



# News Release

## **Takeda to Acquire Inviragen, Inc.**

***Obtains Promising Vaccine Candidates Against Dengue and Hand, Foot and Mouth Disease,  
Advancing Takeda's Commitment to Vaccines and Global Health***

**Osaka, Japan, May 8, 2013, Deerfield, IL and Fort Collins, CO, U.S.A., May 7, 2013** – Takeda Pharmaceutical Company Limited (“Takeda”) and Inviragen, Inc. (“Inviragen”) jointly announced today that Takeda, its wholly owned subsidiary Takeda America Holdings, Inc., and Inviragen, Inc. have entered into a definitive agreement for Takeda to acquire Inviragen for an upfront payment of US\$35 million, and future payments of up to US\$215 million linked to the progress of clinical development and achievement of key commercial milestones. Headquartered in Fort Collins, CO, with facilities in Madison, WI and Singapore, Inviragen is a privately-held biopharmaceutical company specializing in research and development of innovative vaccines for emerging infectious diseases, including dengue and hand, foot and mouth disease (HFMD).

“Takeda has taken another major step toward its goal of establishing a world-class global vaccine business by acquiring Inviragen and its advanced vaccine candidate against dengue, a serious mosquito-borne illness that threatens nearly half of the world’s population,” said Rajeev Venkayya, M.D., executive vice president and head of Takeda’s Vaccine Business Division. “Today’s announcement reinforces Takeda’s commitment to develop innovative vaccines to fight some of the world’s most important infectious diseases.”

Inviragen has created innovative products using its expertise in viral vaccines. The company’s lead candidate, DENVax, is a four-strain recombinant viral vaccine for the prevention of dengue infection. An administration schedule of two doses of DENVax over 90 days is currently being evaluated in Phase 2 clinical trials. In addition to DENVax, Inviragen’s pipeline contains a vaccine candidate to protect against hand, foot and mouth disease (HFMD) caused by enterovirus 71 (EV71), which has completed Phase 1 clinical testing. Inviragen has also developed a recombinant vaccine candidate to protect against chikungunya, currently in preclinical development.

“The acquisition of Inviragen supports Takeda’s overall research and development programs, long-term growth strategy and commitment to improve health through innovation and new technology,” said Tadataka Yamada, M.D., Takeda’s chief medical and scientific officer and member of the Takeda board of directors. “Coming less than a year after the acquisition of LigoCyte with the world’s leading norovirus vaccine candidate, this illustrates Takeda’s commitment to its global vaccine business and global public health.”

Dengue is the most important mosquito-borne viral illness in the world, and is one of four World Health Organization (WHO) future vaccine priorities. It is estimated that about 400 million people worldwide are infected by the dengue virus each year, of which nearly 100 million develop clinical illness. Approximately 500,000 people are hospitalized and 20,000, mostly children, die from severe complications such as hemorrhagic fever. Currently there are only symptomatic treatments available for dengue and dengue hemorrhagic fever, and the only means of prevention is through mosquito control. The number of reported symptomatic dengue infections has increased 30-fold in the past 50 years, and the global footprint of dengue is expanding. HFMD epidemics occur annually throughout the Asia Pacific region, with millions of cases reported yearly since 2010. Chikungunya, which is a mosquito-transmitted virus, has produced epidemics in Africa, India, Asia and Europe. There are no specific treatments or cures for dengue, HFMD or chikungunya. Takeda will work with governments and international organizations to ensure that these vaccines reach the populations that need them around the world.

“This acquisition combines Inviragen’s expertise in viral vaccine research and development and our extensive worldwide network of preclinical and clinical collaborators with Takeda’s resources, product development expertise, and global reach. Together we are well-positioned to bring these promising vaccine candidates to the market,” said Dan Stinchcomb, Ph.D., Inviragen’s chief executive officer. “Inviragen is pleased to become a part of a leading pharmaceutical company that is so strongly committed to developing vaccines that can improve public health worldwide.”

Beyond the substantial expansion of Takeda’s vaccine pipeline, this acquisition will enhance Takeda’s core vaccine R&D capabilities with Inviragen’s vaccine development center in Singapore, in one of the regions where Inviragen’s vaccines will have the greatest impact. “Inviragen has made significant progress in developing key vaccines for emerging infectious diseases in Asia and worldwide, with active support from its international investor base,” said Swee–Yeok Chu, CEO & President EDBI, a strategic investment firm headquartered in Singapore and a major Inviragen investor. “Takeda is an excellent partner to bring these important vaccines to the next stage of development.”

To preserve continuity and build upon Inviragen’s success, Takeda will integrate the Inviragen team into Takeda’s Vaccine Business Division. Pending the satisfaction of customary closing conditions, the deal is expected to close in the next few weeks.

## **Key Strategic Benefits**

Takeda expects the acquisition of Inviragen will:

- Enable Takeda to develop a highly-promising vaccine against dengue, which the World Health Organization calls “the most important mosquito-borne viral disease in the world.”
- Grow Takeda’s product pipeline with vaccine candidates that protect against HFMD and chikungunya.
- Expand Takeda’s current technical capabilities, which include virus-like particle and cell culture technologies, with Inviragen’s live-virus and inactivated virus vaccine capabilities.
- Contribute to Takeda’s overall research and development programs, long-term growth strategy and commitment to improve the health of people and communities everywhere.

