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EDITORIAL

Introducing the Revised WEBbook of Biologics

Robert Eisenberg

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CIS invites you to view the newly updated and expanded WEBbook of Biologics. The WEBbook provides basic information about biologic therapies licensed in the USA in a singular and searchable format, of particular interest to physicians who employ such therapies to treat immunologic and inflammatory disorders.

CIS developed the WEBbook of Biologics 4 years ago under the leadership of Dr. Marc Natter. Inevitably, medical science advances. Accordingly, Dr. Robert Eisenberg, CIS Website editor, and Dr. Richard Shames, CIS Communications Committee Chair, have directed the task of updating all the existing entries, and adding new ones to cover biologics that have recently come on the market.

These are the principles that underlie the update:

1. The WEBbook should contain biologics that are approved in the USA by the FDA. Biologics are therapeutic or diagnostic agents that are produced by living cells or organisms. They are generally proteins or peptides, sometimes with structural modifications. In most cases, they are grown in vitro by culture of bacterial or mammalian cells transfected with recombinant DNA coding for the desired protein product. This applies to all monoclonal antibodies currently approved for commercial use. Agents grown in bacteria have the desired amino acid sequences, but do not have the post-translational modifications, such as glycosylation, that occur in mammalian cells. Sometimes the purified recombinant protein is further modified chemically, for example the conjugation of interferon alpha-2b with polyethylene glycol to make peginterferon alpha-2b.
2. In general, the WEBbook contains all such recombinant proteins. Other biologics are included if they have particular relevance to the practice of clinical immunology. Thus, some listed agents are purified from living beings not modified by recombinant genes, for example C1 Esterase Inhibitor, which is derived from normal human plasma. One unique agent, sipuleucel-T, consists of the patient's own cells that are stimulated in vitro by culture with prostatic acid phosphatase and then reinfused into the patient.
3. The restriction of the WEBbook to FDA-approved compounds should encompass most of the agents in therapeutic use around the world, but some compounds that have approved uses only in countries outside the USA (e.g., sulesomab Fab' or LeukoScan®) will not be covered. The discussions of individual compounds have been carefully limited to those uses that have a labeled indication, even though this may appear to be incomplete in some cases in which an agent may have common off-label use. For reference, the WEBbook has retained a few compounds that were initially FDA approved, but then were either discontinued or withdrawn, usually due to new safety concerns or marketing considerations, e.g. efalizumab. The status of these compounds is clearly indicated in several locations.
4. The WEBbook pages include:
   a. An introductory home page.
   b. A page explaining the nomenclature used for the generic names of compounds.
   c. An index/search page, which lists and links to each of the included compounds both by generic and brand names. The search function will find all references to a given term in the WEBbook pages.
   d. A table listing all the compounds alphabetically by generic name, along with basic information about each.
   e. A summary page for each compound, providing more detailed information.

R. Eisenberg (✉)
Department of Medicine, Rheumatology Division,
University of Pennsylvania,
756 BRB II/III, 421 Curie Blvd,
Philadelphia, PA 19104, USA
e-mail: raemd@mail.med.upenn.edu

5. Every compound's summary page includes a short list of references, such as reports of pivotal trials and systematic reviews, as well as a link to the package insert's FDA-approved drug information.
6. New compounds will appear in the WEBbook as quickly as possible after they are approved. A recent example is pertuzumab, which was approved on June 8, 2012. Existing entries will be updated with new indications, safety concerns, etc., about every 6 months.
7. CIS would very much appreciate feedback from the membership regarding whether you find the compendium to be useful in your clinical or research practice or whether you have any specific suggestions for future iterations. If you find errors, ambiguities, or omissions in the WEBbook, please email the CIS WEBsite editor: raemd@mail.med.upenn.edu.

The following CIS members have contributed to the latest revisions: Zoulfia Allakhverdieva, Mohamed Arredouani, Adrian Casillas, Sherry Fleming, Jeffrey Harris, Rashmi Kaul, Charles Kirkpatrick, Alan Knutsen, Ahmed Metwalia, Stan Naides, Karen Nelson, Lisa Rider, Sergio Rosenzweig, Jack Routes, Len Sigal, James Talmadge, Akaluck Thatayatikom, Geoffrey Thiele, Diane Wara, Haig Tcheurekdjian, and Richard Wasserman. In addition, some of the selections were written in collaboration with a NIT/FIT fellow: Nicole Chase, Karin Chen, Isabela Gonzalez, Sun Jung Kim, Amy Marks, Elena Resnick, Burcin Uygungil, Evan Glen Vista, Kelly Walkovich, Yesim Yilmaz-Demirdag. A special thanks is owed to the CIS administrative staff who did nearly all of the work which transformed text documents into a 21st century website: Jesse Cunningham, Anne Krolikowski, and Michelle Stubblefield.