

## Verastem, Yakult Honsha Co. Ltd sign exclusive license agreement

07 June 2018 | News

**Under the terms of the agreement, Verastem will receive a one-time upfront payment of \$10 million from Yakult. Verastem is eligible to receive up to an additional \$90 million if certain future pre-specified development and commercialization milestones are successfully achieved by Yakult, plus double-digit royalties based on future net sales of duvelisib in Japan. In exchange, Yakult will receive exclusive rights to develop and commercialize duvelisib in Japan, at its own cost and expense.**



Verastem, Inc. and Yakult Honsha Co., Ltd. have announced their entry into an exclusive licensing agreement for Yakult to develop and commercialize Verastem's duvelisib, a first-in-class oral dual inhibitor of phosphoinositide 3-kinase (PI3K)-delta and PI3K-gamma, for the treatment, prevention or diagnosis of all oncology indications in Japan. Verastem's New Drug Application (NDA) for duvelisib is currently under review with the U.S. Food and Drug Administration (FDA) and is seeking full approval for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and accelerated approval for the treatment of relapsed or refractory follicular lymphoma (FL). On April 9, 2018, Verastem announced that the FDA had accepted the NDA for filing with Priority Review.

Under the terms of the agreement, Verastem will receive a one-time upfront payment of \$10 million from Yakult. Verastem is eligible to receive up to an additional \$90 million if certain future pre-specified development and commercialization milestones are successfully achieved by Yakult, plus double-digit royalties based on future net sales of duvelisib in Japan. In exchange, Yakult will receive exclusive rights to develop and commercialize duvelisib in Japan, at its own cost and expense. Yakult will also fund certain global development costs on a pro-rata basis. Verastem will retain all rights to duvelisib outside of Japan.

"In Japan, current therapies to treat CLL/SLL and FL are extremely limited and duvelisib has robust clinical data supporting its efficacy and safety in both indications, which we can build upon," said Masanori Ito, Head of Pharmaceutical Business Division/Managing Executive Officer, Member of the Board of Yakult. "We are eager to collaborate with Verastem to develop duvelisib in these initial hematologic malignancies, and then plan to later expand development to include the additional indications of PTCL and DLBCL. We believe this collaboration underscores our commitment to innovation, growing our

oncology franchise, and commercializing medicines that positively impact the lives of patients in Japan.”

“This agreement is an important, validating achievement for both duvelisib and Verastem Oncology and speaks to the significant global potential of this novel therapeutic for a broad range of hematologic malignancies,” said Robert Forrester, President and Chief Executive Officer of Verastem. “Yakult is an established oncology leader in Japan that successfully markets several branded anti-cancer therapies, including Elplat® and Campto®. We look forward to working with the world-class development, regulatory and commercial teams at Yakult as they advance oral duvelisib toward commercialization in Japan.”