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Allekra Seeks US Partnership For Urinary Tract Asset As Regulatory Filings Approach

Following EU And China Deals

by [Ayisha Sharma](#)

The French firm is searching for a US partner with strong foundations in the hospital sector after securing EU and China deals for its complicated urinary tract infection candidate that combines cefepime and enmetazobactam, which is nearing regulatory submission in key markets.

[Allekra Therapeutics GmbH](#) is on the hunt for a commercialization partner across the Atlantic for its complicated urinary tract infection (cUTI) asset as it prepares imminent filings for the EU and US regulators.

Iain Buchanan, a member of Allekra's supervisory board, told *Scrip* the ideal partner would provide "sales and distribution infrastructure in the US hospital sector as well as the motivation and resources to bring the product to market," but claimed he could not comment on the firm's ongoing discussions. Allekra is planning to submit an EU filing by year end and a US filing in the first quarter of 2023.

The planned US deal is the latest in a spate of collaborations centred on the French firm's lead candidate, a novel blend of two actives with different mechanisms, cefepime and enmetazobactam. The former is a beta-lactam broad spectrum antibiotic while the latter is a beta-lactamase inhibitor that can restore the antibacterial effect of beta-lactams against resistant Gram-negative infections.

In January, the company signed a deal with [ADVANZ PHARMA Corp](#), giving the latter exclusive rights to develop and commercialize cefepime/enmetazobactam in the EU, UK, Switzerland and Norway in return for an undisclosed upfront payment. Under the terms of the deal, Allekra is eligible for development and sales milestones as well as double-digit tiered royalties. (Also see

"Deal Watch: How Did J.P. Morgan Deal-Making Compare To Prior Years?" - Scrip, 17 Jan, 2022.)

The Saint-Louis, France-headquartered firm nabbed a similar agreement with [Shanghai Haini Pharmaceutical Co., Ltd.](#) back in 2020 for the Greater China territories. Shanghai Haini took on responsibility for manufacturing, developing and commercializing the drug across mainland China, Hong Kong, Macau and Taiwan. The deal has a total potential value of \$78m comprised of an upfront payment and development and sales milestones and Allecra is also eligible for tiered royalties.

cUTI refers to UTIs experienced by patients who are immunocompromised or those that present with associated fever, sepsis, urinary obstruction, catheter use or other medical issues. Around 9.4% of urological inpatients develop a cUTI during their hospital stay and the infection can lead to florid urosepsis which can be fatal.

Topline data from the Phase III ALLIUM trial in the disease showed cefepime/enmetazobactam was superior to comparator [Pfizer Inc.](#)'s antibiotic Zosyn (piperacillin/tazobactam) in the primary endpoint of clinical cure and microbiological eradication (79.1% vs 58.9%) at seven days.

Estimates suggest there are more than 600,000 hospital admissions in the US each year for cUTIs with around 80% of these being non-catheter related. Standard of care includes carbapenems, which are broad-spectrum beta-lactam antibiotics. However, the overuse of carbapenems has led to the emergence of carbapenem-resistant pathogens in the US and globally.

Allecra's candidate is essentially designed to treat cUTI patients in hospital settings where beta-lactam resistant Gram-negative pathogens are endemic, Buchanan explained. By providing an alternative treatment option, cefepime/enmetazobactam could help slow the course of or prevent further resistance to carbapenems, he concluded.

Big Pharma Competition Emerging

The cUTI market value across the seven major markets was estimated to total \$1.87bn in 2021 according to a recent report from DelveInsight. The disease pipeline has 20 assets in active clinical development according to the Citeline database Pharmaprojects. Other firms with Phase III programs to watch out for include [Zai Lab Ltd.](#), [GSK plc](#) and [AbbVie Inc.](#).