Whom It May Concern

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NHI Drug Price Listing and Release of Oral Quinolone Antibacterial Agent
“Lasvic® Tablets 75mg”

TOKYO, Japan (November 19, 2019) —Kyorin Pharmaceutical Co., Ltd. (Head office: Chiyoda-ku, Tokyo, President: Shigeru Ogihara), a wholly owned subsidiary of KYORIN Holdings, Inc., announced that the oral quinolone antibacterial drug Lasvic® Tablets 75mg which was received approval from the Ministry of Health, Labor and Welfare as of September 20, 2019 has been listed on the National Health Insurance (NHI) drug price list today.

Lasvic® Tablets 75mg are a novel quinolone antibacterial drug manufactured by Kyorin Pharmaceutical Co., Ltd. as a new treatment for respiratory and ENT infections. By the results of four Clinical Phase I/II studies in Japan in respiratory and ENT infections patients, it was received production/marketing approval. In the two double-blind comparative Phase III clinical study in community-acquired pneumonia and sinusitis patients, non-inferiority of Lasvic to the oral quinolone antibacterial drug that is used generally for respiratory and ENT infections was validated.

Kyorin Pharmaceutical Co., Ltd. aims to further contribute to the treatment of patients by adding Lasvic® Tablets to its product lineup in the respiratory and otolaryngology fields, which one of its priority fields, and by providing up-to-date information on an ongoing basis.

Kyorin Pharmaceutical Co., Ltd. will secure a sales structure of the product and will be scheduled for release on January 8, 2020.

We expect sales of the drug in the initial year to reach 0.9 billion yen. The sales of the drug is factored in consolidated forecast for the fiscal year ending March 31 2020 announced on November 7, 2019.
Brand name: Lasvic® Tablets 75mg
Generic name: Lascufloxacin Hydrochloride
INN: LSFX

Indications:
<Bacterial strains> The genus Staphylococcus, the genus Streptococcus, Pneumococcus, Moraxella (Branhamella) catarrhalis, the genus Klebsiella, the genus Enterobacter, Haemophilus influenzae, Legionella pneumophila, the genus Prevotella and Mycoplasma pneumoniae that are sensitive to this drug

<Diseases> Pharyngitis, stomatitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, middle ear infection, sinusitis

Dosage and Administration: The usual oral dosage for adults is 75mg of lascufloxacin once daily.

NHI price: ¥361.40
Date of production/marketing approval acquiring: September 20, 2019
Date of Drug Price Listing: November 19, 2019
Date of Launch in Japan (estimated): January 8, 2020
Manufacturer and seller: Kyorin Pharmaceutical Co., Ltd.