

DEAL WATCH

Novartis acquires marketing rights for novel broad-spectrum antibiotic

Novartis has signed an agreement with Paratek Pharmaceuticals that entitles Novartis to the worldwide rights to market PTK0796 — a novel broad-spectrum antibiotic capable of fighting multidrug-resistant bacterial infections. The agreement involves an upfront payment of an undisclosed amount from Novartis, with Paratek eligible to receive a total of US\$485 million, including milestone payments. The companies will share the responsibility and costs for the development of PTK0796.

The increasing prevalence of multidrug-resistant bacterial strains, together with the decline in the discovery and development of new antibiotic classes, has made the

effective treatment of many bacterial infections increasingly difficult. “Such multi-drug-resistant organisms pose particular challenges in hospital environments,” explains Professor Richard Wenzel, Virginia Commonwealth University, USA. “Efficacy, an oral regimen, and single daily dosing are desirable characteristics for novel antibiotics, but the ability of these organisms to acquire resistance genes readily, the high level of environmental contamination, inadequate infection control and the limited pipeline of antibiotics severely hamper these goals,” he adds. “There is an urgent need for the identification of new antimicrobial targets and the development of new antibiotics with few side effects,” says Professor Robert Daum, University of Chicago Medical Centre, USA.

In this context, studies of PTK0796 — the first in a new aminomethylcycline class of antibiotics, the activity of which is linked to inhibition of bacterial protein synthesis — are so far encouraging. PTK0796 exhibits potent, broad-spectrum activity against a wide range of bacteria and, most importantly, “...appears to be active against many antibiotic-resistant pathogens, such as methicillin-resistant *Staphylococcus aureus* (MRSA) infections, that have been occurring

in epidemic numbers in the United States” notes Daum. Indeed, in a Phase II study involving 200 patients with complicated skin and skin structure infections (cSSSI), in which approximately 50% of the infecting bacteria were MRSA, once-daily oral or intravenous PTK0796 treatment for 14 days achieved a clinical success rate of 98%, with the drug meeting primary safety and tolerability end points. “The availability of PTK0796 in both oral and parenteral forms suggests that transition from parenteral treatment to an oral treatment phase may be performed easily,” says Daum. This may offer a convenient way for patients to continue antibiotic treatment after leaving the hospital.

However, there are some potential limitations to the application of PTK0796. “In the case where the pathogen is known, health-care providers will prefer to narrow the antimicrobial treatment spectrum to accurately target the causative bacterium. Additionally, previous tetracycline derivatives have not been suitable for children younger than 9 years of age, as they tend to accumulate in teeth and bones, raising concern about unsightly cosmetic defects,” notes Daum.

“Although PTK0796 would not solve all the problems due to burgeoning antibiotic-resistant infections, it could be an interesting addition to the anti-infective armamentarium. Further developmental activities should be conducted to identify its niche,” concludes Daum. PTK0796 is currently in Phase III clinical trials for cSSSI, and clinical trials for a number of other potential indications are under way.