## **Acquisition Summary**

- (1) Acquiring companies: Takeda America Holdings, Inc. and Takeda Pharmaceutical Company Limited
- (2) Shareholders of Inviragen, Inc.: EDBI, Charter Life Sciences, Venture Investors, and Phillip Private Equity
- (3) Payment: Cash
- (4) Number of fully diluted common and preferred stock equivalent to common outstanding shares: 39,035,439
- (5) Acquisition amount: US\$35 million
  - i. In addition to this acquisition amount, the deal consideration includes with future contingent consideration based on the progress of development projects and commercial milestones up to US\$215 million.
- (6) Planned date of completion: Pending the satisfaction of customary closing conditions, the deal is expected to close within 14 days.
- (7) Legal advisor to Takeda: Morgan, Lewis & Bockius LLP
- (8) Financial advisor to Inviragen: Torreya Partners LLC
- (9) Legal advisor to Inviragen: Wilson Sonsini Goodrich & Rosati

## **Profile of Inviragen Inc.:**

- (1) Corporate Name: Inviragen, Inc.
- (2) Headquarters: Fort Collins, CO, U.S.A.
- (3) Wholly owned subsidiary: Inviragen (Singapore) Pte.Ltd., Singapore
- (4) Representative: Dr. Dan Stinchcomb, Co-founder and CEO
- (5) Year of establishment: 2005
- (6) Common Stock Equity: US\$777
- (7) Additional Paid-in Capital: US\$1,979,995
- (8) Shares: Non-listed
- (9) Number of employees: Approximately 50 employees.
- (10) Relationship with Takeda: No matters to report regarding capital, personal and transactional relationship between Takeda and Inviragen.

The impact from this acquisition on Takeda’s consolidated financial statements of fiscal 2013 is expected to minimal.

### **About Dengue Fever**

Nearly half of the world's population live in countries that have frequent dengue outbreaks. The four dengue viruses (DEN - 1, DEN - 2, DEN - 3 and DEN - 4) are spread by the mosquito, *Aedes aegypti*, which is found throughout tropical and subtropical regions. Recent estimates suggest that dengue viruses cause approximately 100 million cases of clinical illness and over 2 million cases of severe dengue disease leading to more than 20,000 deaths every year. For more information on dengue fever, please refer to the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and Dengue Vaccine Initiative (DVI) web sites.

### **About Hand, Foot and Mouth Disease (HFMD)**

Hand, foot and mouth disease is a disease common in children throughout the world and is endemic in the Asia Pacific region where its incidence has been increasing steadily over the past two decades. Although the disease is typically of short duration, there has been an increase in severe HFMD cases associated with EV71. HFMD epidemics have been reported in most Asian countries, particularly Singapore, Taiwan, Malaysia, Thailand, Japan, Korea, Vietnam, Korea, Hong Kong and China.

### **About Chikungunya and the CHIKV Virus**

Chikungunya Virus (CHIKV) is transmitted via mosquito and can cause fever, headache, fatigue, nausea, vomiting, muscle pain, rash and joint pain in those infected. Approximately 30% of patients showing clinical signs experience incapacitating joint pain, or arthritis that may persist for weeks, months, or in some cases years. On rare occasions, CHIKV infection may lead to neurologic and hepatic disease with high illness and mortality rates. CHIKV is considered endemic in 34 countries in Europe, Australia, Asia and Africa.

### **About Inviragen, Inc.**

Inviragen is focused on developing vaccines to protect against infectious diseases worldwide. Inviragen's vaccine to protect against dengue fever is in Phase 2 clinical testing. A vaccine designed to protect children from hand, foot and mouth disease has completed Phase 1 clinical testing. Vaccines to protect against chikungunya and Japanese encephalitis, which affect millions of individuals in Asia, are in development. Vaccines in preclinical research stages include vaccines to protect against new forms of influenza and a combination plague/smallpox vaccine for biodefense. Founded in 2005 with offices in Colorado, Wisconsin and Singapore, Inviragen's investors include EDBI (through Bio\*One Capital, Singapore), Charter Life Sciences (Sunnyvale, CA), Venture Investors (Madison, WI), and Phillip Private Equity (Singapore). See [www.inviragen.com](http://www.inviragen.com) for more details.

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

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com).

## **Takeda's Vaccine Business Division**

Takeda has a proven track record of manufacturing and supplying vaccines in Japan for more than sixty years. Takeda's global vaccine business division was launched in January 2012 to build upon this success, and is headquartered in Deerfield, Illinois. The company acquired LigoCyte Pharmaceuticals and its norovirus vaccine candidate, as well as its proprietary virus-like particle vaccine platform and several preclinical vaccine candidates in October 2012.

## **About EDBI**

EDBI is a leading strategic investment firm headquartered in Singapore with a worldwide presence investing to drive growth opportunities within the knowledge and innovation-intensive sectors of Biomedical Sciences (through its subsidiary Bio\*One Capital), Clean Technologies, Internet & Digital Media, as well as key industries in Singapore. As a value adding investor, EDBI creates sustainable and synergistic partnerships with its portfolio companies, leveraging on its extensive networks and experience to facilitate the companies' growth in Asia and the world, through their operations in Singapore.

Please visit: [www.edbi.com](http://www.edbi.com).

## **Forward-Looking Statements**

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements.

Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; the transaction may not be consummated; the anticipated benefits of the transaction may not be realized; the transaction could disrupt relationships with employees, licensees, customers and other business partners or governmental entities; future sales could be adversely affected by competition or other factors; and integration costs may exceed current expectations. In addition, the combined business could be adversely affected by industry, economic or political conditions outside of Inviragen's or Takeda's control, including general economic conditions in Japan, the United

States and worldwide; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither Inviragen nor Takeda undertake any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

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