

To our press

November 14, 2016  
Institute of Immunology Co.,Ltd.  
OrphanPacific, Inc.

**Announcement of distribution alliance agreement of Flu Virus Kit  
"MinuteRead® Flu"**

Institute of Immunology (Headquarters: Bunkyo-ku, Tokyo, President: Yukio Ito) and OrphanPacific Inc. (Headquarters: Minato-ku, Tokyo, President, Representative Director: Philippe Auvaro) entered into the distribution alliance agreement for Influenza virus kit "MinuteRead® Flu" for which Institute of Immunology obtained the regulatory manufacturing and marketing approval. The launch is scheduled on January 11, 2017 (Manufacturer: Institute of Immunology, Distributor: Orphan Pacific).

In each year, about 14 million people are infected with influenza virus<sup>1)</sup>, and about 1,800 people may die of the infection<sup>2)</sup> in years of high prevalence. The virus becomes infectious one day before the onset (fever) in the infested host and the most infectious 24 to 48 hours after the onset, while the latent period is short: these factors contribute to a rapid increase in the number of influenza patients in a short period of time. Therefore, a quick and accurate diagnosis is important, and now quick test kits are widely used. Especially in the early stage of infection with low viral load, some individuals may be tested negative, and a more sensitive test kit is required.

The influenza rapid diagnostic kit requires an antibody that specifically binds to influenza virus, and the performance of this antibody significantly dictates the performance of the diagnostic kit. Institute of Immunology has the strength in its in-house capability of developing and producing high-performing unique antibodies, including antibodies used for diagnoses of hepatitis viruses. With the capability, we have developed "MinuteRead® Flu" by capitalizing on the antibody technology and know-how cultivated over many years.

"MinuteRead® Flu" is an inspection kit with three properties: (1) rapidity (2) accuracy (3) detectivity even in an early stage of infection with a little viral load.

OrphanPacific believes that support for a swift and more accurate influenza diagnosis will contribute to better medical care, and OrphanPacific decided the distribution agreement for "MinuteRead<sup>®</sup> Flu" developed by Institute of Immunology.

1) National Institute of Infectious Diseases

<http://www.nih.go.jp/niid/images/idsc/disease/influ/fludoco1314.pdf> (last accessed on 2016/11/9)

<http://www.nih.go.jp/niid/images/idsc/disease/influ/fludoco1415-2.pdf> (last accessed on 2016/11/9)

<http://www.nih.go.jp/niid/images/idsc/disease/influ/fludoco1516.pdf> (last accessed on 2016/11/9)

2) Population dynamics statistics of Ministry of Health, Labor and Welfare

<http://www.mhlw.go.jp/toukei/saikin/hw/jinkou/kakutei05/hyo7.html> (last accessed on 2016/11/9)

### **The summary of "MinuteRead<sup>®</sup> Flu"**

Trade name: MinuteRead<sup>®</sup> Flu

Purpose of use: Detection of influenza type A or type B antigen in nasal swab  
(Diagnostic aid for influenza virus infection)

Packing: 10 tests

Manufacturing marketing approval date: September 23, 2016

Release date: January 11, 2017 (planned)

Suggested retail price: 9,800 yen

Manufacturer: Institute of Immunology

Distributor: Orphan Pacific Co., Ltd.

### **[Corporate Profile]**

#### **Institute of Immunology Co.,Ltd.**

Institute of Immunology is an IVD manufacturer founded in August 1979 and has been supplying in Japan and overseas diagnostic reagents for serious infectious diseases caused by pathogens including hepatitis B virus, helicobacter pylori and monoclonal antibodies as well as a variety of reagents for research purposes based on its base technology for antibody development and manufacturing.

Headquarters: [Address] 1-1-10 Bunkyo, Bunkyo-ku Tokyo

President: Yukio Ito

Capital: 100 million yen (as of the end of November 2015)

#### **OrphanPacific, Inc.**

OrphanPacific is a joint venture company founded in 2012 to create a new business of

medical drugs especially for orphan drugs, by CMIC Holdings, which is the largest CRO in Japan, and MEDIPAL HOLDINGS CORPORATION, the largest pharmaceutical distribution company.

Headquarters: [Address] 1-1-1 Shibaura Minato-ku, Tokyo

President, Representative Director: Philippe Auvaro

Capital: 100 million yen (as of the end of September 2016)

[Contact department of inquiries for this announcement]

Institute of Immunology Co.,Ltd.

4<sup>th</sup> Sales and Marketing Division Tel: (03) -3814-4081

OrphanPacific,Inc.

Corporate Planning Department Tel: (03) -6779-8151