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News

Synagis[®] May Reduce Subsequent Recurrent Wheezing in Preterm Infants

Prophylaxis with Synagis (Palivizumab) Decreases Incidence of Recurrent Wheeze by Almost Half

MONTRÉAL, December 12, 2007 – A new study published in the Journal of Pediatrics reports that preventing serious respiratory syncytial virus (RSV) infections with Synagis[®] (palivizumab) in premature infants may reduce recurrent wheezing in the first few years of life by almost half.¹

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The study, which included three Canadian trial sites, showed that premature infants without chronic lung disease who received Synagis prior to the study had a 49 percent reduction in the incidence of recurrent wheezing compared with preterm infants who did not receive Synagis. The two-year study also found a 51 percent reduction in the incidence of physician-diagnosed recurrent wheezing in the Synagis group compared with untreated infants.

"Previous studies have already shown Synagis to be highly effective in preventing RSV-related hospitalizations in premature infants," said Dr. Ian Mitchell, pediatric respirologist at Alberta Children's Hospital and an investigator in the study. "This new study is important because it reveals that, by preventing RSV, Synagis may protect premature infants from long-term recurrent wheezing and so reduce the frequency of their doctor visits."

Synagis is a biologic therapy known as a monoclonal antibody that is administered monthly to pediatric patients at high risk of contracting RSV (e.g. premature infants) to prevent serious lower respiratory tract infection caused by this virus, a leading cause of viral respiratory infection among infants.

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¹Op. cit. Journal of Pediatrics; July 2007: 34-42.

Most children with RSV develop an upper respiratory tract infection with symptoms resembling a cold. In preterm infants, however, the infection has an increased risk of progressing to a lower respiratory tract infection that may require hospitalization, mechanical ventilation and intensive care. Beyond the acute consequences of infection, epidemiologic data suggest a link between early RSV-associated hospitalization and chronic respiratory complications, such as recurrent wheezing and asthma, which may extend into adolescence² and early adulthood.³

The leading cause of hospitalization for infants under age two⁴, RSV-related infections are responsible for 5,800 hospitalizations annually in Canada.⁵ Furthermore, children who experience RSV early in life tend to have high rates of subsequent recurrent wheezing.⁶ Wheezing is a whistling sound made by air passing through airways narrowed by inflammation or muscle spasms.

RSV season usually starts in the fall and runs through the spring.⁷ In Canadian infants and children, RSV is the most common cause of lower respiratory tract infections such as bronchiolitis and pneumonia.⁸ Approximately two-thirds of Canadian infants are infected with RSV during their first year of life, and virtually all children will have been infected by their second birthday.⁹

Clinical Trial Design

The study was conducted at 27 trial sites in Canada, Germany, the Netherlands, Poland, Spain and Sweden. Canadian trial sites were located in Vancouver, Saskatoon and Calgary.

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² Stein RT, Sherrill D, Morgan WJ, Holberg CJ, Halonen M, Taussig LM, et al. Respiratory syncytial virus in early life and risk of wheeze and allergy by age 13 years. *Lancet* 1999;354:541-5.

³ Korppi M, Piippo-Savolainen E, Korhonen K, Remes S. Respiratory morbidity 20 years after RSV infection in infancy. *Pediatr Pulmonol* 2004;38:155-60.

⁴ Dalhousie Medical Research Foundation. <http://www.dmr.ca/inside.asp?cmPageID=103>. 2007.

⁵ Oh PI, Lanctôt KL, Yoon A et al. Palivizumab prophylaxis for respiratory syncytial virus in Canada: utilization and outcomes. *Pediatr Infect Dis J* 2002; 21:1-2.

⁶ Op. cit. *Journal of Pediatrics*; July 2007: 34-42.

⁷ Abbott/MedImmune news release: New Study in *Journal of Pediatrics* Suggests Synagis® (Palivizumab) May Reduce subsequent Recurrent Wheezing in Preterm Infants. June 29, 2007. p.4.

⁸ National Center for Disease and Infection Control.

<http://www.cdc.gov/nicdod/dvrd/revb/respiratory/rsvfeat.htm>. Jan 21, 2005.

⁹ Sorrentino M, Powers T and the Palivizumab Outcomes Study Group. Effectiveness of palivizumab: evaluation of outcomes from 1998 to 1999 respiratory syncytial virus season. *Pediatr Infect Dis J* 2000; 19(11): 1068-70.

Researchers followed a group of preterm infants (born <35 weeks gestational age) who received at least three doses of Synagis for RSV prophylaxis during their first year of life, and a matched group of preterm infants not treated with Synagis. The Synagis group consisted of 191 preterm infants who were less than 36 months of age and who were not hospitalized for RSV. The control group included 230 preterm children who were matched by chronologic and gestational age: 76 had been hospitalized for RSV and 154 had not. Study subjects were followed for 24 months beginning at a mean age of 19 months.

The primary endpoint of the study was the incidence of recurrent wheezing, defined as three or more episodes of wheezing in the preceding 12 months. An episode of wheezing was defined as one or more consecutive days of wheezing, preceded and followed by a healthy period of at least one week. The study also evaluated the incidence of physician-diagnosed recurrent wheezing, defined as three or more episodes of wheezing in the prior 12 months, as verified by a physician at a physician's office, emergency room or hospital.

Clinical Trial Results

After following these children for two years, the results showed the following key findings:

The incidence of recurrent wheezing was 49 percent lower among children who received Synagis compared with those who did not (13 percent vs. 26 percent, $p=0.001$). There was also significantly less physician-diagnosed recurrent wheezing in the group that received Synagis (8 percent vs. 16 percent, $p=0.011$).

In addition, infants who received Synagis had a significantly longer time to onset of both recurrent wheezing and physician-diagnosed recurrent wheezing, compared with the combined non-prophylaxed group.

About Synagis

Synagis is a humanized monoclonal antibody approved and available in Canada for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of contracting RSV.

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The safety and efficacy of Synagis were established in infants with broncho-pulmonary dysplasia, infants with a history of prematurity (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease. The first dose of Synagis should be administered prior to the commencement of the RSV season, which usually starts in the fall. Patients, including those who develop an RSV infection, should continue to receive monthly doses throughout the RSV season. Synagis is currently available in 62 countries.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs 65,000 people and markets its products in more than 130 countries.

In Canada, Abbott is headquartered in Montréal, Québec, employs almost 2,000 people and is one of the “50 Best Employers in Canada,” according to a survey by Hewitt Associates.

Abbott’s news releases and other information are available on the company’s Web sites at www.abbott.ca and www.abbott.com.

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