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HALO, Halozyme, BAX, Baxter, announce positive results, 03/22/2013

Baxter And Halozyme Announce Positive Opinion For HyQvia For Treatment Of Primary And Secondary Immunodeficiencies In The European Union

LONDON, March 22, 2013 /PRNewswire / --

Baxter International Inc. (BAX **) and Halozyme**

Therapeutics, Inc., (
HALO
) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (
EMA
CHMP
) has granted a Positive Opinion to Baxter for the use of
HyQvia
(solution for subcutaneous use) as replacement therapy for adult patients with primary and secondary immunodeficiencies
. The product is a combination of human normal immunoglobulin (
IGSC
, 10%) and recombinant human hyaluronidase

, which facilitates the dispersion and absorption of the IGSC .

"This recommendation supports our efforts to improve the overall quality of care for patients. This therapy, when approved by the European Commission, would offer patients the option to administer their therapy at home, in a single subcutaneous site every three to four weeks, resulting in potentially lower systemic adverse reactions compared to intravenous treatments," said Ludwig Hantson, Ph.D., president of Baxter's BioScience

business. "We look forward to introducing HyQvia as a new patient-friendly therapeutic option for immunodeficient patients."

The application was based on results from a phase III, prospective, open-label, non-controlled design clinical trial, which evaluated the safety and effectiveness of HyQvia in the prevention of acute serious bacterial infections, and the pharmacokinetic parameters compared to immunoglobulin administered

intravenously. The objective of the study was to infuse a 3-or 4-week dose of the therapy in a single subcutaneous site. The acute serious bacterial infection rate in the study was 0.025 per patient per year, which is below the required efficacy threshold of 1.0 (serious bacterial infections per patient per year). In the tolerability assessment of HyQvia , the most frequently reported adverse reactions were infusion site reactions (20% of infusions), headache (3% of infusions), fatigue (1% of infusions) and pyrexia (fever) (1% of infusions). Upon receiving marketing authorization from the European Commission, Baxter plans

**to launch
HyQvia
in selected countries in the European Union later this year.**

**"Recognizing that the path to approval for any biologic is a long journey, I would like to thank and congratulate the teams at Halozyme and Baxter who have worked tirelessly to advance this therapeutic option for patients," said Gregory I. Frost, Ph.D., president and chief executive officer,
Halozyme
Therapeutics.**

Sources: Baxter, Halozyme, OxBridge Research,
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