

Selected literature

■ **Hepatitis B vaccine.** de Boer A, McNeil S, Halperin SA, et al. Safety and immunogenicity of a novel hepatitis B vaccine adjuvanted with immunostimulatory sequence (ISS) in renal pre-dialysis and dialysis patients. [abstract]. *Am J Kidney Dis.* 2010;55(4):B51.

■ **Seasonal influenza vaccine.** Chi RC, Rock MT, Neuzil KM. Immunogenicity and safety of intradermal influenza vaccination in healthy older adults. *Clin Infect Dis.* 2010;50(10):1331–1338.

Selected websites

www.nvic.org/default.aspx
National Vaccine Information Center

www.cdc.gov/
The Centers for Disease Control and Prevention

www.niaid.nih.gov/about/organization/vrc/pages/default.aspx
National Institute of Allergy and Infectious Diseases Vaccine Research Center

Vaccines

New drugs

Product type/proposed indication	FDA status/notes
hepatitis B vaccine (Heplisav) Dynavax Technologies	prevention of hepatitis B in patients who are less likely to respond to current hepatitis B vaccines such as patients undergoing hemodialysis, HIV patients, and those with chronic liver disease
DTP, hepatitis B, Hib and polio vaccine (Hexaxim) Sanofi Pasteur	phase 3 (BLA filing anticipated in 3Q 2011)
HibMenCY (Menhibrix) GlaxoSmithKline Vaccines	combination of DTP-HepB-Polio-Hib vaccine for disease prevention
herpes simplex virus vaccine (Simplrix) GlaxoSmithKline Vaccines	phase 3
V710 Intercell AG/Merck	prevention of hepatitis B in patients who are less likely to respond to current hepatitis B vaccines such as patients undergoing hemodialysis, HIV patients, and those with chronic liver disease
HibMenCY (Menhibrix) GlaxoSmithKline Vaccines	combination of DTP-HepB-Polio-Hib vaccine for disease prevention
herpes simplex virus vaccine (Simplrix) GlaxoSmithKline Vaccines	phase 3
V710 Intercell AG/Merck	prevention of hepatitis B in patients who are less likely to respond to current hepatitis B vaccines such as patients undergoing hemodialysis, HIV patients, and those with chronic liver disease

New indications/formulations

Product type/proposed indication	FDA status/notes
DTP vaccine (Adacel) Sanofi Pasteur	prevention of diphtheria, tetanus, and pertussis in children aged 4 to 6 years
seasonal influenza vaccine (Flu-ID) Sanofi Pasteur	phase 3
meningococcal vaccine (Menactra) Sanofi Pasteur	seasonal influenza vaccine as new intradermal micro-injection
meningococcal vaccine (Menactra) Sanofi Pasteur	prevention of meningococcus in infants and toddlers aged 9 to 12 months.
pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 protein] (Prevenar 13 Adult) Pfizer	phase 3
pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 protein] (Prevenar 13 Adult) Pfizer	prevention of infectious pneumococcal disease in adults

The purpose of Drug Watch is to keep drug decision-makers informed about pharmaceuticals in late-stage development. In each column, 1 or more disease areas or drug classes are presented. The column is researched and compiled by editorial advisory board member **Michele B. Kaufman, PharmD**, president, PRN Communications, Inc, a consulting/medical writing and editing firm.