

## **Takeda and Frazier Healthcare Partners Announce Collaboration to Launch HilleVax, Inc. to Develop Clinical Stage Norovirus Vaccine Candidate**

### ***Takeda Will Focus its Efforts on Dengue, Zika and Pandemic Vaccines***

**Cambridge, Mass. and Menlo Park, Calif., July 29, 2021** – Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](#)) (Takeda) and Frazier Healthcare Partners (Frazier) today announced a collaboration to launch HilleVax, Inc. (HilleVax), a biopharmaceutical company to develop and commercialize Takeda's norovirus vaccine candidate. Takeda has granted a license to HilleVax for the exclusive development and commercialization rights to its norovirus vaccine candidate, HIL-214 (formerly TAK-214), worldwide outside of Japan, in exchange for upfront consideration, as well as future cash milestones and royalties on net sales. Takeda will retain commercialization rights in Japan and HilleVax will integrate certain Japan development activities into its global development. Takeda remains committed to vaccines, and this collaboration allows Takeda to focus its global resources on dengue, COVID-19, pandemic influenza and Zika, in addition to the vaccines it currently distributes in Japan.

HIL-214, which is a virus-like particle (VLP) based vaccine candidate, completed a randomized, placebo-controlled Phase 2b field efficacy study in 4,712 adult subjects in which HIL-214 was well-tolerated and demonstrated clinical proof of concept in preventing moderate-to-severe cases of acute gastroenteritis from norovirus infection.<sup>1</sup> To date, the candidate has been studied in nine human clinical trials with safety data from over 4,500 subjects and immunogenicity data from over 2,000 subjects.

"Takeda and Frazier have a history of successfully partnering together, and we are confident in HilleVax's capabilities to progress HIL-214, the most advanced norovirus vaccine candidate in development with the potential to address the huge global burden of norovirus-associated acute gastroenteritis," said Rajeev Venkayya, M.D., President of the Global Vaccine Business Unit, Takeda. "This will allow Takeda to focus its efforts and resources on our dengue vaccine, which we have begun filing for licensure around the world, our pandemic programs, and our partnership with the US Government to develop a Zika vaccine."

Norovirus is a common intestinal infection marked by diarrhea, vomiting, abdominal cramps, nausea and sometimes fever that may lead to clinically significant dehydration.<sup>2</sup> Norovirus is recognized as the leading cause of acute gastroenteritis across the age spectrum.<sup>3</sup> It is estimated that norovirus causes nearly 700 million cases of illness and more than 200,000 deaths worldwide per year with significant additional economic and social burden.<sup>3</sup> No vaccines are currently approved for norovirus infection, and HIL-214 continues to be the most advanced norovirus vaccine candidate in human clinical trials.

"Following our successful partnership to form Phathom Pharmaceuticals, we are extremely pleased to partner again with Takeda to form HilleVax," said Tachi Yamada, M.D., co-founder of HilleVax and Venture Partner with Frazier. "Norovirus causes significant morbidity and mortality as well as tremendous economic and social costs worldwide. We believe that HIL-214 represents an important opportunity to address this immense unmet need."

### **Takeda's Commitment to Vaccines**

Vaccines prevent 2 to 3 million deaths each year and have transformed global public health. For more than 70 years, Takeda has supplied vaccines to protect the health of people in Japan. Today, Takeda's global vaccine business is applying innovation to tackle some of the world's most challenging infectious diseases, such as dengue, COVID-19, pandemic influenza and Zika. Takeda's team brings an outstanding track record and a wealth of knowledge in vaccine

development and manufacturing to advance a pipeline of vaccines to address some of the world's most pressing public health needs. For more information, visit [www.TakedaVaccines.com](http://www.TakedaVaccines.com).

### **About Takeda Pharmaceutical Company Limited**

Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.tse.co.jp/eng/stock)) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries and regions. For more information, visit <https://www.takeda.com>.

### **About Frazier Healthcare Partners**

Founded in 1991, Frazier Healthcare Partners is a leading provider of growth and venture capital to healthcare companies. With nearly \$4.8 billion total capital raised, Frazier has invested in over 200 companies, with investment types ranging from company creation and venture capital to buyouts of profitable lower-middle market companies. The firm's Growth Buyout team invests in healthcare and pharmaceutical services, medical products and related sectors. The Life Sciences team invests in therapeutics and related areas that are addressing unmet medical needs through innovation. Frazier has offices in Seattle, WA and Menlo Park, CA, and invests broadly across the US, Canada, and Europe. For more information about Frazier Healthcare Partners, visit the company's website at <http://www.frazierhealthcare.com>.

### **About HilleVax**

HilleVax is a biopharmaceutical company focused on the development and commercialization of novel vaccine candidates. Its initial program, HIL-214, is a virus-like particle (VLP) based vaccine candidate in development for the prevention of moderate-to-severe acute gastroenteritis caused by norovirus infection. For more information about HilleVax, visit the company's website at <http://www.HilleVax.com>.

### **Takeda Pharmaceutical Company Limited Forward-Looking Statements**

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which

Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: <https://www.takeda.com/investors/sec-filings/> or at [www.sec.gov](http://www.sec.gov). Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

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**CONTACTS:**

<b>Takeda Media Contacts:</b>	
<b>Japanese Media</b> Ryoko Matsumoto <b>ryoko.matsumoto@takeda.com</b> +81 (0) 3-3278-3414	<b>Media Outside Japan</b> Amy Atwood <b>amy.atwood@takeda.com</b> +1-774-571-3316
<b>For HilleVax, Inc.:</b> David Socks <b>info@hillevax.com</b> +1-650-325-5156	<b>For Frazier Healthcare Partners:</b> Liz Park <b>liz.park@frazierhealthcare.com</b> +1-650-319-1831

**References**

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<sup>1</sup> Sherwood J, et al. Vaccine 2020; 38(41):6442-6449

<sup>2</sup> <https://www.cdc.gov/norovirus/index.html> [accessed 2021 April 27].

<sup>3</sup> Hall AJ, et al. Expert Rev Vaccines 2016;15(8):949-951