• The worldwide incidence of new cancer patients is forecast to increase from 4.2 million cases in the major cancer markets in 2005 to 4.6 million in 2010.

• It is estimated that the worldwide cancer marker will be worth 85.3 billion in 2010.

Inventors: Donald P. Bottaro et al. (NCI).

Relevant Publications

1. Atabey N, Gao Y, Yao Z-J, Breckenridge D, Soon L, Soriano JV, Burke TR Jr, Bottaro DP. Potent blockade of Hepatocyte Growth Factor-stimulated cell motility, matrix invasion and branching morphogenesis by antagonists of Grb2 Src homology 2 domain interactions. J Biol Chem. 2001 Apr 27;276(17):14308–14314. [PubMed: 11278639].
2. Shi Z-D, Wei C-Q, Wang X, Lee K, Liu H, Zhang M, Vasselli J, Bottaro DP, Linehan WM, Yang D, Burke TR Jr. Macrocyclization in the design of tetra-tetrapeptide mimetics that display potent inhibition of Grb2 SH2 domain binding in whole cell systems. In: Peptide Revolution: Genomics, Proteomics Therapeutics. Chorev, M and Sawyer, TK, Eds. American Peptide Society, pp 515–517, 2003.
3. Soriano JV, Lui N, Gao Y, Yao Z-J, Ishibashi T, Underhill C, Burke TR Jr, Bottaro DP. Inhibition of angiogenesis by growth factor receptor bound protein 2-Src homology 2 domain bound antagonists. Mol Cancer Ther. 2004 Oct;3(10):1289–1299. [PubMed: 15486196].
4. Shi Z-D, Karki RG, Worthy KM, Bindu LK, Dharmawardana PG, Nicklaus MC, Bottaro DP, Fisher RJ, Burke TR Jr. Utilization of a nitrobenzoxadiazole (NBD) fluorophore in the design of a Grb2 SH2 domain-binding peptide mimetic. Bioorg Med Chem Lett. 2005 Mar 1;15(5):1385–1388. [PubMed: 15713392].
5. Kang S-U, Shi, Z-D, Worthy KM, Bindu LK, Dharmawardana PG, Choyke SJ, Bottaro DP, Fisher RJ, Burke TR Jr. Examination of phosphoryl-mimicking functionalities within a macrocyclic Grb2 SH2 domain-binding platform. J Med Chem. 2005 Jun 16;48(12):3945–3948. [PubMed: 15943469].
6. Shi Z-D, Peruzzi B, Dharmawardana PG, Leech T, Appella E, Worthy KM, Bindu LK, Fisher RJ, Bottaro DP, Burke TR Jr. Synthesis and use of C-terminally biotinylated peptidomimetics with high Grb2 SH2 domain-binding affinity. In: Understanding Biology Using Peptides, Blondelle SE (Ed), American Peptide Society, pp 208–209, 2005.
7. Dharmawardana PG, Peruzzi B, Giubellino A, Burke TR Jr, Bottaro DP. Molecular targeting of growth factor receptor-bound 2 (Grb-2) as an anti-cancer strategy. Anti-Cancer Drugs 2006 Jan;17(1):13–20. [PubMed: 16317285].
8. Liu F, Worthy KM, Bindu L, Giubellino A, Bottaro DP, Fisher RJ, Burke TR Jr. Utilization of achiral alkenyl amines for the preparation of high affinity Grb2 SH2 domain-binding macrocycles by ring-closing metathesis. Org Biomol Chem. 2007 Jan 21;5(2):367–372. [PubMed: 17205182].
9. Giubellino A, Gao Y, Lee S, Lee M-J, Vasselli JR, Medepalli S, Trepel JB, Burke TR Jr, Bottaro DP. Inhibition of tumor metastasis by a growth factor receptor bound protein Src domain-binding antagonist. Cancer Res. (Priority Report) 2007 Jul 1;67(13):6012–6016. [PubMed: 17616655].

Patent Status: U.S. Patent Application No. 11/525,672 filed 22 Sep 2006 (HHS Reference No. E–265–1999/2–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Urologic Oncology Branch of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Grb2 SH2 domain antagonists as anti-cancer drugs. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: October 29, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–27912 Filed 11–3–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0132]

Guidance for Industry: Cellular Therapy for Cardiac Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Cellular Therapy for Cardiac Disease" dated October 2010. The guidance document provides sponsors who are developing cellular therapies for the treatment of cardiac disease with recommendations on the design of preclinical and clinical studies and on the chemistry, manufacturing and controls (CMC) information that should be included in an investigational new drug application (IND) for cellular therapy for cardiac disease. The guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Somatic Cell Therapy for Cardiac Disease" dated March 2009.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for

Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Sabina Reilly, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4095.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Cellular Therapy for Cardiac Disease," dated October 2010. This guidance document provides sponsors who are developing cellular therapies for the treatment of cardiac disease with recommendations regarding the: (1) Design of preclinical and clinical studies, (2) CMC information that should be included in an IND for cardiac cellular therapy, and (3) information about the product's delivery system that should be submitted. This guidance also includes a discussion of regulatory considerations regarding cellular delivery systems.

In the **Federal Register** of April 2, 2009 (74 FR 14992), FDA announced the availability of the draft guidance entitled "Guidance for Industry: Somatic Cell Therapy for Cardiac Disease" dated March 2009. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, additional changes were made to improve the document. The guidance announced in this notice finalizes the draft guidance dated March 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the IND regulations (21 CFR part 312) have been approved under OMB control number 0910–0014, the good laboratory practice regulations (21 CFR part 58) have been approved under OMB control number 0910–0119, the investigational device exemption (IDE) regulations (21 CFR part 812) have been approved under OMB control number 0910–0078, and the informed consent regulations (21 CFR part 50) have been approved under OMB control number 0910–0130.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *http://www.regulations.gov*.

Dated: October 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27881 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: December 2–3, 2010.

Time: 11 a.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact: Donald L. Schneider, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5160, MSC 7842, Bethesda, MD 20892, (301) 435–1727, *schneidd@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: BST Member Conflict Review Panel.

Date: December 2, 2010.

Time: 1:15 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National of Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call.)

Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–408–9971, *fanp@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Behavioral and Social Consequences of HIV/AIDS.

Date: December 3, 2010.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call.)

Contact Person: Jose H. Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Chromatin Insulators.

Date: December 7–8, 2010.

Time: 8 a.m. to 9 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting.)

Contact Person: Michael H. Chaitin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435–0910, *chaitinm@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 29, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–27915 Filed 11–3–10; 8:45 am]

BILLING CODE 4140–01–P