GlobalData»

The earlier-than-expected FDA approval of Portola Pharmaceuticals' Bevyxxa (betrixaban) will imminently bring relief to a patient population with an extremely high unmet need, as currently no anticoagulant therapy is approved for the prophylaxis of venous thromboembolism (VTE) for acute medically ill patients. It also means that Bevyxxa will secure a critical market position in this lucrative space, given the size of this population, according to GlobalData , a leading data and analytics company.

IMAGE FOR PUBLICATION, PLEASE CLICK HERE: 'Total venous thromboembolism (VTE) sales, 2016-2026'

The acutely medically ill population includes patients with heart failure, stroke, infection, pulmonary disease, and overall any patients who are at risk for thromboembolic complications due to moderate or severe restricted mobility in either the hospital setting or post-discharge period. GlobalData epidemiologists estimate that the size of this population in seven major markets (7MM*) is over 23 million, which is a significantly high number of patients compared with the size of the patient pool requiring VTE treatment after the VTE event has already occurred.

Valentina Gburcik, PhD, Healthcare Analyst at GlobalData , comments: "The extended use of Bevyxxa in this large patient population will give Portola a great boost when entering into the novel oral anticoagulant (NOAC) space, where it will compete against established key players, Johnson & Johnson/Bayer's Xarelto, Boehringer Ingelheim's Pradaxa, Bristol-Myers Squibb's Eliquis, and Daiichi Sankyo's Savaysa.

"Although some of these therapies might be used off-label for VTE prophylaxis in acute medically ill patients, none have been granted approval for the treatment of this extended population yet."

In addition, the upcoming launch of Portola's own Factor Xa reversal agent/antidote, andexanet alfa, which is currently in the pre-registration phase in the US and EU, will further boost Bevyxxa's prospects. Since the approval of the first NOAC, Pradaxa, there has always been a level of hesitation among physicians and patients, mainly because of the lack of a

reversal agent in the event of traumatic bleeding.

Gburcik adds: “Despite Portola being a relatively small company, with the approval of Bevyxxa in this large patient population with high unmet needs combined with the soon-to-come antidote that will offer an additional level of security to patients and physicians, the company is in a great position to conquer a large chunk of the lucrative VTE prophylaxis space. We forecast that the VTE market will be worth 2.85bn in 2026.”

* 7MM = US, France, Germany, Italy, Spain, UK and Japan