstraZeneca ($AZN) are awaiting approval for the antibiotic ceftazidime-avibactam (CAZ-AVI) as a treatment for hospitalized adult patients with complicated intra-abdominal infection and Cubist ($CBST) has won approval for Zerbaxa (ceftolozane/tazobactam) to treat serious infections caused by susceptible Gram-negative bacteria, Finafloxacin has unique selling points.

"Those products are intravenous whereas Finafloxacin is both oral and intravenous in fewer doses daily and has safety and efficacy parameters that make it a gold standard," Dally said.

In June 2014, the firm was given Qualified Infectious Disease Product Designation, introduced in 2012 as a provision of the FDA Safety and Innovation Act to encourage development of treatments for serious or life-threatening infections caused by bacteria or fungi. The designation opens up exclusive marketing rights for as long as 10 years if the candidate successfully completes Phase III trials.

The same month, a topical form for outer ear infection successfully passed Phase III trials in North America and will be marketed for swimmer's ear by its partner with North American rights, Alcon Pharmaceuticals, this year, Dally said.

The company now hopes to find a partner to take the product into Asia, a particular focus because a key investor is the Singapore Economic Development Board.

- here's the FDA swimmer's ear release
- Finafloxacin background

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