



Press Release

KaliVir Immunotherapeutics and Astellas Enter Worldwide Exclusive Licensing Agreement for Development and Commercialization of VET2-L2 Novel Oncolytic Virus

- The Collaboration will Accelerate the Research and Development of Next-generation Immuno-Oncology Therapies -

PITTSBURGH, PA and TOKYO, December 7, 2020 – KaliVir Immunotherapeutics LLC (CEO: Helena Chaye, Ph.D., J.D., “KaliVir”) and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) announced today that they entered into a worldwide licensing agreement for the research, development, and commercialization of VET2-L2, an intravenously administered oncolytic virus for Immuno-Oncology, as well as a research collaboration to generate a Second Product, a follow-on virus.

KaliVir holds its unique technology platform based on genetically modified vaccinia virus, and is developing VET2-L2, an oncolytic vaccinia virus as their lead program. VET2-L2, which is delivered by intravenous administration, reaches and destroys cancer cells and activates anti-cancer immunity through expression of therapeutic transgenes. KaliVir’s vaccinia virus-based oncolytic viral immunotherapies can be delivered intravenously to cancer patients, eliminating the need for complicated procedures of the direct intra-tumoral administration and enables access for a broader patient population. VET2-L2 is in preclinical stage.

This collaboration, which combines KaliVir’s expertise in the development of oncolytic viruses with Astellas’ capabilities in advanced drug development and its global business experience, will enable both parties to develop new Immuno-Oncology therapies.

Under the terms of the agreement, Astellas will pay to KaliVir up to US\$56 million in the form of an upfront payment and other payments to support research and preclinical activities related to VET2-L2 and the Second Product. Additionally, Astellas may pay up to US\$307 million and up to US\$271 million for development, regulatory and commercialization of VET2-L2 and Second Product, respectively. Astellas also may make royalty payments on net sales of each licensed product.

“We are thrilled that Astellas has chosen KaliVir, and specifically VET2-L2, our lead product candidate, to add to their oncology program. VET2-L2, a multi-mechanistic, intravenously-delivered oncolytic vaccinia virus, has demonstrated strong preclinical data prompting us to plan our initial clinical trial for VET2-L2,” said KaliVir CEO Helena Chaye, Ph.D., J.D. “With Astellas’ excellent track record for drug development and commercialization, we believe that their commitment to collaborating with KaliVir represents strong third-party validation for our VET platform. We are committed to bringing this exciting product to cancer patients and believe that our collaboration with Astellas will expedite our ability to do this.”

Naoki Okamura, Representative Director, Corporate Executive Vice President, Chief Strategy Officer and Chief Financial Officer, at Astellas said, “We, at Astellas, have positioned Immuno-Oncology as one of the Primary Focuses of our R&D strategy, and we are committed to developing the next generation of Immuno-Oncology therapies through new modalities and technologies. Oncolytic viruses are one of the therapies in which we are particularly focused as we strive to provide new options for patients who have no effective treatment options. We expect this KaliVir collaboration to enhance our pipeline and further expand our cancer treatment options as we work to develop innovative medical solutions that turn innovative science into VALUE for patients.”

About KaliVir Immunotherapeutics, Inc.

KaliVir Immunotherapeutics is an early stage biotech company developing cutting-edge, next-generation oncolytic viral immunotherapy programs. The company has developed a unique vaccinia virus-based platform that can generate potent novel oncolytic vaccinia viruses with modifications to maximize viral replication and to enhance intravenous delivery and spread (Vaccinia Enhanced Template “VET” Platform). VET Platform utilizes the large transgene capacity of the vaccinia virus to deliver therapeutics matched to tumor immunophenotypes to stimulate patients’ immune systems and modify the tumor microenvironment. KaliVir’s oncolytic product candidates are designed to be safe, potent and systemically deliverable to treat cancer patients across multiple tumor types. KaliVir is now advancing multiple therapeutic candidates toward the clinic. For more information, please visit www.kalivir.com.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

Astellas Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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