Merck to Acquire VelosBio

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Acquisition Strengthens Merck’s Oncology Pipeline with VLS-101, an Investigational Antibody-Drug Conjugate to Treat Hematological Malignancies and Solid Tumors

KENILWORTH, N.J. & SAN DIEGO--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and VelosBio Inc. today announced that the companies have entered into a definitive agreement pursuant to which Merck, through a subsidiary, will acquire all outstanding shares of VelosBio for $2.75 billion in cash, subject to certain customary adjustments. VelosBio is a privately held clinical-stage biopharmaceutical company committed to developing first-in-class cancer therapies targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1). VelosBio’s lead investigational candidate is VLS-101, an antibody-drug conjugate (ADC) targeting ROR1 that is currently being evaluated in a Phase 1 and a Phase 2 clinical trial for the treatment of patients with hematologic malignancies and solid tumors, respectively.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201105005543/en/

“At Merck, we continue to bolster our growing oncology pipeline with strategic acquisitions that both complement our current portfolio and strengthen our long-term growth potential,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “Pioneering work by VelosBio scientists has yielded VLS-101, which in early studies has provided notable evidence of activity in heavily pretreated patients with refractory hematological malignancies, including mantel cell lymphoma and diffuse large B-cell lymphoma.”

In October 2020, VelosBio announced the initiation of a Phase 2 clinical trial (NCT04504916) to evaluate VLS-101 for the treatment of patients with solid tumors, including patients with triple-negative breast cancer (TNBC), hormone
receptor-positive and/or HER2-positive breast cancer, and non-squamous non-small-cell lung cancer (NSCLC). In early clinical trials, VLS-101 demonstrated a manageable safety profile and early signs of anti-tumor activity. Results of a Phase 1 clinical trial, to be presented virtually at the 62nd American Society of Hematology Annual Meeting (Dec. 5-8, 2020), showed that VLS-101 resulted in objective clinical responses, including complete responses, in 47% (n=7/15) of patients with mantle cell lymphoma (MCL) and 80% (n=4/5) of patients with diffuse large B-cell lymphoma. Patients in this Phase 1 trial had been heavily pretreated with other anticancer medications, and their cancers had failed to respond or had relapsed after initially responding to these other anticancer medications. In addition, VelosBio is developing a preclinical pipeline of next-generation ADCs and bispecific antibodies targeting ROR1 with the potential to complement VLS-101 by offering alternative methods of tumor cell killing.

“Merck is a recognized leader in oncology, and this acquisition reflects the hard work and commitment of all the employees at VelosBio in advancing the science of ROR1,” said Dave Johnson, founder and chief executive officer at VelosBio. “We are very pleased that Merck has recognized the value of our first-in-class ROR1-directed investigational therapeutics. As part of Merck’s oncology pipeline, our lead product candidate, VLS-101, is now well positioned to achieve its maximum potential to benefit appropriate cancer patients in need.”

The closing of the transaction, which is subject to approval under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions, is expected by the end of 2020.

Merck was represented by Gibson Dunn & Crutcher LLP as legal advisor and J.P. Morgan Securities LLC as financial advisor. VelosBio was represented by Cooley LLP as legal advisor and Centerview Partners LLC as financial advisor.

**About VLS-101**

VLS-101 is an investigational ADC comprising a monoclonal antibody targeting ROR1 that is linked to a chemotherapeutic agent called monomethyl auristatin E (MMAE). After the antibody binds to ROR1 on cancer cells, the ADC is designed to enter those cells and release MMAE to destroy the cancer cells. In mouse models of human hematologic malignancies and solid tumors, VLS-101 showed robust antitumor activity. VLS-101 is in clinical development for patients with previously treated hematologic malignancies and solid tumors. The U.S. Food and Drug Administration has granted VLS-101 orphan drug and fast track designations for the treatment of MCL.

**Merck’s Focus on Cancer**

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck, the potential to bring new hope to people with cancer drives our purpose and supporting accessibility to our cancer medicines is our commitment. As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the largest development programs in the industry across
more than 30 tumor types. We also continue to strengthen our portfolio through strategic acquisitions and are prioritizing the development of several promising oncology candidates with the potential to improve the treatment of advanced cancers. For more information about our oncology clinical trials, visit www.merck.com/clinicaltrials.

About Merck

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

About VelosBio

VelosBio Inc. is a clinical-stage biopharmaceutical company committed to transforming the lives of patients with cancer by developing first-in-class therapies targeting ROR1. Its lead candidate, VLS-101, is a ROR1-directed ADC being developed for patients with hematologic malignancies and solid tumors. The company is utilizing its ROR1-targeting antibody-based technology to develop a pipeline of ADCs and bispecific antibody product candidates for the treatment of hematologic malignancies and solid tumors. VelosBio is headquartered in San Diego. For more information, please visit www.velosbio.com.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care
legislation in the United States and internationally; global trends toward health care cost containment; 
technological advances, new products and patents attained by competitors; challenges inherent in new product 
development, including obtaining regulatory approval; the company's ability to accurately predict future market 
conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; 
dependence on the effectiveness of the company's patents and other protections for innovative products; and the 
exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of 
new information, future events or otherwise. Additional factors that could cause results to differ materially from 
those described in the forward-looking statements can be found in the company's 2019 Annual Report on Form 10-K 
and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet 
site (www.sec.gov).

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