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GSK Statement: Voluntary hold of Arepanrix (adjuvanted H1N1 pandemic vaccine) lot number A80CA007A in Canada

Following discussions with Health Canada, GlaxoSmithKline (GSK) has advised provincial and territorial health authorities, as a precautionary measure, to put on hold one lot of Arepanrix vaccines bearing the lot number **A80CA007A** until investigations being undertaken by GSK, Health Canada and the Public Health Agency of Canada (PHAC) have been completed.

GSK is committed to the highest standards of patient safety and care, and is taking this action as a result of a higher than expected rate of serious allergic reactions (anaphylaxis) related to this lot number compared to other lots. These observations have not been reported with vaccines from any other lots and therefore no other lots are impacted by this voluntary hold.

GSK continues to work with Health Canada to ensure that each vaccine lot released to the provinces and territories meets the highest quality and safety standards. The vaccination programme remains ongoing.

To date, approximately 15 million doses of Arepanrix have been distributed in Canada and, overall, the frequency of severe allergic reactions following immunisation is less than 1 event per 100,000 doses. This rate does not exceed the rates typically reported for other vaccines.

The vast majority of suspected adverse reactions reported to date in association with the vaccine have related to the signs and symptoms of recognised side-effects listed in the product information. The most common side-effects reported in clinical trials were tiredness, headache, fever, joint/muscle pain, and swelling, pain, redness or a hard lump at the injection site.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2008.

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