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Horizon Pharma plc Announces Availability of QUINSAIR™ (levofloxacin inhalation solution) in Canada for the Treatment of Specific Lung Infections in Adults with Cystic Fibrosis

DUBLIN, Ireland, Dec. 22, 2016 (GLOBE NEWSWIRE) -- Horizon Pharma plc (NASDAQ:HZNP), a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs, and its affiliate Horizon Therapeutics Canada Limited, today announced that QUINSAIR™ (levofloxacin inhalation solution) is now available in Canada for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis (CF). QUINSAIR is the first inhaled fluoroquinolone antibiotic to receive marketing authorization from Health Canada.

"Prevalence of *Pseudomonas aeruginosa* is high among people with cystic fibrosis and chronic management is often required after a patient is infected with these bacteria," said Jared Rhines, vice president and general manager, Canada, LATAM and APAC, Horizon Pharma. "Horizon has a long-term commitment to people living with rare diseases, and we're looking forward to working with healthcare professionals and patient organizations that address the needs of the Canadian cystic fibrosis community at risk for these insidious infections."

CF is a rare, life-threatening genetic disease affecting approximately 75,000 people worldwide,¹ and more than 4,100 people in Canada.² It is the most common fatal genetic disease among Canadian young adults, and primarily affects the digestive system and lungs. While disease severity differs among people living with CF, persistent and ongoing infections in the lungs are the most frequent cause of death.³ *Pseudomonas aeruginosa* is one of the most common bacteria causing lung infections in people living with CF.⁴

"It is very important that healthcare professionals in Canada have access to a variety of medicines for people with cystic fibrosis dealing with *Pseudomonas aeruginosa* infections," said Norma Beauchamp, president and chief executive officer, Cystic Fibrosis Canada. "Once established in the airways, this bacteria becomes very difficult to eliminate, often requiring aggressive treatment with multiple therapies. QUINSAIR provides an inhaled option and we're pleased that it is now available in Canada."

For more information about the availability of QUINSAIR in Canada, including Horizon's patient support programs, please call 1-844-823-4226.

Horizon acquired QUINSAIR as part of its acquisition of Raptor Pharmaceutical Corp. in October 2016.

About QUINSAIR™

QUINSAIR is a proprietary inhaled formulation of levofloxacin, a fluoroquinolone antibiotic, which is approved in Canada for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with CF. Administration of QUINSAIR with the high efficiency Zirela® Nebulizer System (PARI Pharma GmbH) allows for the direct delivery of high concentrations of active drug to the site of infection in approximately five minutes. QUINSAIR is contraindicated in patients with hypersensitivity to levofloxacin, a history of tendon disorders related to fluoroquinolones and patients who may be pregnant or breast feeding. QUINSAIR's safety was evaluated in two double-blind, placebo-controlled studies and an active comparator study in which the most frequently reported adverse reactions were cough/productive cough, dysgeusia and sputum increase.

For More Information:

Please consult the product monograph at <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp> for important information relating to warnings, precautions, adverse reactions, drug interactions and dosing information which have not been discussed in this press release.

About Horizon Pharma plc

Horizon Pharma plc is a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. The Company markets 11 medicines through its orphan, rheumatology and primary care business units. For more information, please visit

www.horizonpharma.com. Follow [@HZNPplc](https://twitter.com/HZNPplc) on Twitter or view careers on our [LinkedIn](#) page.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the potential of QUINSAIR to treat patients with cystic fibrosis. These forward-looking statements are based on management expectations and assumptions as of the date of this press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include whether QUINSAIR will be successfully commercialized and sufficiently available in Canada, as well as those factors described in Horizon's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and Horizon does not undertake any obligation to update or revise these statements, except as may be required by law.

References:

1. Cystic Fibrosis Foundation. What is Cystic Fibrosis. Web. 16 Dec 2016. <https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/>
2. Cystic Fibrosis Canada. The Canadian Cystic Fibrosis Registry. Web. 19 Dec 2016. <https://cysticfibrosis.uberflip.com/i/705240-cystic-fibrosis-canada-registry>
3. Cystic Fibrosis Canada. About CF: What is Cystic Fibrosis. Web. 16 Dec 2016. <http://www.cysticfibrosis.ca/about-cf>
4. Davies JC. "Pseudomonas aeruginosa in cystic fibrosis: pathogenesis and persistence." *Paediatric Respiratory Review*. Web. 16 Dec 2016. <https://www.ncbi.nlm.nih.gov/pubmed/12297059>

Contacts:

Investors:

Tina Ventura

Senior Vice President, Investor Relations

Investor-relations@horizonpharma.com

U.S. Media Contact:

Matt Flesch

Executive Director, Product Communications

media@horizonpharma.com

Ireland Media Contact:

Ray Gordon

Gordon MRM

ray@gordonmrm.ie

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